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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

THE BULLETIN

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

NEW ORGANISMS

NON-NOTIFIED APPLICATIONS RECEIVED

Application Code: S2602004

Applicant: Eric Walton

Purpose: Determination whether or not the plants *Musa ornata, Musa manii* are new organisms under section 26 of the HSNO Act

Date Application Received: 1 July 2002

Application Code: S2602008

Applicant: New Zealand Cactus and Succulent Society

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

Date Application Received: 4 July 2002

Application Code: GMD01244

Applicant: Victoria University of Wellington

Purpose: To develop in containment *Escherichia coli* modified with DNA from Drosophila, mice, tuatara, blue duck, parakeets, livestock and commercial fish species (transfer of ACNGT approved organisms to approved status under the HSNO Act)

Date Application Received: 26 July 2002

Application Code: GMD02077

Applicant: Fonterra Co-operative Group

Purpose: To genetically modify approved *Escherichia coli* and yeast strain with dairy bacteria or *Streptococcus thermophilus* in small scale lab experiments to change the levels of proteins expressed by these bacteria in order to assess the effects of these proteins

Date Application Received: 23 August 2002

STALLED APPLICATIONS

Application Code: GMD02078

Applicant: Genesis Research and Development Corporation Ltd

Purpose: To develop in containment Tobacco mosaic tobamovirus, Narcissus mosaic potexvirus, Rye grass mosaic potyvirus, Watermelon mosaic virus, Tamarillo mosaic virus, Zucchini mosaic virus and Tobacco tobravirus viral vectors to study gene function

Date Application Received: 27 August 2002

Date Application Stalled: 27 August 2002

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

There are no new organism applications currently open for submissions

ERMA NEW ZEALAND
PO Box 131 Wellington
Phone: +64 4 916 2426 Fax: +64 4 914 0433
Email: info@ermanz.govt.nz
Website: www.ermanz.govt.nz

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following application on 2 August 2002

Application Code: GMC02004

Applicant: University of Auckland

Purpose: Import of genetically modified rats for investigating the role a rhodopsin mutation plays in retinitis pigmentosa with a long-term aim to understand the disease and develop therapeutic interventions

Description of Organisms: *Rattus norvegicus*, Sprague-Dawley strain, P23H mutant human rhodopsin

Decision: Approved with Controls

ERMA Approval Code: GMC001187

Controls:

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

1. To limit the likelihood of any accidental release of any organism or any viable genetic material[2]:

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

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

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

2. To exclude unauthorised people from the facility:

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

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

3.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

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

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

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

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

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

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

6. Inspection and monitoring requirements for containment facilities:

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

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

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

3 An inspector appointed under the Biosecurity Act.

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

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

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

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

8. Additional controls:

8.1 The applicant shall obtain approval from University of Auckland Animal Ethics Committee before carrying out the proposed research.

The Environmental Risk Management Authority reached a decision on the following application on 29 August 2002

Application Code: GMD02067

Applicant: University of Canterbury

Purpose: To develop in containment strains of *Salmonella typhimurium* and *Escherichia coli* modified with an invasion protein ipaC gene from *Shigella fexneri* plasmid vector

Description of Organisms: *Salmonella typhimurium* (Loeffler 1892) Castellani and Chalmers 1919, *Escherichia coli* (Migula 1895) Castellani and Chalmers 1919

Decision: Approved with Controls

ERMA Approval Code: GMD002178 – GMD002179

Controls:

In order to provide for the matters detailed in Part I of the Third Schedule to the Act, Containment controls for development and field testing of genetically modified organisms[4], the approved organisms are subject to the following controls:

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

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 construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the:

a) MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms, at laboratory Physical Containment Level 2 (PC2) for *Salmonella typhimurium*

b) MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms, at laboratory Physical Containment Level 1 (PC1) for *Escherichia coli*

c) Australian New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects of containment and facilities

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. 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.

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.

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

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

6. Inspection and monitoring requirements for containment facilities:

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

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

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

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

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

The Environmental Risk Management Authority reached a decision on the following application on 29 August 2002

Application Code: GMD02068

Applicant: University of Canterbury

Purpose: To develop in containment *Escherichia coli* and *Burkholderia gladioli pv agaricicola* for examining the molecular and biochemical process by which it causes 'cavity disease' in white button mushrooms *Agaricus bisporus*

Description of Organisms: *Burkholderia gladioli pv agaricicola* (Severini 1913) Yabuuchi et al. 1993 strain 164

Escherichia coli (Migula 1895) Castellani and Chalmers 1919, strainDH5a

Burkholderia gladioli pv agaricicola (Severini 1913) Yabuuchi et al. 1993 strain 164

Decision: Approved with Controls

ERMA Approval Code: GMD002180 – GMD002181

Controls:

In order to provide for the matters detailed in Part I of the Third Schedule to the Act, Containment controls for development and field testing of genetically modified organisms[7], the approved organisms are subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material[8]:

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 construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the:

a) MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms, at laboratory Physical Containment Level 2 (PC2) for *Burkholderia gladioli pv agaridicola*

b) MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms, at laboratory Physical Containment Level 1 (PC1) for *Escherichia coli*

c) Australian New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects of containment and facilities

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:

6 An inspector appointed under the Biosecurity Act.

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

3.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

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

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

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

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

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

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

6. Inspection and monitoring requirements for containment facilities:

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

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

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

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

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

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 the controls was made by the Authority on 11 March 2002.

Application Code: NOC98004

Applicant: Malaghan Institute of Medical Research

Purpose: To import into containment seven genetically modified strains of mouse (*Mus musculus*) for the purpose of experimental medical research

Original Control:

3. The containment facility is to be operated and constructed in accordance with the:

(a) Malaghan Institute's Biomedical Research Unit's Operating Procedure 1998;

(b) Australian/New Zealand Standard AS/NZS 2243.3:1995; and

(c) once approved by MAF, the MAF Regulatory Authority Animal Health and Welfare Standard 154.03.03, Transitional and Containment Facilities for Vertebrate Laboratory Animals, Ministry of Agriculture and Forestry.

Amended Control:

3. The containment facility is to be operated and constructed in accordance with the:

a) Malaghan Institute's Biomedical Research Unit's Operating Procedure 1998;

b) Australian/New Zealand Standard AS/NZS 2243.3:1995 Safety in Laboratories: Part 3(Microbiology), physical containment level 2 (PC2); and

c) MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.03, Containment Facilities for Vertebrate Laboratory Animals.

9 An inspector appointed under the Biosecurity Act.

The following amendment to the controls was made by the Authority on 11 March 2002

Application Code: NOC98005

Applicant: Landcare Research, Lincoln

Purpose: To import into containment ten species of subtropical native Australian plants, in order to confirm the host specificity of gorse thrips (*Sericothrips staphylinus, Haliday*) before being considered for importation and release into Australia

Original Controls:

1. **The containment facility is to be operated and constructed in accordance with the:**

   (a) Procedures for the Importation and Quarantine of Live Insects and Other Arthropods, into the Landcare Research Invertebrate Quarantine Facility H. Gourlay and R. Hill, June 1994 or equivalent, and

   (b) MAF Regulatory Authority Standard 154.02.08: Transitional and Containment Facilities for Invertebrates, Ministry of Agriculture and Forestry.

Amended Controls:

1. **The containment facilities shall be approved by Ministry of Agriculture and Forestry (MAF) in accordance with the MAF Biosecurity Authority/ ERMA New Zealand Standards 154.02.08 Transitional and Containment Facilities for Invertebrates.**

1.1 The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the:

   a) MAF Biosecurity Authority/ERMA New Zealand Standard 154.02.08: Transitional and Containment Facilities for Invertebrates;

   b) Australian/New Zealand Standard AS/NZS 2243.3:1995 Safety in Laboratories: Part 3: (Microbiology), at Physical Containment Level 2 (PC2); and

   c) The controls of the Authority.

1.2 Subject to the controls listed that facility will be deemed to be appropriate for containing non genetically modified plants.

The following amendment to the controls was made by the Authority on 11 March 2002

Application Code: NOC99005

Applicant: University of Otago

Purpose: To import into containment genetically modified *Arabidopsis thaliana* plants containing flowering genes or maize transposon elements, plus marker, herbicide and/or kanamycin resistance genes, to identify and study genes involved in flowering

Original Controls:

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

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

   (b) Australian New Zealand Standard AS/NZS 2243.3:1995 Safety in Laboratories: Part 3: (Microbiology), at Plant House Level PC2.

4.2 Prior to seedpod maturity the entire inflorescence shall be enclosed in a plastic bag, secured at the base, with the inflorescence bent over to collect the seed in the bottom of the plastic bag and to prevent spillage of seed and transfer out of containment.

Amended Controls:

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

   (a) MAF Biosecurity Authority/ERMA New Zealand Standard 155.04.09: Containment Facilities for New Organisms (including GMO) of Plant Species.

   (b) Australian/New Zealand Standard AS/NZS 2243.3:1995 Safety in Laboratories: Part 3: (Microbiology), at Plant House Level Physical Containment level 2 (PC2).

4.2 Prior to seedpod maturity the entire inflorescence shall be enclosed in a plastic bag, secured at the base, with the inflorescence bent over to collect the seed in the bottom of the plastic bag and to prevent spillage of seed and transfer out of containment.

The following amendment to the controls was made by the Authority on 11 March 2002

Application Code: NOC99023

Applicant: Landcare Research Institute of New Zealand

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

Original Control:

1.5 Approval to import the unidentified saprobic and plant pathogenic bacteria and fungi into containment shall be only for importation into the Landcare Research Limited ICMP Collection, Mt Albert. Unidentified organisms therefore may not be transferred to, or imported by other facilities under this approval.

Amended Control:

1.5 Approval to import the unidentified saprobic and plant pathogenic bacteria and fungi into containment shall be only for importation into the Landcare Research Limited ICMP Collection, Mt Albert. Unidentified organisms therefore may not be transferred to, or imported by other facilities under this approval. The applicant shall ensure that only those saprobic and plant pathogenic bacteria and fungi shall be imported that could not have any significant effect on New Zealand's fauna, and which are not pathogenic to mammals. The organisms that could have significant effect are those that could cause major disruption for New Zealand's export market access for commodities, or could cause significant economic impact on the domestic production of those commodities, or could cause potentially significant adverse effects on the environment.

The following amendment to the controls was made by the Authority on 11 March 2002

Application Code: NOC01006

Applicant: New Zealand Forest Research Institute Limited

Purpose: To import into containment *Wollemia nobilis* (Wollemi pine) for propagation by seed, cuttings, tissue culture, organogenesis, or embryogenesis as part of a recovery plan.

Original Control:

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

   a) Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.04.09 Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species;

   b) Australian New Zealand Standard AS/NZS 2243.3: 2002 Safety in Laboratories: Part 3: (Microbiological Aspects and Containment Facilities), Plant House Physical Containment Level 2 (PC2); and the controls of the Authority.

Amended Control:

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

   a) Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 155.04.09 Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species;

   b) Australian New Zealand Standard AS/NZS 2243.3: 2002 Safety in Laboratories: Part 3: (Microbiological Aspects and Containment Facilities), Plant House Physical Containment Level 2 (PC2); and the controls of the Authority.

The following amendment to the controls was made by the Authority on 30 May 2002

Application Code: GMF98007

Applicant: Crop and Food Research

Purpose: To field test, in the Canterbury region over 5 years, potato cultivars genetically modified for increased resistance to bacterial soft rots, to evaluate resistance and yield performance of individual lines.

Original Controls:

2. The containment location is to be at the site identified in the application and shall be used solely for the field testing of transgenic potatoes.

3. At all times only authorised persons shall have knowledge of the location of the site and access to the containment location.

16. The containment location shall be left fallow for three years after the completion of the field test

21. The containment location shall be monitored for at least three years for presence of volunteer transgenic potatoes, or until no further volunteers appear, and volunteer tubers/plants shall be destroyed (by incineration or autoclaving) prior to flower buds forming on the plants.

Amended Controls:

2. The trial site shall be on land owned and operated by the institute. The inspector nominated by MAF and the Chief Executive of the Authority shall be notified prior to any location changes and these changes shall be within the general vicinity identified in the application and be related to information available to the Authority at the time the decision was signed.

3. At all times only authorised persons shall have access to the containment location (the farm), and only specified personnel shall have knowledge of the location of the trial site.

3.1 The trial site is to be monitored daily (on weekdays) for interference other than by authorised personnel.

3.2 The gates of the containment location shall be locked from 6pm to 8am on weekdays, with key access outside of these times controlled by the farm manager.

16. The containment location shall be left fallow for at least three years after the completion of the field test as per control 21.

21. The containment location shall be monitored for a minimum of three years for presence of volunteer transgenic potatoes, and subsequently for 12 months beyond the appearance and removal of any volunteers. Volunteer tubers/plants shall be destroyed (by incineration or autoclaving) prior to flower buds forming on the plants.

The following amendment to the controls was made by the Authority on 30 May 2002

Application Code: GMF98008

Applicant: Crop and Food Research

Purpose: To field test, in the Canterbury region over 5 years, potato cultivars genetically modified for increased resistance to potato tuber moth, to evaluate resistance and yield performance of individual lines.

Original Controls:

2. The containment location is to be at the site identified in the application and shall be used solely for the field testing of transgenic potatoes.

3. At all times only authorised persons shall have knowledge of the location of the site and access to the containment location.

16. The containment location shall be left fallow for three years after the completion of the field test

21. The containment location shall be monitored for at least three years for presence of volunteer transgenic potatoes, or until no further volunteers appear, and volunteer tubers/plants shall be destroyed (by incineration or autoclaving) prior to flower buds forming on the plants.

Amended Controls:

2. The trial site shall be on land owned and operated by the institute. The inspector nominated by MAF and the Chief Executive of the Authority shall be notified prior to any location changes and these changes shall be within the general vicinity identified in the application and be related to information available to the Authority at the time the decision was signed.

3. At all times only authorised persons shall have access to the containment location (the farm), and only specified personnel shall have knowledge of the location of the trial site.

3.1 The trial site is to be monitored daily (on weekdays) for interference other than by authorised personnel.

3.2 The gates of the containment location shall be locked from 6pm to 8am on weekdays, with key access outside of these times controlled by the farm manager.

16. The containment location shall be left fallow for at least three years after the completion of the field test as per control 21.

21. The containment location shall be monitored for a minimum of three years for presence of volunteer transgenic potatoes, and subsequently for 12 months beyond the appearance and removal of any volunteers. Volunteer tubers/plants shall be destroyed (by incineration or autoclaving) prior to flower buds forming on the plants.

The following amendment to the controls was made by the Authority on 11 March 2002

Application Code: GMF99004

Applicant: AgResearch Limited

Purpose: To field test in containment in the Waikato region, genetically modified sheep with an inactivated myostatin gene, to increase the understanding of myostatin function in order to identify the effects on sheep muscularity.

New Controls Added:

4.2 No part or product of the transgenic organism shall be ingested by any person at any time.

DELEGATED AUTHORITY

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

Applicant: AgResearch, Ruakura

Institution application code: GMO02/ARR001

Purpose: To allow the routine production of genetically modified mice

ERMA Approval code(s): GMD002183

Description of organism: *Mus musculus* modified with non human genes and commercially available markers eg Lac Z, GFP

Decision: Approved with controls (PC2)

Applicant: AgResearch, Ruakura

Institution application code: GMO02/ARR002

Purpose: To develop low risk genetically modified insect cell cultures for the production of recombinant proteins. This is an update of GMO00/ARR011

ERMA Approval code(s): GMD002184

Description of organism: Insect cell lines SF9, SF21, 'High Five' as modified by insect cell plasmids: pXINsect-DEST 48, pXINsect-DEST39 and pBmA:neo

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO01/HRA055

Purpose: Identification of secreted and membrane targeted gene products from plants, invertebrates, fungi and bacteria

ERMA Approval code(s): GMD002185-2186

Description of organism: *Escherichia coli* and *Saccharomyces cerevisiae* as modified by yeast two-hybrid vectors containing plant, invertebrate, fungal and bacterial DNA of genes containing membrane targeting signals

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO01/HRA056

Purpose: To construct a genomic DNA library for the isolation of mocrosatellite loci, and to clone PCR products from targeted gene regions from native fish species fro conservation genetics research

ERMA Approval code(s): GMD002187

Description of organism: *Escherichia coli* as modified by DNA and cDNA from Galaxias species

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO01/HRA057

Purpose: Extension of the gene library project of cloning the genes into plasmids to include cloning the genes into the genome of bacteriophages. Libraries to initially screen for proteinase inhibitors. Update of GMO00/HRA036.

ERMA Approval code(s): GMD002188

Description of organism: *Escherichia coli* modified by genes from *Cucurbita maxima* (squash) and *Epiphyas postivittana* (a Leptidopteran insect)

Decision: Approved with controls (PC1 and PC2)

Applicant: Massey University

Institution application code: GMO00/MU027a

Purpose: To facilitate structural studies on various tributyrin esterases to define activities of enzymes, determine catalytic mechanisms and substrate specifities, and allow eventual in vitro mutagenesis of coding sequences for structure-function studies. This is an update of GMO00/MU027

ERMA Approval code(s): GMD002189

Description of organism: *Escherichia coli* as modified by DNA from *Lactococcus lactis sp. lactis, Streptococcus pyogenes, Streptococcus equi, Streptococcus gordonii* and *Streptococcus mutans* coding for enzymes with siginficant sequence homology to that of tributyrin esterase from *Lactococcus lactis*, and for lypolytic enzymes which have similar activity but less homology to tributyrin esterase from *Streptococcus thermophilus, Lactococcus lactis, sp.lactis, Lactococcus lactis sp.cremoris, Lactobacillus rhamnosus* and *Lactobacillus lactis*

Decision: Approved with controls (PC2)

Applicant: Massey University

Institution application code: GMO02/MU002

Purpose: To learn more about the speciation of the kiwi and the moa by analysing and comparing mitochondrial and nuclear DNA sequences

ERMA Approval code(s): GMD002190

Description of organism: *Escherichia coli* as modified with kiwi and moa DNA

Decision: Approved with controls (PC2)

Applicant: University of Auckland

Institution application code: GMO02/UA015

Purpose: To develop transfected mammalian cells for studies of cell proliferation, migration and differentiation, with particular reference to identification of the molecular pathways that regulate normal mammalian development and cancer formation

ERMA Approval code(s): GMD002192-2197

Description of organism: *Escherichia coli* (Non conjugative K12 and B strains), *Saccharomyces cerevisiae, Drosophila melanogaster* cell lines, *Homo sapiens* cell lines, *Mus musculus* cell lines and *Rattus norvegicus* cell lines modified with human, mouse and rat genes encoding: STIM proteins, Notch pathway proteins, cell interaction receptors, extracellular matrix receptors, transcriptional regulators of differentiation, and nontranslated RNA and Wnt pathway proteins, growth factors and receptors, and cell cycle regulators

Decision: Approved with controls (PC1)

Applicant: University of Auckland

Institution application code: GMO02/UA014

Purpose: To develop oligonucleotide riboprobes for in situ studies to determine the role of glucocorticoid receptors, glutamate receptors, glutamate transporters and the glutamate receptor transcription factor (REST) in the formation of brain damage

ERMA Approval code(s): GMD002191

Description of organism: *Escherichia coli* (Non conjugative K12 and B strains) modified with Sheep genes (*Ovis aries*) encoding glucocorticoid receptors, glutamate receptors, glutamate transcriptional factors and REI-silencing transcriptional factor family of proteins

Decision: Approved with controls (PC1)

Applicant: University of Auckland

Institution application code: GMO02/UA016

Purpose: To add proteins to the study of long term diabetic complications. Update of GMO01/UA015

ERMA Approval code(s): GMD002198-2204

Description of organism: *Escherichia coli* (K12 and B strains), *Saccharomyces cerevisiae, Homo sapiens* cell lines, *Rattus norvegicus* cell lines, *Mus musculus* cell lines, *Criteculus griseus* cell lines and *Cercopithecus aethiops* cell lines modified with rat (*Rattus norvegicus*), mouse (*Mus musculus*), and human (*Homo sapiens*) genes encoding NADH oxidases, myoinositol oxidases and NADPH oxidases

Decision: Approved with controls (PC1)

Applicant: University of Otago

Institution application code: GMO02/UO010

Purpose: To produce recombinant proteins from baculovirus vectors in cell lines derived from *Spodoptera frugiperda* and *Trichoplusia ni* to study immune responses

ERMA Approval code(s): GMD002205-2206

Description of organism: *Spodoptera frugiperda* insect cell lines and *Trichoplusia ni* insect cell lines modified with AcNPV Baculovirus (*Baculo Gold* derivative) and pAcAB3, pAcUW51, pVL1392/1392 Baculovirus transfer vectors and their derivatives; mouse genes involved in the immune system such as major histo compatibility complex (MHC) genes, cytokines, ligands for costimulations (e.g. CD40/CD40L) and T cell receptors

Decision: Approved with controls (PC1)

Applicant: University of Otago

Institution application code: GMO02/UO013

Purpose: To develop *Escherichia coli* and *Candida albicans* in order to determine whether a particular gene (HEX1) contributes to the virulence of the yeast *Candida albicans*

ERMA Approval code(s): GMD002207-2208

Description of organism: *Escherichia coli* strain K12 derivatives modified with pUC9; HEX1 and URA3 genes from *Candida albicans* and hisG gene from *Salmonella typhimurium*

Candida albicans strain CAI4 as modified with pUC9; HEX1 and URA3 genes from *Candida albicans* and hisG gene from *Salmonella typhimurium*

Decision: Approved with controls (PC1 and PC2)

Applicant: University of Otago

Institution application code: GMO02/UO017

Purpose: To characterise the Virus-like Particles (VLP) discovered in the reproductive tract of *Microctonus aethiopoides* introduced into New Zealand as a bio-control agent of *Sitona discoideus*

ERMA Approval code(s): GMD002209

Description of organism: Escherichia coli K12 and B strain derivatives modified with non conjugative plasmids derived from ColE1, such as pBluescript and pLitmus; DNA from virus-like particles from the parasitoid wasp *Microctonus aethiopoides*

Decision: Approved with controls (PC1)

Applicant: University of Otago

Institution application code: GMO02/UO018

Purpose: To develop *E.coli* and *Candida albicans* in order to determine whether a particular gene (APRI) contributes to the virulence of the yeast *C.albicans*

ERMA Approval code(s): GMD002210-2211

Description of organism: *Escherichia coli* K12 derivatives and *Candida albicans* strains CAI4 modifed with pUC9; APR1 and URA3 genes from *Candida albicans*; hisG gene from *Salmonella typhimurium*

Decision: Approved with controls (PC1 and PC2)

Applicant: University of Otago

Institution application code: GMO02/UO021

Purpose: Construction of *Escherichia coli* plasmids for the manipulation, study and expression of poxvirus genes and antigenic genes for the purpose of studying gene structure and function, immune function and for vaccine development. Update replaces ACNGT 94/95/7, GMO00/UO046

ERMA Approval code(s): GMD002212

Description of organism: *Escherichia coli* K12 or B derivatives modified with non-conjugative plasmids containing DNA from *Echinococcus granulosus* with appropriate regulatory sequences and reporter genes as required

Decision: Approved with controls (PC1)

Applicant: University of Otago

Institution application code: GMO02/UO026

Purpose: To clone and sequence human autoantigen genes. Autoantigen genes encode proteins that are involved in the development of autoimmune diseases in humans. These genes will be cloned and sequenced for further analysis

ERMA Approval code(s): GMD002213

Description of organism: *Escherichia coli* K12 or B strains (crippled laboratory strains) and their derivatives modified with non-conjugative plasmids such as pBluescript and pLitmus; cDNA of human autoantigen genes such as Ro52 and CEWP-B

Decision: Approved with controls (PC1)

HAZARDOUS SUBSTANCES

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

Application Code: HSR02041

Applicant: Virbac Laboratories NZ Limited

Purpose: To import for release an antiparasitic (VBLA) for use in production animals

Date Application Received: 7 August 2002

Date Publicly Notified: 21 August 2002

Date Submissions Close: 2 October 2002

NON NOTIFIED APPLICATIONS RECEIVED

Application Code: HSC02006

Applicant: Syngenta Crop Protection Limited

Purpose: To import the fungicide azoxystrobin into containment to conduct field trials to provide information on the development of new formulations

Date Application Received: 28 August 2002

Application Code: HSC02007

Applicant: Syngenta Crop Protection Limited

Purpose: To import into containment a number of experimental adjuvants to conduct small-scale contained field trials to provide information on the development of the adjuvants

Date Application Received: 28 August 2002

APPLICATIONS STALLED

Application Code: HSR02036

Applicant: Reckitt Benckiser (NZ) Limited

Purpose: To import RB-2-106 a household insect repellant

Date Application Received: 1 August 2002

Date Application Stalled: 12 August 2002

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following application on 8 April 2002

Application code: HAZ01001

Applicant: ERMA New Zealand

Purpose: To determine under Section 26 whether vaccines containing Thiomersal are hazardous

Description of Substances: Vaccines containing between 0.005% – 0.1% thiomersal and no other hazardous ingredients

Classifications: 6.5B

Decision: Determined to be a hazardous substance

The Environmental Risk Management Authority reached a decision on the following application on 5 August 2002

Application code: HSR02010

Applicant: CPI Group

Purpose: For the approval to import Fujifilm Developer LP-D3 and Fujifilm Replenisher LP-D3R. These constitute two components of the Fujifilm Brilla LP-N3 system used in the printing industry in high performance plate-making equipment

Description of Substances:
Fujifilm Developer LP-D3
Fujifilm Replenisher LP-D3R

Classifications: Fujifilm Developer - 6.1E, 8.1A, 8.2C, 8.3A, 9.1D
Fujifilm Replenisher - 6.1E, 8.1A, 8.2B, 8.3A, 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000013 – HSR000014

Controls:

Control Code[10]	Regulation[11]	Explanation[12]
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls**	
T2	Regulations 29, 30	Controlling exposure in places of work through setting of WESs
T3	Regulations 5(1), 6	Fujifilm Replenisher Only Requirements for keeping records of use
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
Code	**Hazardous Substances (Identification) Regulations 2001**	
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge belong to Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, clarity and durability of information
I2, I8	Regulations 8, 14	Priority identifiers for Fujifilm Developer and Fujifilm Replenisher
I9, I10, I11, I16	Regulations 18, 19, 20, 25	Secondary identifiers for Fujifilm Developer and Fujifilm Replenisher

10 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 and is also contained in the ERMA New Zealand *User Guide to the Controls Regulation.*

11 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.

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

I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Requirements for using concentration ranges
I19	Regulations 29 – 31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported
I21	Regulations 37 – 39, 47 – 50	General documentation requirements for Fujifilm Developer and Fujifilm Replenisher Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request
I22, I28	Regulations 40, 46	Specific documentation requirements for Fujifilm Developer and Fujifilm Replenisher
I29	Regulations 51 – 52	Duties of persons in charge of places with respect to signage
I30	Regulations 53	Advertising corrosive and toxic substances
Code	**Hazardous Substances (Packaging) Regulations 2001**	
P1	Regulations 5, 6, 7 (1), 8	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility
P3, P13, P14	Regulations 9, 19 – 20	Packaging requirements for Fujifilm Developer Packaging requirements for Fujifilm Replenisher
PG2	Schedule 2	Fujifilm Replenisher ONLY 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 Packaging Group II
PG3	Schedule 3	Fujifilm Developer ONLY 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 Packaging Group III
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D4, D5	Regulations 8, 9	Disposal requirements for Fujifilm Developer and Fujifilm Replenisher
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements regarding disposal
D8	Regulations 13, 14	Documentation requirements regarding disposal

Code	Hazardous Substances (Emergency Management) Regulations 2001	
EM1	Regulations 6, 7, 9 – 11	General level 1 emergency management information requirements
EM2, EM6, EM7	Regulations 8(a), 8(e), 8(f)	Additional level 1 emergency management information requirements for Fujifilm Developer and Fujifilm Replenisher
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

The Environmental Risk Management Authority reached a decision on the following application on 16 August 2002

Application code: HSR02009

Applicant: Osmose New Zealand

Purpose: To manufacture Protim Antimould, a fungicide treatment for timber and wood products

Description of Substances: Protim Antimould

Classifications: 6.1D, 6.4A, 6.5B, 6.9B, 9.1A, 9.3C

Decision: Approved with Controls

ERMA Approval Code: HSR000017

Controls:

Control Code[13]	Regulation[14]	Explanation[15]
Code	**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 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
T8	Regulation 28	Controls on Vertebrate Poisons
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls**	
E1	Regulations 32 – 45	Limiting exposure to ecotoxic substances
E5	Regulations 5, 6	Requirements for keeping records of use
Code	**Hazardous Substances (Identification) Regulations 2001**	
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge

13 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 and is also contained in the ERMA New Zealand *User Guide to the Controls Regulation.*

14 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.

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

		Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information
I3	Regulation 9	Priority identifiers for ecotoxic substances
I8	Regulation 14	Priority identifiers for 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
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Requirements for using concentration ranges
I19	Regulations 29 – 31	Alternative information in certain cases
I20	Regulation 36 (8)	Durability of information for class 6.1 substances
I21	Regulations 37 – 39, 47 – 50	Documentation required in places of work Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request
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
Code	**Hazardous Substances (Packaging) Regulations 2001**	
P1	Regulations 5, 6, 7 (1), 8	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility
P3	Regulation 9	Requirement for substances packed in limited quantities
P13, P15	Regulation 19, 21	Packaging requirements for toxic and ecotoxic substances
PG3	Schedule 3	This schedule provides the test methods for packaging that required to be tested in accordance with this schedule. The tests correlate to the packaging requirements of UN Packing Group III.
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D4, D5	Regulation 8, 9	Disposal requirements for toxic and ecotoxic substances
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements
D8	Regulations 13, 14	Documentation requirements
Code	**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

The Environmental Risk Management Authority reached a decision on the following application on 16 August 2002

Application code: HSR02015

Applicant: **Harvey Farms, Division of Inghams Enterprises (NZ) Pty Limited**

Purpose: To manufacture Harvey's Dairy Farmix as a feed supplement for dairy cows containing Monensin sodium (3%) in a premix dosage form

Description of Substances: Harvey's Dairy Farmix

Classification: 6.1C, 6.5B, 8.3A, 9.3B

Decision: Approved with Controls

ERMA Approval Code: HSR000019

Controls:

Control Code[16]	Regulation[17]	Explanation[18]
Code	**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 substances
T5	Regulation 8	Requirements for protective clothing and equipment
T7, E8	Regulation 10	Restrictions on the carriage on passenger service vehicles
T8	Regulation 28	Controls on Vertebrate Poisons
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls**	
E4	Regulations 50 – 51	Controls relating to protection of terrestrial vertebrates

16 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 and is also contained in the ERMA New Zealand *User Guide to the Controls Regulation*.

17 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.

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

Code	Hazardous Substances (Identification) Regulations 2001	
I1	Regulations 6, 7, 32-35, 36 (1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Duritability of Information
I2, I3, I8	Regulations 8, 9, 14	Priority identifiers
I9, I10, I11, I16	Regulation 18, 19, 20, 25	Secondary identifiers
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Requirements for using concentration ranges
I19	Regulations 29 – 31	Alternative information in certain cases
I20	Regulation 36 (8)	Durability of information
I21	Regulations 37 – 39, 47 – 50	Documentation required in places of work Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request
I22, I23, I28	Regulations 40, 41, 46	Specific documentation requirements
I29	Regulations 51 – 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising corrosive and toxic substances
Code	**Hazardous Substances (Packaging) Regulations 2001**	
P1	Regulations 5, 6, 7 (1), 8	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing Regulation 8 – Compatibility
P3, P13, P14, P15	Regulations 9, 19, 20, 21	Packaging requirements
PG3	Schedule 3	This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III.
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D4, D5	Regulation 8, 9	Disposal requirements for toxic, corrosive and ecotoxic substances
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements
D8	Regulations 13, 14	Documentation requirements
Code	**Hazardous Substances (Emergency Management) Regulations 2001**	
EM1	Regulations 6, 7, 9 – 11	Level 1 emergency management
EM2, EM6, EM7	Regulation 8(a), 8(e), 8(f)	Additional 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
EM13	Regulation 42	Level 3 emergency management requirements – signage

The Environmental Risk Management Authority reached a decision on the following application on 26 August 2002

Application code: HSR02011

Applicant: Key Industries Limited

Purpose: To import Key Lime Sulphur for use as a pesticide on New Zealand orchards for control of scale insects, fungi, mites and lichen

Description of Substances: Key Lime Sulphur

Classification: 6.1D, 6.3B, 6.5B, 8.3A, 9.1D, 9.3C

Decision: Approved with Controls

ERMA Approval Code: HSR000020

Controls:

Control Code[19]	Regulation[20]	Explanation[21]
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls**	
T2	Regulations 29, 30	Controlling exposure in places of work
T3	Regulations 5 (1), 6	Requirements for keeping records of use
T4, E6	Regulation 7	Requirements for equipment use
T5	Regulation 8	Requirements for protective clothing and equipment
T7, E8	Regulation 10	Restrictions on the carriage on passenger service vehicles
T8	Regulation 28	Controls on Vertebrate Poisons
E4	Regulations 50 – 51	Controls relating to the protection of terrestrial vertebrates

19 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 and is also contained in the ERMA New Zealand *User Guide to the Controls Regulation*.

20 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.

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

Code	Hazardous Substances (Identification) Regulations 2001	
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	**General identification requirements** **Regulation 6 – Identification duties of suppliers** **Regulation 7 – Identification duties of persons in charge** **Regulations 32 and 33 – Accessibility of information** **Regulations 34, 35, 36(1) – (7) – Comprehensibility, clarity and durability of information**
I2, I8	Regulations 8, 14	**Priority identifiers**
I9, I10, I11, I16	Regulations 18, 19, 20, 25	**Secondary identifiers**
I17	Regulation 26	**Use of Generic Names**
I18	Regulation 27	**Requirements for using concentration ranges** **This control provides the option of providing concentration ranges for those ingredients whose concentrations are required to be stated on the product label**
I19	Regulations 29 – 31	**Alternative information in certain cases** **Regulation 29 – Substances in fixed bulk containers or bulk transport containers** **Regulation 30 – Substances in multiple packaging** **Regulation 31 – Alternative information when substances are imported**
I20	Regulations 36 (8)	**Durability of information for class 6.1 substances**
I21	Regulations 37 – 39, 47 – 50	**General documentation requirements** **Regulation 37 – Documentation duties of suppliers** **Regulation 38 – Documentation duties of persons in charge of places of work** **Regulation 39 – General content requirements for documentation** **Regulation 47 – Information not included in approval** **Regulation 48 – Location and presentation requirements for documentation** **Regulation 49 – Documentation requirements for vehicles** **Regulation 50 – Documentation to be supplied on request**
I22, I28	Regulations 40, 46	**Specific documentation requirements for KEY LIME SULPHUR**
I29	Regulations 51 – 52	**Duties of persons in charge of places with respect to signage**
I30	Regulations 53	**Advertising corrosive and toxic substances**
Code	**Hazardous Substances (Packaging) Regulations 2001**	
P1	Regulations 5, 6, 7 (1), 8	**General packaging requirements** **Regulation 5 – Ability to retain contents** **Regulation 6 – Packaging markings** **Regulation 7(1) – Requirements when packing hazardous substance** **Regulation 8 – Compatibility**
P3, P13, P14, P15	Regulations 9, 19 – 21	**Packaging requirements**
PG3	Schedule 3	**This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III**

Code	Hazardous Substances (Disposal) Regulations 2001	
D4, D5	Regulations 8, 9	**Disposal requirements**
D6	Regulation 10	**Disposal requirements for packages**
D7	Regulations 11, 12	**Information requirements regarding disposal**
D8	Regulations 13, 14	**Documentation requirements regarding disposal**
Code	**Hazardous Substances (Emergency Management) Regulations 2001**	
EM1	Regulations 6, 7, 9 – 11	**General level 1 emergency management information**
EM2, EM6, EM7	Regulations 8(a), 8(e), 8(f)	**Additional 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**

The Environmental Risk Management Authority reached a decision on the following application on 29 August 2002

Application code: HSR02019

Applicant: SST Australia Pty Ltd

Purpose: To import formulated Waiken for use as a plant growth regulator to initiate bud-break in New Zealand orchards

Description of Substances: Waiken

Classification: 6.3A, 6.4A, 6.5B, 6.8A, 6.9B, 9.1A, 9.2C

Decision: Approved with Controls

ERMA Approval Code: HSR000021

Controls:

Control Code[23]	Regulation[24]	Explanation[25]
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls**	
T2	Regulations 29, 30	**Controlling exposure in places of work**
T3	Regulations 5(1), 6	**Requirements for keeping records of use**
T4, E6	Regulation 7	**Requirements for equipment use**
T5	Regulation 8	**Requirements for protective clothing and equipment**
T7, E8	Regulation 10	**Restrictions on the carriage on passenger service vehicles**
E5	Regulations 5(2), 6	**Requirements for keeping records of use**

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 and is also contained in the ERMA New Zealand *User Guide to the Controls Regulation.*

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.

E7	Regulation 9	**Approved Handler requirements**
Code	**Hazardous Substances (Identification) Regulations 2001**	
	The Identification Regulations prescribe requirements with regard to identification of hazardous substances in terms of: 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 places where there are large quantities of the substance.	
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	**General identification requirements** **Regulation 6 – Identification duties of suppliers** **Regulation 7 – Identification duties of persons in charge** **Regulations 32 and 33 – Accessibility of information** **Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information**
I3	Regulation 9	**Priority identifiers for ecotoxic substances**
I9, I11, I16	Regulations 18, 20, 25	**Secondary identifiers**
I17	Regulation 26	**Use of Generic Names**
I18	Regulation 27	**Requirements for using concentration ranges**
I19	Regulations 29 – 31	**Alternative information in certain cases** **Regulation 29 – Substances in fixed bulk containers or bulk transport containers** **Regulation 30 – Substances in multiple packaging** **Regulation 31 – Alternative information when substances are imported**
I21	Regulations 37 – 39, 4 7– 50	**Documentation required in places of work** **Regulation 37 – Documentation duties of suppliers** **Regulation 38 – Documentation duties of persons in charge of places of work** **Regulation 39 – General content requirements for documentation** **Regulation 48 – Location and presentation requirements for documentation** **Regulation 49 – Documentation requirements for vehicles** **Regulation 50 – Documentation to be supplied on request**
I23	Regulation 41	**Specific documentation requirements for ecotoxic substances**
I29	Regulations 51 – 52	**Duties of persons in charge of places with respect to signage**
Code	**Hazardous Substances (Packaging) Regulations 2001**	
P1	Regulations 5, 6, 7 (1), 8	**General packaging requirements** **Regulation 5 – Ability to retain contents** **Regulation 6 – Packaging markings** **Regulation 7(1) – Requirements when packing hazardous substance** **Regulation 8 – Compatibility**
P3	Regulations 9, 19, 21	**Packaging requirements for substances packed in limited quantities**

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**
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D4, D5	Regulations 8, 9	**Disposal requirements for toxic substances**
D6	Regulation 10	**Disposal requirements for packages**
D7	Regulations 11, 12	**Information requirements**
D8	Regulations 13, 14	**Documentation requirements**
Code	**Hazardous Substances (Emergency Management) Regulations 2001**	
EM1	Regulations 6, 7, 9 – 11	**Level 1 emergency management information: General requirements**
EM6, EM7	Regulations 8(e), 8(f)	**Information requirements for toxic/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**
Code	**Hazardous Substances (Personnel Qualification) Regulations 2001**	
AH1	Regulations 4 – 6	**Approved Handler requirements (including test certificate and qualification requirements)**

DELEGATED AUTHORITY

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

Application code: HSR02016

Applicant: The New Zealand Association for Animal Health and Crop Protection (AGCARM)

Purpose: To import or manufacture for release thiomersal contained in otherwise non-hazardous animal vaccines at 0.005% – 0.1% w/v

Description of Substances: vaccines containing between 0.005% – 0.1% thiomersal and no other hazardous ingredients

Classifications: 6.5B

Decision: Approved with Controls

ERMA Approval Code: HSR000015

Controls:

Control Code[25]	Regulation[26]	Explanation[27]
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls**	
T4	Regulation 7	Requirements for equipment used to handle substances
T5	Regulation 8	Requirements for protective clothing and equipment
T7	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Code	**Hazardous Substances (Identification) Regulations 2001**	
I1	Regulations 6, 7, 32 – 35, 36(1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge
I9	Regulation 18	Secondary identifiers for all hazardous substance
I16	Regulation 25	Secondary identifiers
I18	Regulation 27	Requirements for using concentration ranges
I19	Regulations 29 – 31	Alternative information in certain cases
I21	Regulations 37 – 39, 47 – 50	Documentation required in places of work Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request
I28	Regulation 46	Specific documentation requirements for toxic substances
Code	**Hazardous Substances (Packaging) Regulations 2001**	
P1	Regulations 5, 6, 7(1), 8	General packaging requirements Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility
P3	Regulation 9	Requirement for substances packed in limited quantities
P13	Regulation 19	Packaging requirements for toxic substances
PG3	Schedule 3	This schedule provides the test methods for packaging that is required to be tested accordance with this schedule. The tests correlate to packaging requirements equivalent to UN Packaging Group III
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D4	Regulation 8	Disposal requirements for toxic and corrosive substances
D6	Regulations 10(1), 10(2)(b), 10(3)	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements for manufacturers, importers and suppliers
D8	Regulations 13, 14	Documentation requirements
Code	**Hazardous Substances (Emergency Management) Regulations 2001**	
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

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

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

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

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

Application code: HSR02037

Applicant: Syngenta Crop Protection Limited

Purpose: To import Touchdown IQ a non-selective systemic herbicide contagfnfnnining the active ingredient glyphosate. It is intended for use for the control of annual and perennial grass and broadleaf weeds in a wide range of situations

Description of Substances: Touchdown IQ

Classifications: 6.5B, 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000016

Controls:

Control Code[28]	Regulation[29]	Explanation[30]
Code	**Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls**	
T1	Regulations 11 – 27	Limiting exposure to toxic substances
T2	Regulations 29, 30	Controlling exposure in places of work
T4, E6	Regulation 7	Requirements for equipment used to handle substances
T5	Regulation 8	Requirements for protective clothing and equipment
T7	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Code	**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

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

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

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

Code	Hazardous Substances (Identification) Regulations 2001	
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information
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
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Requirements for using concentration ranges
I19	Regulations 29 – 31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported
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
Code	**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
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 Packaging Group III (Refer to control code P13)
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D4, D5	Regulations 8, 9	Disposal requirements for toxic and ecotoxic substances
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements
D8	Regulations 13, 14	Documentation requirements
Code	**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

The Chief Executive of the Environment Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following application on 13 August 2002

Application code: HSR02039

Applicant: AGRENZ Limited

Purpose: To import Mosquito Dunks containing *Bacillus thuringiensis* Berliner var. *israelensis*, Serotype H-14 as the active ingredient for the control of mosquito larvae

Description of Substances: Mosquito Dunks

Classification: 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000018

Controls:

Control Code[31]	Regulation[32]	Explanation[33]
Code	**Hazardous Substances Classes (6, 8, and 9) control regulations**	
E6	Regulation 7	Requirements for equipment used to handle substances
E8	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Code	**Hazardous Substances (Identification) Regulations 2001**	
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information
I9	Regulation 18	Secondary identifiers for all hazardous substances
I11	Regulation 20	Secondary identifiers for ecotoxic substances
I19	Regulations 29 – 31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported

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

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

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

I21	Regulations 37 – 39, 47 – 50	**Documentation required in places of work**
I29	Regulations 51 – 52	**Duties of persons in charge of places with respect to signage**
Code	**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**
Code	**Hazardous Substances (Disposal) Regulations 2001**	
D5	Regulations 9	**Disposal requirements for toxic and ecotoxic substances**
D6	Regulation 10	**Disposal requirements for packages**
D7	Regulations 11, 12	**Information requirements**
D8	Regulations 13, 14	**Documentation requirements**
Code	**Hazardous Substances (Emergency Management) Regulations 2001**	
EM1	Regulations 6, 7, 9 – 11	**Level 1 emergency management information: General requirements**
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**
EM13	Regulation 42	**Level 3 emergency management requirements – signage**

TEST CERTIFIERS

The Chief Executive of the Environmental Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following applications on 20 August 2002

Application Code: TST02014

Applicant: Colin Perrin

Address: C/- Manawatu District Council
135 Manchester Street
Feilding

Decision: Approved with Controls

ERMA Approval Code: TST000008
Requirements for which a test certificate may be issued, and limitations

Facilities, locations etc: Locations where Class 2.1.1, 2.1.2, 3.1, 3.2, 4, 5.1.1, 5.1.2, or 5.2 substances are present