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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

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

There are no new organism applications currently open for submissions.

APPLICATIONS RECEIVED

Application Code: GMC02011

Applicant: University of Otago

Purpose: To import into containment the mutant *Lactobacillus reuteri* strain 100-23. Insertion of a replication-defective plasmid may encode properties essential for colonisation of the gut allowing study of the microbial ecology of the gastrointestinal tract

Date Application Received: 28 January 2003

Application Code: NOC02004

Applicant: Landcare Research

Purpose: This root and stem boring weevil may be considered for eventual release as a biocontrol agent for the problem pastoral and environmental weed Californian thistle (*Cirsium arvense*) found throughout New Zealand

Date Application Received: 27 January 2003

DECISIONS ON APPLICATIONS

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

Application code: GMC02009

Applicant: University of Otago

Purpose: To import into containment GM mice for use in studying the action of vitamin C and its relevance to the development of diseases associated with inflammation such as chronic lung disease, arthritis and atherosclerosis

Description of Organism: *Mus musculus* (Linnaeus 1758) strain B6.129P2-Gulo^{tm1Unc}/Ucd

Decision: Approved with Controls

ERMA Approval Code: GMC001194

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

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 sub lethally damaged by being frozen, dried, heated, or affected by chemical.

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ERMA New Zealand

operation of the containment facility shall inform all personnel involved in the handling of the organisms of the Authority's controls.

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

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

2. To exclude unauthorised people from the facility:

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

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

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

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

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

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

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

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

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

6. Inspection and monitoring requirements for containment facilities:

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

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

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

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

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

The Environmental Risk Management Authority reached a decision on the following application on 18 December 2002

Application code: S2602005

Applicant: Mrs A J Waine

Purpose: Determination that that 16 species of bulbs are not new organisms under section 26 of the HSNO Act

Description of Organism: *Calochortus amoenus* Greene (Family Liliaceae), *Cardiocrinum giganteum* (Stearn. Family Liliaceae), *Cyrtanthus falcatus* (R. A. Dyer. Family Amaryllidaceae), *Erythronium elegans* Hamond & Chambers (Family Liliaceae), *Fritillaria cirrhosa* D. Don (Family Liliaceae), *Fritillaria michailovskyi* (Fomine. Family Liliaceae), *Fritillaria stenanthera* (Reg.) Reg. (Family Liliaceae), *Geissorhiza mathewsii* (L. Bolus. Family Iridaceae), and *Lachenalia pusilla* (Eckl. ex Kunth. Family Liliaceae), *Lilium albanicum* Griseb (Family Liliaceae), *Sissyrinchium junceum* (Family Iridaceae), *Trillium maculatum* Rafinesqne

3 An inspector appointed under the Biosecurity Act.

(Family Liliaceae), and *Tulipa aucheriana* Baker (Family Liliaceae)

Decision: The above are not new organisms under section 26 of the HSNO Act

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

Application code: GMD02121

Applicant: Forest Research Institute

Purpose: To develop genetically modified *Abies nordmanniana* (Nordmanns fir) with genes coding for pest and pathogen resistance, genes coding for wood quality traits antibiotic and herbicide resistance genes, and genes involved in reproductive development

Description of Organism: *Abies nordmanniana* (LK) modified by the following:

Vector system

- Vectors for gene transfer are pUC18/19 or pBIN 19

Resistance genes for selection

- hpt II from *Escherichia coli* (Gritz & Davies, 1983) driven by the CaMV35S-promoter and terminated by CaMV35S-polyA, both from the Cauliflower Mosaic Virus (Franck et al., 1980)
- npt II from *Escherichia coli* (Beck et al., 1982) driven by the CaMV35S-promoter and terminated by CaMV35S-polyA, both from the Cauliflower Mosaic Virus (Franck et al., 1980)
- bar from *Streptomyces hygroscopicus* (Kumada et al., 1988)
- csr1-1 or ALS gene (also termed HRA or aro-A) from *Arabidopsis thaliana* (Brasileiro 1992, Haughn 1986, Li et al., 1992)

Reporter genes

- uidA from *Escherichia coli* (Jefferson et al., 1986) with or without intron sequences of cat1 from *Ricinus communis* (Suzuki et al., 1994)
- gfp from *Aequoria victoria* (Prasher et al., 1992)

Resistance genes against pest and disease

- SCAB gene (ScFv gene) from a mouse cell line (Jones et al 1993)
- Bt gene (Cry1Ac) from *Bacillus thuringiensis*
- The lectin (*Galanthus nivalis* aggluthin) gene from *Galanthus nivalis*

Wood trait related genes

- Sucrose biosynthesis genes (Wang et al., 1999; Sturm and Tang, 1999; Tang and Sturm, 1999)
- Mannose related genes (Martins et al., 1999)
- Glucose related genes (Nakajima et al., 1999)
- Arabinogalactan protein related genes (Li and Showalter, 1996)
- Cellulose biosynthesis and metabolism genes

Wood / xylem development regulating genes

- TED3 from *Zinnia elegans* (Demura and Fukuda 1994)
- PALE from *Populus* (Hertzberg and Olsson, 1998)
- Cellulose binding domain gene

Embryogenic and reproductive development genes

- *Arabidopsis* LEAFY gene (Weigel et al, 1992)
- *Arabidopsis* CONSTANS gene (Putterill et al 1995)
- *Pinus radiata* PRFLL gene (Mellerowicz et al, 1998)
- *Arabidopsis* APETALA1 gene (Iris and Sussex 1990)
- *Pinus radiata* LTP and CHS genes (Walter, pers comm)
- Barnase and Barstar genes (Hartley 1988, Paddon and Hartley 1985)
- *Pinus radiata* germin gene (Walter, pers comm)

Promoters

- Cauliflower Mosaic Virus (CaMV) promoter (35S) (Franck et al., 1980)
- maize ubiquitin promoter (Christensen, 1989):
- *Agrobacterium tumefaciens* nos (Nopalin Synthase) promoter:
- lac promoter
- *Pinus radiata* polyubiquitin gene promoter (Moyle, pers. comm.)
- TED3 promoter (Igarashi et al 1998)
- PALE promoter from *Populus* and *radiata pine* (Olsson and Walter, pers. comm.)
- Tissue specific promoters such as those associated with wood development (CAD and cOMT promoters, Wagner pers. comm.)
- CHS and LTP promoters from *Pinus radiata* (Walter, pers comm)

- PRFLL promoter from *Pinus radiata* (Walter, pers comm)
- FMV promoter from Figworth Mosaic Virus (Maiti et al., 1997)

Decision: Approved with Controls

ERMA Approval Code: GMD002392

Controls:

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

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

   a) Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms at Physical Containment Level 1 (PC1) and 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 at Physical Containment Level 2 (PC2).

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

2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standards 154.03.02 and 155.04.09, and controls imposed by this decision.

3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor[4] and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.

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

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

Application code: S2602010

Applicant: University of Auckland

Purpose: Determination whether or not *Artemia franciscana* (Kellogg 1906) is a new organism under section 26 of the HSNO Act

Description of Organism: *Artemia franciscana* (Kellogg 1906)

Decision: *Artemia franciscana* (Kellogg 1906) is not a new organism under section 26 of the HSNO Act

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The Environmental Risk Management Authority reached a decision on the following applications on 17 January 2003

Application code: GMC02010 and GMD02099

Applicant: University of Auckland

Purpose: To import into containment a human adenovirus ONYX-411 as a cancer specific replicating viral vector to deliver therapeutic genes to human tumour xenografts.

To develop in containment ONYX-015 and ONYX-411 adenoviruses modified with prodrug-activating genes to improve their utility in cancer treatment and reporter genes to assist in tracking their spread within tumour tissue.

Description of Organism:

Approved for importation: Human adenovirus subgroupC serotype2/5 chimera, ONYX-411 (GMC02010) modified by a deletion in the E3b region, deletion of bases from the E1A gene, and replacement of E1A and E4 promoters with part of the human E2F1 promoter.

Approved for development after importation of adenovirus ONYX-411: Human adenovirus subgroupC serotype2/5 chimera, ONYX-015 (GMD02099) modified by the introduction of therapeutic *Escherichia coli* nitroreductase gene (nfsB), and other bacterial nitroreductase genes; and reporter genes for *Renilla reniformis* green fluorescent protein and *Photinus pyralis* luciferase.

Human adenovirus subgroupC serotype2/5 chimera, ONYX-411 (GMD02099) modified by the introduction of therapeutic *Escherichia coli* nitroreductase gene (nfsB), and other bacterial nitroreductase genes; and reporter genes for *Renilla reniformis* green fluorescent protein and *Photinus pyralis* luciferase.

4 An inspector appointed under the Biosecurity Act.

Decision: Approved with Controls

ERMA Approval Code: GMC001195 and GMD002397 — 2398

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part I Containment Controls for Development and Field Testing of Genetically Modified Organisms[5] of the Act, the Authority's approval of this applications GMC02010 and GMD02099 is subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material[6]:

1.1 The person responsible for a particular research area and/or 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 facilities in which the organisms are maintained shall be registered by the Ministry of Agriculture and Forestry (MAF) Biosecurity Authority in accordance with the:

a) MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 Containment Facilities for Micro organisms at Physical Containment Level 2 (PC2) as specified in the Australian New Zealand standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities at Laboratory for the adenoviruses and cell lines.

b) MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.03: Containment Facilities for Vertebrate Laboratory Animals at PC2 as specified in the Australian New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities at Laboratory for the mice.

c) Animal Welfare Advisory Committee (AWAC) and National Animal Ethics Advisory Committee (NAEAC) guidelines administered by MAF.

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

Additional controls:

1.3 The genetically modified adenoviruses shall be handled within a Class II biological safety cabinet. All virally contaminated material shall be treated and/or sealed whilst still within the Class 2 Biohazard cabinet to minimise the risk of accidental exposure to aerosols.

1.4 At all times gloves and eye protection shall be worn when handling viruses and virus-related material. Face respiratory protection will also be worn when handling virus or virus-related material outside Class 2 hoods or during any procedures requiring the handling of viral titre greater than 1013 particles/ml.

1.5 Dishes and plates of cells containing human-infectious viruses shall be handled in larger trays or similar containers suitable for providing traps for accidental spills.

1.6 Tissue cultures infected with human-infectious or potentially human-infectious viruses shall be kept in incubators dedicated to the use of human-infectious viruses.

1.7 Human-infectious viruses or infected cell lines shall be stored in a section of the freezer specifically designated for this purpose and clearly marked to this effect. Similarly, ampoules of frozen infected cell lines shall be stored in a separate section of the liquid nitrogen tank.

1.8 Mice shall be securely immobilised prior to injection of the adenoviruses to ensure that they do not escape or lead to inadvertent injection of the researchers.

2. To exclude unauthorised people from the facility:

2.1 The applicant shall comply with the requirements contained in the standards listed in control 1.2 relating to 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 The applicant shall comply with the requirements contained in the standards listed in control 1.2 relating to exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

3.2 No animal (other than authorised persons) will be permitted to leave the facilities in which virus-injected animals are house).

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

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

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

4.1 The applicants shall comply with the requirements contained in the standards listed in control 1.2 relating to the prevention of unintended release of the organism by experimenters working with the organism.

4.2 Under no circumstances should investigators be infecting cultures of their own cells, or of their immediate relatives, or those of other staff of the laboratory.

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

5.1 The applicants shall comply with the requirements contained in the standards listed in controls 1.1 and 1.2 relating to the provision of an eradication plan to deal with any escaped organisms.

5.2 If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor[7], the Ministry of Agriculture and Forestry and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected).

5.3 If modifications to the viruses or incidences in the laboratory result in increased unexpected pathogenicity, infectivity or virulence the applicant shall notify the Chief Executive of ERMA New Zealand immediately the event is noticed (and at least within 24 hours of event being detected).

6. 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 applicant shall provide a final report of the effectiveness of the containment controls to the Authority at the completion of the research programme.

6.4 The applicant shall report to the Authority whenever a nitroreductase gene is used other than that specified in the organism description, identifying the new nitroreductas genes and its characteristics.

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

7.1 The applicant shall inform all personnel involved in the experiments of the Authority's controls.

7 An inspector appointed under the Biosecurity Act.

AMENDMENTS TO APPROVALS

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

DELEGATED AUTHORITY

Applicant: Crop and Food Research, Lincoln

ERMA Approval Code: GMD002399 — 2402

Institution Code: GMO02/CFR003

Purpose: Transformation of ectomycorrhizal basidiomycete fungi to further understand the process of tree root colonisation

Description of Organism: *Escherichia coli* DH5alpha, *Agrobacterium tumefaciens* AGL1, *Boletus edulis* and *Lactarius deliciosus* modified with pCAMBIA; gfp; non-native fungal promoters/terminators

Decision: Approved with controls / PC1 and PC2

Applicant: Crop and Food Research, Lincoln

ERMA Approval Code: GMD002403

Institution Code: GMO02/CFR004

Purpose: Cloning genomic, mitochondrial and chloroplast DNA fragments from *Allium* vegetables for sequencing, functional analysis and gene mapping studies

Description of Organism: *Escherichia coli* modified with organelle or genomic DNA from vegetable species of genus *Allium* (onion, shallot, scallion, garlic, chive)

Decision: Approved with controls / PC2

Applicant: Crop and Food Research, Lincoln

ERMA Approval Code: GMD002404 — 2405

Institution Code: GMO03/CFR001

Purpose: The same as application GMO00/CFR001 and update GMO01/CFR007, but using the new technology RNAi to silence genes within the onion carbohydrate pathway

Description of Organism: *Escherichia coli* and *Agrobacterium tumefaciens* modified with a sucrose transferase gene silencing construct

Decision: Approved with controls / PC2

Applicant: Crop and Food Research, Lincoln

ERMA Approval Code: GMD002406 — 2413

Institution Code: GMO02/CFR005

Purpose: To include the chlorophyll ab binding protein promoter; to include use of *Rosea* locus in our GMO research on *Brassica* transformation.
Update of GMO01/CFR003 and GMO00/CFR002

Description of Organism: *Escherichia coli, Agrobacterium rhizogenes, Agrobacterium tumefaciens, Arabidopsis thaliana, Brassica napus, Brassica oleracea, Brassica rapa* and *Nicotiana tabacum* modified with constructs containing the cab promoter and constructs containing the *rosea* locus.

Decision: Approved with controls / PC2

Applicant: Crop and Food Research, Palmerston North

ERMA Approval Code: GMD002414 — 2429

Institution Code: GMO02/CFP002

Purpose: To develop in containment plants with enhanced selenium uptake mechanisms and targeted selenium metabolism in order to produce useful levels of selenium-containing compounds with anticancer properties

Description of Organism: *Escherichia coli, Saccharomyces cerevisiae, Agrobacterium tumefaciens, Agrobacterium rhizogenes, Arabidopsis thaliana, Curcurbita maxima, Curcurbita pepo, Brassica oleracea, Brassica napus, Brassica rapa, Brassica juncea, Allium cepa, Solanum tuberosum, Nicotiana tabacum, Nicotiana plumbaginifolia, Asparagus officinalis* modified with cDNAs, and selenium or sulphur metabolism or uptake genes/cDNAs sourced from *Arabidopsis thaliana, Curcurbita maxima, Curcurbita pepo, Brassica oleracea, Brassica napus, Brassica rapa, Brassica juncea, Allium cepa, Solanum tuberosum, Nicotiana tabacum, Nicotiana plumbaginifolia, Asparagus officinalis.*

Decision: Approved with controls / PC1 and PC2

Applicant: Crop and Food Research, Palmerston North

ERMA Approval Code: GMD002430 — 2434

Institution Code: GMO02/CFP003

Purpose: To develop new organisms to be used in research to gain understanding of plant pigment biosynthesis and the mechanisms controlling pigment production and to generate new varieties of ornamental plants

Description of Organism: *Escherichia coli* and *Saccharomyces cerevisiae* modified with cDNAs, and flavonoid biosynthetic and regulatory genes/cDNAs sourced from *Agapanthus praecox*, *Alstromeria* spp., *Antirrhinum majus, Antirrhinum orontium, Anthurium andraeanum, Arabidopsis thaliana, Ceanothus papillosus, Chrysanthemum* spp. (and commercial hybrids), *Columnea* spp., *Cymbidium* spp., *Cyclamen persicum, Daucus carota, Dianthus* spp., (and commercial cultivars), *Eustoma grandiflorum, Felicia amelloides, Gerbera hybrida, Impatiens aurantiaca, Kohleria eriantha, Linaria maroccana* (and commercial cultivars), *Lycopersicum esculentum, Malus* spp. (crab and commercial apple cv.s), *Nemesia strumosa* (and commercial cultivars), *Pelargonium X domesticum, Pelargonium X hortorum, Pelargonium X hederaefolium, Petunia hybrida* and 'Mitchell', *Sandersonia aurantiaca, Sinningia cardinalis, Triticum aestivum, Vaccinium* spp. and hybrids, *Rubus* spp., *Viola* spp., *Zea mays, Coreopsis* spp., *Cosmos* spp., *Linaria vulgaris, Linaria genistifolia, Limonium* spp., *Zinna* hybrids; or modified with carotenoid biosynthetic & regulatory genes/cDNAs sourced from *Adonis aestivalis, Arabidopsis thaliana, Capsicum annuum, Chrysanthemum* spp. (commercial hybrids), *Lycopersicum esculentum, Petunia* spp., Orchids (*Cymbidium, Dendrobium* and *Disa*), *Impatiens aurantiaca, Lactuca sativa* or modified with *Betalain* biosynthetic and regulatory genes/cDNAs sourced from *Amanita muscaria, Bougainvillea glabra, Chenopodium rubrum*, *Dorotheanthus bellidiformis, Beta vulgaris, Portulaca grandiflora, Phytolacca Americana, Mesembryanthemum crystallinum. Agrobacterium tumefaciens, Nicotiana tabacum* and *Nicotiana Benthamiana* modified with flavonoid biosynthetic and regulatory genes/cDNAs sourced from *Agapanthus praecox, Alstromeria* spp., *Antirrhinum majus, Antirrhinum orontium, Anthurium andraeanum, Arabidopsis thaliana*, *Ceanothus papillosus,*

Chrysanthemum spp. (and commercial hybrids), *Columnea* spp., *Cymbidium* spp., *Cyclamen persicum, Daucus carota, Dianthus* spp., (and commercial cultivars), *Eustoma grandiflorum, Felicia amelloides, Gerbera hybrida, Impatiens aurantiaca, Kohleria eriantha, Linaria maroccana* (and commercial cultivars), *Lycopersicum esculentum, Malus* spp. (crab and commercial apple cv.s), *Nemesia strumosa* (and commercial cultivars), *Pelargonium X domesticum, Pelargonium X hortorum, Pelargonium X hederaefolium, Pelargonium hybrida* and 'Mitchell', *Sandersonia aurantiaca, Sinningia cardinalis, Triticum aestivum, Vaccinium* spp. and hybrids, *Rubus* spp., *Viola* spp., *Zea mays, Coreopsis* spp., *Cosmos* spp., *Linaria vulgaris, Linaria genistifolia, Limonium* spp., *Zinna hybrids* or modified with carotenoid biosynthetic and regulatory genes/cDNAs sourced from *Adonis aestivalis, Arabidopsis thaliana, Capsicum annuum, Chrysanthemum* spp. (commercial hybrids), *Lycopersicum esculentum, Petunia* spp., Orchids (*Cymbidium, Dendrobium* and *Disa*), *Impatiens aurantiaca, Lactuca sativa* or modified with *Betalain* biosynthetic & regulatory genes/cDNAs sourced from *Amanita muscaria, Bougainvillea glabra, Chenopodium rubrum, Dorotheanthus bellidiformis, Beta vulgaris, Portulaca grandiflora, Phytolacca Americana, Mesembryanthemum crystallinum*

Decision: Approved with controls / PC1 and PC2

Applicant: Crop and Food Research, Palmerston North

ERMA Approval Code: GMD002435 — 2471

Institution Code: GMO02/CFP004

Purpose: To update applications GMO00/CFP001, GMO00/CFP009 and GMO01/CFP002 to include new pigment biosynthesis and regulatory genes and some new reporter genes

Description of Organism: *Escherichia coli, Sacharomyces cerevisiae, Agrobacterium tumefaciens, Agrobacterium rhizogenes, Arabidopsis thaliana, Chrysanthemum* sp, *Cyclamen persicum, Eustoma grandiflorum, Cymbidium, Dendrobium, Disa, Pelargonium X domesticum, Pelargonium X hederaefolium, Pelargonium X hortorum, Petunia hybrida, Petunia* 'Mitchell', *Sandersonia aurantiaca, Viburnum opulus, Viburnum plicatum, Daucus carota, Fragaria Xananassa, Prunus domestica, Prunus avium, Prunus cerasus, Ribes sativum, Ribes nigrum, Rubus ulmifolius, Rubus idaeus, Solanum tuberosum, Vaccinium australe, Vaccinium ashei, Vaccinium myrtillus* and *Vitus vinifera* modified with betalin biosynthetic and regulatory genes/cDNAs sourced from *Amanita muscaria, Bougainvillea glabra, Chenopodium rubrum, Dorotheanthus bellidiformis, Beta vulgaris, Portulaca grandiflora, Phytolacca Americana, Mesembryanthemum crystallinum* or modified with carotenoid biosynthetic and regulatory genes/cDNAs sourced from *Lactuca sativa* or modified with floral identity genes acting as regulators of pigment production, sourced from *Antirrhinum majus, Anthurium andraeanum, Arabidopsis thaliana, Daucus carota, Zea mays, Lycopersicum esculentum, Petunia* spp., *Malus* spp., *Vaccinium* spp. and hybrids, *Gerbera hybrid, Sinningia cardinalis Antirrhinum majus, Antirrhinum andraeanum, Sinningia cardinalis* and *Zea mays* isolated tissues modified with betalin biosynthetic & regulatory genes/cDNAs sourced from *Amanita muscaria, Bougainvillea glabra, Chenopodium rubrum, Dorotheanthus bellidiformis, Beta vulgaris, Portulaca grandiflora, Phytolacca Americana, Mesembryanthemum crystallinum* or modified with carotenoid biosynthetic and regulatory genes/cDNAs sourced from *Lactuca sativa* or modified with floral identity genes acting as regulators of pigment production, sourced from *Antirrhinum majus, Anthurium andraeanum, Arabidopsis thaliana, Daucus carota, Zea mays, Lycopersicum esculentum, Petunia* spp., *Malus* spp., *Vaccinium* spp. and hybrids, *Gerbera hybrid, Sinningia cardinalis.*

Decision: Approved with controls / PC1 and PC2

Applicant: Landcare Research, Auckland

ERMA Approval Code: GMD002472

Institution Code: GMO02/HRA071

Purpose: To develop genetic markers to assist in improving the effectiveness of the heather beetle (*Lochmaea suturalis*), introduced for the control of weed heather

Description of Organism: *Escherichia coli* K12 or B strains modified with standard plasmid vectors containing genomic DNA from *Lochmaea suturalis.*

Decision: Approved with controls / PC1 and PC2

Applicant: Massey University

ERMA Approval Code: GMD002393 — 2395

Institution Code: GMO02/MU015

Purpose: To identify genes involved in *Candida albicans* dimorphism

Description of Organism: *Escherichia coli* modified with non-conjugative vectors containing *Candida albicans* DNA Z (in PC1) or Non-conjugative vectors containing *Candida albicans* DNA (in PC2) *Candida albicans* modified with Integrative vectors or nucleic acids containing *Candida albicans* and *Saccharomyces cerevisiae* genes and DNA *Saccharomyces cerevisiae* modified with yeast cloning vectors containing *Candida albicans* DNA.

Decision: Approved with controls / PC1 and PC2

Applicant: University of Auckland

ERMA Approval Code: GMD002482 — 2483

Institution Code: GMO02/UA021

Purpose: To add further therapeutic vectors to the study of cDNAs with therapeutic potential in the fight against cancer and to use the commercial IMPACT kit for purification of recombinant proteins.
Update of GMO99/UA026

Description of Organism: *Escherichia coli* (DH5 alpha and MC1061/P3) as modified by pCDM8 and pcDNA with mouse (*Mus musculus*) genes encoding cytokines and chemokines and as modified by IMPACT vectors with mouse (*Mus musculus*) genes encoding cytokines and chemokines. *Mus musculus* injected with pCDM8 and pcDNA with mouse (*Mus musculus*) genes encoding cytokines and chemokines.

Decision: Approved with controls / PC1 and PC2 (mice)

Applicant: University of Auckland

ERMA Approval Code: GMD000793 — 0794

Institution Code: GMO00/UA051s67A

Purpose: Study of genes involved in neurodegenerative disorders such as Alzheimer's disease, stroke and Parkinson's

Description of Organism: *Escherichia coli* and Mammalian cell lines (from rat (c6 glioma), mouse (Raw macrophage and P19), Chinese hamster and African green monkey) as modified by expression vectors containing human, mouse and rat gene inserts encoding; genes involved in cell death and apoptosis; genes involved in nerve cell plasticity; genes involved in inflammation associated with Alzheimer's disease; promoter-reporter constructs.

Decision: Approved with Controls / PC1

Applicant: University of Auckland

ERMA Approval Code: GMD001568 — 1569

Institution Code: GMO00/UA046s67A

Purpose: To allow a change in study design to accommodate different cloning systems and transcriptional regulator genes

Description of Organism: *Escherichia coli* (K12 strains) and *Saccharomyces cerevisiae* as modified by plasmid and phagemid cloning systems and transcriptional factors.

Decision: Approved with Controls / PC1

Applicant: University of Auckland

ERMA Approval Code: GMD002473 — 2474

Institution Code: GMO02/UA013

Purpose: To investigate the role of the NOD2 gene in Crohn's disease

Description of Organism: *Escherichia coli* strains B & K12 modified by non-conjugative vectors with human NOD2 cDNA

Human cell lines (*Homo sapiens*) THP-1, U937, HL160, 293T and normal and patient Crohn's disease monocytes as modified with pSV3, pCDM8 and pcDNA vectors with human NOD2 cDNA.

Decision: Approved with controls / PC1

Applicant: University of Auckland

ERMA Approval Code: GMD002475 — 2481

Institution Code: GMO02/UA019

Purpose: To investigate the use of recombinant adeno-associated viral vectors (rAAV) for gene therapy for neurological disorders and functional genomic studies.
Update of GMO00/UA032, GMO00/UA054 and GMO01/001A

Description of Organism: *Escherichia coli* and human cell lines (*Homo sapiens*); SF9 insect cell lines, baculovirus and cell lines from rats (*Rattus norvegicus*), mouse (*Mus musculus*)

and human (*Homo sapiens*); Rats (*Rattus norvegicus*) as modified by recombinant Adeno-associated vector plasmids expressing: Hsp 70, Hsp 40, Hsp 90, CHIP, Hip, Hop and related chaperone family genes from mouse (*Mus musculus*), rat (*Rattus norvegicus*) and human (*Homo sapiens*). Human (*Homo sapiens*) genes involved in the pathogenesis of Alzheimer's disease: Presenilin, amyloid precursor protein (APP), tau, BRI and related family members including truncated and mutant forms. Rat (*Rattus norvegicus*) and human (*Homo sapiens*) genes encoding leptin and leptin receptors. Mouse (*Mus musculus*), rat (*Rattus norvegicus*) and human (*Homo sapiens*) genes encoding glutamate receptor subunits and related modulator of glutamate receptor signalling. Human (*Homo sapiens*) genes encoding full length mutant and truncated Huntington proteins. Rat (*Rattus norvegicus*) and human (*Homo sapiens*) genes encoding Pael receptor and other related genes involved in Parkinson's Disease. Mouse (*Mus musculus*) U6 RNA promoter. SiRNA genes directed at the following transcripts:

1. Human-Huntington – mutant and wild-type
2. Rat and human Brain Derived Neural factor
3. Rat and human Dopamine transporter
4. Hsp 70, Hsp 40, Hsp 90, CHIP, Hip, Hop and related chaperone family genes from mouse (*Mus musculus*), rat (*Rattus norvegicus*) and human (*Homo sapiens*)
5. Enhanced Green Fluorescent Protein

Decision: Approved with controls / PC1 and PC2

Applicant: University of Auckland

ERMA Approval Code: GMD002484 — 2486

Institution Code: GMO02/UA025

Purpose: To develop high efficiency recombinant expression systems to produce the high amount of membrane proteins necessary for functional and structural studies

Description of Organism: *Escherichia coli* K12 and B strains, *Saccharomyces cerevisiae* and *Spodoptera frugiperda* cell lines modified by non-conjugative vectors with genes encoding proteins of:

1. aquaporin family
2. the carbohydrate, alcohol and organic acid transporter families
3. Amino acid, amine and peptide transporter families
4. Monovalent ion transporter families
5. Dinovalent ion transporter families
6. Connexin families
7. Nucleoside, purine, pyrimidine transporters

From any species of bacteria, fungi, plant or eukaryotic animal excluding the following:

1. Homo sapiens (humans)
2. Native flora or fauna
3. Valued species
4. CITES protected species

Decision: Approved with controls / PC1

Applicant: University of Auckland

ERMA Approval Code: GMD002487

Institution Code: GMO02/UA026

Purpose: To amend the project 'Cloning of bacterial homologues of mammalian amino acid transporters'. Update of GMO00/UA026

Description of Organism: *Escherichia coli* K12 strains (with sub-types) as modified by vectors pBluescript, pET19-b, pET17-b containing genes from *Fusobacterium nudeatum.*

Decision: Approved with controls / PC1

Applicant: University of Auckland

ERMA Approval Code: GMD002488 — 2504

Institution Code: GMO02/UA027

Purpose: To include the application of RNA interference methodology to the study of neuroendocrine cell biology. Update of GMO00/UA055, GMO00/UA068, GM02/UA010

Description of Organism: *Escherichia coli* (K12 and B strains), SF9 insect cell lines and cell lines from human (*Homo sapiens*), rat (*Rattus rattus, Rattus norvegicus*), mouse (*Mus spretus, Mus musculus*), hamster (*Cricetus cricetus*), cattle (*Bos taurus, Bos indicus*), dog (*Canis familiaris*), chinese hamster (*Cricetulus griseus*), Golden hamster (*Microcricetulus aureus*), rabbit (*Orcylagus cuniculus*), sheep (*Ovis aries*), pig (*Sus scrofa*) and toad (*Xenpus laevis*) or *Escherichia coli* (K12 and B strains) and cell lines from human (*Homo sapiens*) or Cell lines from human (*Homo sapiens*),

rat (*Rattus rattus, Rattus norvegicus*), mouse (*Mus spretus, Mus musculus*), hamster (*Cricetus cricetus*), cattle (*Bos taurus, Bos indicus*), dog (*Canis familiaris*), chinese hamster (*Cricetulus griseus*), Golden hamster (*Microcricetulus aureus*), rabbit (*Orcylagus cuniculus*), sheep (*Ovis aries*), pig (*Sus scrofa*) and toad (*Xenpus laevis*) as modified by nonconjugative vectors or recombinant Adeno-associated vector plasmids or recombinant Adeno-associated vectors containing type III Pol III promoters siRNA directed at mammalian and bacterial:

1. Genes involved in cell death and survival
2. Genes involved in cell attachment, cell migration and cell:cell association
3. Genes involved in hormone and neuropeptide biosynthesis, intracellular sorting and targeting
4. Nerve and endocrine cell growth
5. Colourometric and fluorometric reporter genes

Decision: Approved with controls / PC1 and PC2

Applicant: University of Otago

ERMA Approval Code: GMD002505

Institution Code: GMO02/UO027

Purpose: To clone human DNA in *Escherichia coli* for use in pharmacogenic studies.
Update of GO01/UO024

Description of Organism: *Escherichia coli* K12 modified with non-conjugative plasmid and phage vectors; human DNA relevant to pharmacogenetics.

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002506

Institution Code: GMO02/UO031

Purpose: To evaluate the potential use of genetically modified orf viruses as vaccine vectors for parasitic diseases of sheep

Description of Organism: Orf virus strains NZ2 and NZ7 modified with beta-galactosidase and beta-glucuronidase reporter genes from *Escherichia coli*; synthetic promoters that resemble poxvirus promoters, vaccinia virus early/late promoter P7.5, VV late promoter P11, VV early/late promoter PH5, orf virus late promoter PF1; genes for drug selection: xanthine guanine phosphoribosyl transferase (*gpt*), neomycin/kanamycin resistant gene (*neo*); genes encoding protective antigens, 45W, 18k and 16k of *Taenia ovis* or EG95 *Echinoccus granulosus*.

Decision: Approved with controls / PC2

Applicant: University of Otago

ERMA Approval Code: GMD002507

Institution Code: GMO02/UO033

Purpose: To introduce cosmids of *Mycobacterium bovis* DNA into *Escherichia coli* K12 derivatives.
Update of GMO00/UO031 and GMO99/UO014

Description of Organism: *Escherichia coli* K12 derivatives modified with Cosmid pYUB18; genomic DNA from *Mycobacterium bovis*

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002508

Institution Code: GMO02/UO034

Purpose: To construct a library of the human dental plaque microbial metagenome in *Escherichia coli* in order to supply plaque diversity and identify novel microbial metabolites

Description of Organism: *Escherichia coli* K12 derivatives such as DH10B modified with non-conjugative plasmid such as pUC and pBluescript and including bacterial artificial chromosome vectors such as PBeloBAC11; genomic DNA prepared from a mixed culture microbial biofilm comprising microorganisms originating from human supragingival plaque.

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002509

Institution Code: GMO02/UO035

Purpose: To provide molecular tools with which to understand the genetics and inheritance of desired phenotypic traits in animals of economic importance. The update includes the use of DNA from additional species and the use of new vectors.
Update of GMO00/UO050

Description of Organism: *Escherichia coli* K12 or B strains modified with non conjugative plasmid vectors such as pRSET, pSPORT, pEGFP, pGFP and pM-1 plasmids; DNA from marmoset (*Callithrix jacchus)*, domestic cat (*Felis catus*) and chicken (*Gallus gallus*).

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002510

Institution Code: GMO02/UO040

Purpose: *Escherichia coli* will be modified with genetic material from mice, rats, sheep and cattle to provide tools for functional genomic studies that elucidate the biological roles of genes

Description of Organism: *Escherichia coli* K12 and B strains modified with non conjugative plasmid vectors such as pET, pIND, pBluescript series, pPRO-EX, pGEM series, pUC19, pcDNA3, pGL3, pGFP, pBLCAT, pBK-CMV and others derived from pBR322, and bacteriophage vectors; genomic DNA and cDNA from mouse (*Mus musculus*), rat (*Rattus norvegicus*), sheep (*Ovis aries*) and cattle (*Bos taurus*).

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002511

Institution Code: GMO02/UO042

Purpose: To clone & express random fragments of restriction-digested *Helicobacter pylori* DNA that may be found within outer membrane vesicles (OMV) that are shed from the surface of these bacteria. Update of GMO00/UO026

Description of Organism: *Escherichia coli* K12 and B strains such as DH5alpha modified with non-conjugative plasmids such as pZERO; DNA fragments from *Helicobacter pylori*.

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002512-2513

Institution Code: GMO02/UO046

Purpose: To construct libraries of DNA sequences from the bacterial inhabitants of the gut of specific pathogen free rodents

Description of Organism: *Escherichia coli* K12 derivatives such as DH10B or similar modified with bacterial artificial chromosome (non conjugative plasmids) vectors such as pBeloBAC11, or similar; *Bacillus subtilis* modified with non conjugative plasmid vectors such as pEG597, or similar. Modified with DNA fragments from uncharacterised bacteria in the gut microflora of specific pathogen free HLA-B27/B2 microglobulin rats and the gut microflora of interleukin-10 deficient mice that have been inoculated with gut microflora from specific pathogen free wild type mice.

Decision: Approved with controls / PC1 and PC2

Applicant: University of Otago

ERMA Approval Code: GMD02396

Institution Code: GMO02/UO015

Purpose: To develop *Escherichia coli* strains modified with genomic DNA or cDNA, involved in either embryonic or larval development, or containing transposable element sequences from Arthropods and Onychophora

Description of Organism: *Escherichia coli* derivatives K12 and B modified with non-conjugative plasmid and bacteriophage vectors; DNA from *Drosophila melanogaster* (fruit fly), *Musca domestica* (house fly), *Apis mellifers* (honey bee), *Locusta migratoria* (migratory locust), *Teleogryllus commodus* (black field cricket), *Tetranychus urticae* (two spotted mite), *Tetranychus lintearius* (gorse spider mite), *Phalagium opilio* (European harvestman), *Dolomedes minor* (nurseryweb spider), *Varroa jacobsoni* (varroa mite), *Procyliosoma* sp (common pill millipede), *Siminthirus viridis* (lucerne fles), *Thrips obscuratus* (flower thrip), *Thrips tabaci* (Onion thrip), *Acyrthosiphon pisum* (Pea aphid), *Rhopalosiphum padi* (apple grain aphid), *Acyrthosiphon kondoi* (bluegreen lucerne aphid), *Chelifer cancroides* (book pseudoscorpion), *Lithobius forcificatus* (garden centipede), *Porcellio scaber* (garden woodlouse), Peripatoides 'Dunedin' *Peripatoides novaezealandiae*.

Decision: Approved with controls / PC1

HAZARDOUS SUBSTANCES

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

Application Code: HSR02058

Applicant: Energy Efficiency & Conservation Authority

Purpose: To seek approval for the manufacture, release, handling and use of petrol-ethanol blends not exceeding 10% ethanol by volume

Date Application Received: 20 December 2002

Date Publicly Notified: 30 January 2003

Date Submissions Close: 13 March 2003

Application Code: HSR02059

Applicant: Department of Conservation

Purpose: The application is to import Rotenone for use in fresh water as a piscicide for the eradication of invasive fish and aquatic invertebrates, and in marine water as a sampling tool for cryptic fish

Date Application Received: 5 December 2002

Date Publicly Notified: 5 December 2002

Date Submissions Close: 14 February 2003

Application Code: HSR02062

Applicant: Adria New Zealand Limited

Purpose: To import Pyrus 400SC as a fungicide for disease control in apples and grapes

Date Application Received: 9 December 2002

Date Publicly Notified: 19 December 2002

Date Submissions Close: 27 February 2003

NON NOTIFIED APPLICATIONS RECEIVED

Application Code: HSC02014

Applicant: Bayer New Zealand Limited

Purpose: To field test the substance Larvin SC to assess the efficacy on Springtails in forage brassicas and Argentine Stem Weevil and Black Beetle in grasses

Date Application Received: 6 January 2003

Application Code: HSC02016

Applicant: Bayer New Zealand Limited

Purpose: To conduct under NZ conditions, small plot field testing of Dicarzol 500 to establish the efficacy, crop safety and residue profile of the product in controlling target pest species using various rates of product diluted in water

Date Application Received: 23 January 2003

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following application on 3 December 2002

Application code: HSR02041

Applicant: Virbac Laboratories NZ Limited

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

Description of Substances: VBLA

Classifications: 9.1A, 9.2C, 9.3C, 9.4A, 6.1D, 6.5B, 6.8B, 6.9B

Decision: Approved with Controls

Controls:

Control Code[8]	Regulation[9]	Explanation[10]
	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

8 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/publications/) and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations.*

9 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.

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

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 for vertebrate poisons
E1	Regulations 32 — 45	Limiting exposure to ecotoxic substances, the environmental exposure limit (EEL) approach
E2	Regulations 46 — 48	Restrictions on use of substances in application areas
E3	Regulation 49	Controls relating to protection of terrestrial invertebrates
E4	Regulations 50 — 51	Controls relating to protection of terrestrial vertebrates
E5	Regulations 5(2), 6	Requirements for keeping record of use
	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
I3, I8	Regulation 9, 14	Priority identifiers
I9, I11, I16	Regulation 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
I20	Regulation 36(8)	Durability of information for class 6.1 substances
I21	Regulations 37 — 39, 47 — 50	Documentation required in places of work
I23, I28	Regulation 41, 46	Specific documentation requirements
I29	Regulations 51, 52	Signage requirements
I30	Regulation 53	Advertising corrosive 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, P15	Regulation 19, 21	**Packaging requirements**
PG3	Schedule 3	**This schedule describes the test methods for packaging required to be tested in accordance with this requirement. The tests in Schedule 3 correlate to the packaging requirements of UN Packaging Group III.**
	Hazardous Substances (Disposal) Regulations 2001	
D4, D5, D6	Regulation 8 — 10	**Disposal requirements**
D7	Regulations 11, 12	**Information requirements**
D8	Regulations 13, 14	**Documentation requirements**
	Hazardous Substances (Emergency Management) Regulations 2001	
EM1	Regulations 6, 7, 9 — 11	**Level 1 emergency management information: General requirements**
EM6, EM7	Regulation 8(e) and (f)	**Information requirements for toxic and 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 13 December 2002

Application code: HSR02005

Applicant: Altex Coatings Limited

Purpose: To import and manufacture ranges of copper co-biocide antifouling paints in a range of colours for marine use

Description of Substances:

Ablative A antifouling range

Ablative A1 antifouling range

Ablative B antifouling range

Hard A antifouling range

Hard B antifouling range

Alloy antifouling range

Waterbased antifouling range

Classifications: Ablative A antifouling range – 3.1C, 6.1D, 6.3B, 6.4A, 6.5B, 6.6B, 6.8B, 6.9B, 9.1A, 9.3C

Ablative A1 antifouling range – 3.1C, 6.1D, 6.1E, 6.3B, 6.4A, 6.5B, 6.8B, 6.9B, 9.1A, 9.3B

Ablative B antifouling range – 3.1C, 6.1D, 6.3B, 6.4A, 6.5B, 6.9B, 9.1A, 9.3C

Hard A antifouling range – 3.1C, 6.1D, 6.3B, 6.4A, 6.5B, 6.8A, 6.9B, 9.1A, 9.3C

Hard B antifouling range – 3.1C, 6.1D, 6.3B, 6.4A, 6.5B, 6.8A, 6.9B, 9.1A, 9.3C

Alloy antifouling range – 3.1C, 6.1D, 6.3B, 6.4A, 6.5B, 6.8B, 6.9A, 9.1A, 9.3C

Waterbased antifouling range – 6.1D, 6.3B, 6.4A, 6.8A, 6.9B, 9.1A, 9.3C

Decision: Approved with Controls

Controls:

Controls for the Ablative A, Ablative A1, Ablative B, Hard A, Hard B and Alloy antifouling ranges

Control Code[11]	Regulation[12]	Explanation[13]
	Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001 – Flammable Property Controls	
F1	Regulation 7	General test certification requirements
F3	Regulation 55	General limits on flammable substances
F5	Regulations 58 — 59	Requirements regarding hazardous atmosphere zones for flammable liquids
F6	Regulations 60 — 70	Requirements to prevent unintended ignition of flammable liquids
F11	Regulation 76	Segregation of incompatible substances
F12	Regulations 77 — 78	General requirement for hazardous substance locations for flammable substances
F14	Regulation 81	Test certification requirements for facilities where class 3.1 substances are 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 flammable substances, including requirements for protective equipment and clothing
		Substitute Controls for Flammable Properties **If the facility is currently subject to the to the Dangerous Goods (Class Three – Flammable Liquids) and the Dangerous Goods (Licensing Fees) Regulations, including the requirement to have a dangerous goods licence, these DG regulations will apply in place of the HSNO Hazardous Substances (Classes 1 to 5 Controls) Regulations for flammable substances (control codes F1-F17) until the class three flammable liquids are deemed assessed and approved by regulations under section 160(1)(a) of the HSNO Act.** **In addition, until such time as the HSNO Bulk Storage Tank Regulations come into force, the provisions of the Dangerous Goods regulations relating to the storage of flammable liquids in bulk must be complied with.**
	Flammable Property Controls, Toxic Property Controls and Ecotoxic Property Controls	
F2, T7, E8		Restrictions on the carriage of hazardous substances on passenger service vehicles
	Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls	
T1	Regulations 11 — 27	Limiting exposure to toxic substances through setting of TELs
T2	Regulations 29, 30	Controlling exposure in places of work through setting of WESs
T4, E6	Regulation 7	Requirements for equipment used to handle substances
T5	Regulation 8	Requirements for protective clothing and equipment
	Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls Controls	
E1	Regulations 32 — 45	Limiting exposure to ecotoxic substances through setting of EELs

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/publications/) 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.

E5	Regulations 5(2), 6	Requirements for keeping records of use
	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
I3, I5, I8	Regulations 9, 11, 14	Priority identifiers for ecotoxic, flammable and toxic substances
I9, I11, I13, I16	Regulations 18, 20, 22, 25	Secondary identifiers for ecotoxic, flammable and 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 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	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 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
I23, I25, I28	Regulations 41, 43, 46	Specific documentation requirements for ecotoxic, flammable and 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 Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility
P3, P5, P13, P15, PG2	Regulations 9, 11, 19, 21, Schedule 2	Specific packaging requirement
	Hazardous Substances (Disposal) Regulations 2001	
D2, D4, D5	Regulations 6, 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, EM4, EM6, EM7	Regulations 6, 7, 8(c), 8(e), 8(f), 9 — 11	Level 1 emergency management information requirements
EM8	Regulations 12 — 16, 18 — 20	Level 2 emergency management information requirements
EM9	Regulation 17	Extra content for flammable substances
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

Recommendations:

Approved Handler Requirements

The Committee recommends that, in place of the approved handler control, the following information should be provided with these products:

- an information sheet providing guidelines on the application, use and removal of antifoulants in a manner that reduces the risks to the environment
- an 0800 helpline number should be available at all times for boat owners to obtain relevant information with respect to environmental management relating to the application, use and removal of antifoulants

The Committee also strongly encourages industry to develop an ERMA New Zealand approved code of practice for the application and removal of antifouling paints relevant to the New Zealand context, and to run awareness campaigns so that boat owners will have a better knowledge and understanding of the potential (human health and environmental) risks involved with such activities.

Controls for the waterbased antifouling range

Control Code[14]	Regulation[15]	Explanation[16]
	Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001	
T1	Regulations 11 — 27	Limiting exposure to toxic substances through setting of TELs
T2	Regulations 29, 30	Controlling exposure in places of work through setting of WESs
T4, E6	Regulation 7	Requirements for equipment used to handle substances

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/publications/) and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

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

T5	Regulation 8	Requirements for protective clothing and equipment
T7, E8	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	
E1	Regulations 32 — 45	Limiting exposure to ecotoxic substances through setting of EELs
E5	Regulations 5(2), 6	Requirements for keeping records of use
	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
I3, I8	Regulations 9, 14	Priority identifiers for ecotoxic and toxic substances
I9, I11, I16	Regulations 18, 20, 25	Secondary identifiers for ecotoxic and 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
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 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
I23, I28	Regulations 41, 46	Specific documentation requirements for ecotoxic and 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 Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility

P3, P13, P15, PG2	Regulations 9, 19, 21, Schedule 2	**Specific 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), (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**
	Hazardous Substances (Tracking) Regulations 2001	
TR1	Regulations 4(1), 5, 6	**Tracking Requirements**

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

Application code: HSC02005

Applicant: DuPont New Zealand Limited

Purpose: To conduct small plot field testing of Compounds DP1902 10SC and DP2902 10SC to determine the efficacy of the products in controlling target pest species using various rates of products diluted in water

Description of Substances: DP1902 10SC and DP2902 10SC

Decision: Approved with Controls

ERMA Approval Code: HSC000028 — 000029

Controls:

For the purpose of these Controls, the following terms are defined:

- Trial site – the commercial or private property where the trial is to be conducted.
- Trial plot – a defined area within the trial site where the crops to be tested are located.
- Trial period – the period of time when the trial will proceed from spraying to when the plot can be reused (about 8 months).
- Approval period – the period in which trials can be conducted (up to 3 years).
- Trial director – the person nominated to be in charge of the conduct of the trial.
- Spray drift – the occurrence of spray moving off the target area/trial plot due to wind, or poor application technique.

1. To limit the likelihood of escape of any contained hazardous substances or contamination by hazardous substances

1.1 The trials shall be undertaken in accordance with the Management Plan, which accompanied the application except where the following controls direct otherwise. Modifications of the Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.

1.2 Trial plot area will be a maximum of 20m^2 for each substance.

1.3 The substances will be diluted prior to use and applied by way of hand-held spray-application equipment, using low pressure compressed air, on plots specifically designated and marked for each treatment.

1.4 The substances will be applied in the volumes and concentrations according to the test protocols described in Appendix 1 Addendum C of the application.

1.5 The trial plot locations shall be chosen so as to prevent any of the substances entering any surface water or groundwater system.

1.6 All trial plots must be at least 50 metres from buildings where people live or work (commercial and research glasshouses being an exception), and at least 100m from public roads.

1.7 The maximum amount of substance for the trials is limited to 40 gai (grams active ingredient) at each trial site.

1.8 The maximum amount of active ingredient to be imported for all the trials is limited to 120 gai.

1.9 The substances will be securely packed in containers that are identified in accordance with the Hazardous Substances (Identification) Regulations 2001 and a Material Safety Data Sheet (MSDS) will accompany each shipment.

1.10 Transport of the substances will be undertaken by local chemical transport and customs experts employed for the purpose, with a MSDS accompanying transport.

1.11 Storage will be in accordance with the Code of Practice for the Management of Agrichemicals NZS8409:1999.

1.12 Any portion of the substances surplus to requirements will be returned to DuPont New Zealand Ltd for disposal.

1.13 Spraying and mixing must be in accord with Section 5 of Code of Practice for the Management of Agrichemicals NZS8409:1999.

1.14 Solid waste, namely treated produce, will be disposed of by ploughing in.

1.15 No treated produce shall be consumed by people or animals or offered for sale.

2. To exclude organisms or control organisms

2.1 Grazing animals shall be excluded from all trial plots, including buffer zones, by a stock proof fence for the duration of the trial period. The trial period means the period of the date of initial application of the substances to the date of site close-off in accordance with Control 6.3.

2.2 Bird scaring devices shall be located on or near the trial plots.

3. To exclude unauthorised people

3.1 Access to the trial site(s) shall be by permission of the Trial Director or owner of the property on which it is located. The trial site(s) or plot(s) shall be secured by stock proof fencing and all potential access points shall be sign-posted indicating that unauthorised access is not allowed, that the plot is subject to a trial, and that crops and produce should not be removed or disturbed.

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

4.1 The amount of material taken into each trial site will be pre-measured so as to be sufficient for the application to the designated plots.

4.2 The dispensing of the substance from the original imported container will be in a controlled environment (for example, storage area) to minimise inadvertent release, spillage, and unnecessary exposure. Dispensing will take place prior to transportation to each trial site for application.

4.3 The mixing of the substances will occur in a controlled environment (for example, a building or storage area) and comply with section 5.5 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

4.4 Any surplus spray mix shall be disposed of within the trial site(s) by being further diluted and sprayed over a marked and designated non-crop area and non-grazed area at the site.

4.5 The equipment used shall be rinsed after use with water and/or the appropriate detergent or decontaminant, and the rinsate disposed of within the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.

4.6 The disposal areas referred to in controls 4.4 and 4.5 shall be chosen so as to prevent any of the substances entering any surface water or groundwater system.

4.7 Empty containers used to transport the substances may be disposed of according to the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

5. To control the effects of any accidental release of the substance

5.1 Any accidental spillage of the unmixed substances or spray mix shall be contained with absorbent material and the spillage area decontaminated by washing with a bleach solution, mopping up and disposing the spill material (including mops). The spill material shall be disposed of by certified hazardous waste disposal contractors.

5.2 To minimise the effects of any accidental release of the substances, the container labels or MSDS will carry appropriate safety precautions and relevant first aid measures for immediate action pending medical attention.

5.3 All personnel involved with preparing and spraying the substances must wear appropriate protective clothing.

6. Inspection and monitoring requirements

6.1 The Trial Director or nominated researcher will keep track of all use of the substances as per section 5.9.1 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

6.2 Prior to the initial application of the substances, the Trial Director shall inform Occupational Safety & Health, Head Office [Attn: HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand in writing of the locations of the trial sites. The Trial Director shall inform OSH and ERMA New Zealand in writing on completion of the field trials.

6.3 Site close off – The Trial Director shall ensure that the test substances in the whole of the trial site, including the areas used for disposal of any surplus mix and rinse, shall be below international cut-off levels for toxicological or ecotoxicological concern, or show that the environmental fate of these components is such that they are not readily available and will not move off the site.

6.4 If for any reason a breach of containment occurs, the Trial Director will notify OSH and ERMA New Zealand within 24 hours of the event.

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

6.6 This approval is for up to 3 years from the date on which this approval is given.

7. Qualifications required of the person responsible for implementing the controls

7.1 The personnel applying the substances to the crops shall be GROWSAFE certified.

The Environmental Risk Management Authority reached a decision on the following application on 16 December 2003

Application code: HSC02011

Applicant: Taranaki NuChem Limited

Purpose: To manufacture and field trial various substances made up of combinations of currently registered fungicidal actives and inert components for use in the agricultural and horticultural markets

Description of Substances: Max Cl 30, Max Cl 60, TNL 1811

Decision: Approved with Controls

ERMA Approval Code: HSC000030 — 000032

Controls:

1. To limit the likelihood of escape of any contained hazardous substance or contamination by hazardous substance

1.1 Total trial plot area over the 5 trial sites will be a maximum of 200m^2 for TNL 1811 and 600m^2 for Max Cl.

1.2 The substances will be diluted prior to use and applied by way of hand-held spray-boom application equipment, using compressed CO_2 or air on plots specifically designated and marked for each treatment.

1.3 The formulations will be applied in the volumes and concentrations according to the test protocols described in Appendix 4 of the application.

1.4 The trial plots chosen will not be contiguous to any water source.

1.5 All trial plots must be at least 50 metres from buildings where people live or work (commercial and research glasshouses being an exception), and at least 100m from public roads.

1.6 Access to the trial plot(s) will be by permission of the Trial Director or owner of the property on which it is located.

1.7 The properties containing the trial plots will be secured by stock proof fencing at the boundaries of the property. There will be a sign situated at the edge of the trial plot closest to the entry point into the field where the trial plot is situated indicating that unauthorised access is not allowed, that the plot is subject to a trial, and that the crops should not be removed or disturbed.

1.8 The substances will be securely packed in containers being identified in accordance with the Hazardous Substances (Identification) Regulations 2001 and a MSDS will accompany each shipment.

1.9 The transportation of the substances will comply with the Land Transport Rule: Dangerous Goods 1999.

1.10 Storage will be in accordance with the Code of Practice for the Management of Agrichemicals NZS8409:1999.

1.11 Any portion of the substances or spray mix surplus to requirements will be returned to TNL for disposal according to the waste management protocol.

1.12 Spraying must be in accord with Section 5 of the Code of Practice for the Management of Agrichemicals NZS8409:1999.

1.13 Solid waste, namely treated produce, will be disposed of by either ploughing in, composting, or at an appropriate local authority operated landfill.

1.14 No treated produce shall be consumed by people or animals or offered for sale.

2. To exclude organisms or control organisms

2.1 Grazing animals will be excluded from all trial sites for the duration of the trial period.

3. To exclude unauthorised people

3.1 Only authorised personnel will be permitted access to the trial plots.

3.2 There will be a sign situated at the edge of the trial plot closest to the entry point into the field where the plot is located, indicating that unauthorised access is not allowed, that the plot is subject to a trial, and that the crops should not be removed or disturbed.

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

4.1 The amount of substances taken into each trial site will be pre-measured at the storage facility so as to be sufficient for the application to the designated plots.

4.2 The dispensing of the substances from the original imported container will be in a controlled environment (for example, storage area) to minimise inadvertent release, spillage, and unnecessary exposure to the environment. Dispensing will take place prior to transportation to each trial site for application, and will not be carried out on the trial site.

4.3 Unused material, including any surplus mixed product, if any, will be returned to TNL. Handling and disposal of any wastes will be carried out in such a way as not to jeopardise the integrity of the studies, including provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

4.4 The mixing of the substances will comply with Section 5.5 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

5. To control the effects of any accidental release of the substance

5.1 Any accidental spillage of the unmixed substances or spray mix shall be contained with absorbent clay and returned to TNL for disposal according to the waste management protocol.

5.2 To minimise the effects of any accidental release of the substances, the container labels or MSDS will carry appropriate safety precautions and relevant first aid measures for immediate action pending medical attention.

6. Inspection and monitoring requirements

6.1 The Trial Director or nominated researcher will keep track of all use of the substances as per Section 5.9.1 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

6.2 Occupational Safety & Health[17] (OSH) and ERMA New Zealand are to be informed in writing of the locations and the start, prior to the start of the trials, and with respect to completion of the field trials, within four months of the latter.

6.3 The applicant shall monitor the trial plots for substance and residue levels at the end of the trial to ensure that these fall below the threshold for any hazardous effect, before permitting the plots to be re-used for any other purpose.

17 Head Office, Attention HSNO Project Manager (or equivalent position)

6.4 If for any reason a breach of containment occurs, the Trial Director will notify OSH and ERMA New Zealand immediately, or within 24 hours of the event being noticed.

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

6.6 This approval is for 3 years from the date on which this approval is given.

7. Qualifications required of the person responsible for implementing the controls

7.1 The personnel applying the substances to the crops will be TNL personnel and will be qualified to carry out trial work, this includes being trained to wear appropriate protective clothing.

The Environmental Risk Management Authority reached a decision on the following application on 21 January 2003

Application code: HSR02036

Applicant: Reckitt Benckiser (New Zealand) Limited

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

Description of Substances: RB-2-106

Classifications: 6.3B, 9.1A, 9.4A

Decision: Approved with Controls

ERMA Approval Code: HSR000042

Controls:

Control Code[18]	Regulation[19]	Explanation[20]
	Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls	
T4, E6	Regulation 7	Requirements for equipment used to handle substances
T7, E8	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	
E1	Regulations 32 — 45	Limiting exposure to ecotoxic substances
E3	Regulation 49	Controls relating to protection of terrestrial invertebrates eg beneficial insects
	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
I3	Regulation 9	Priority identifiers for RB-2-106
I9, I11, I16	Regulations 18, 20, 25	Secondary identifiers for RB-2-106
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

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

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

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

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 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
I23, I28	Regulations 41, 46	Specific documentation requirements for RB-2-106
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 Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility
P3, P13, P15, PG3	Regulations 9, 19, 21, Schedule 3	Packaging requirements for RB-2-106
	Hazardous Substances (Disposal) Regulations 2001	
D4, D5	Regulations 8, 9	Disposal requirements for RB-2-106
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements
D8	Regulations 13, 14	Documentation requirements
	Hazardous Substances (Emergency Management) Regulations 2001	
EM1	Regulations 6, 7, 9 — 11	Level 1 emergency management information: Recommended requirements
EM6, EM7	Regulations 8(e), 8(f)	Recommended Information requirements for RB-2-106
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 28 January 2003

Application code: HSC02013

Applicant: Dow AgroSciences Limited

Purpose: To import for field testing toxic and ecotoxic analogues of aminosulfone formulated as WRS-X-A1 to assess their ability to control plant damaging fungi in various fruit and vegetable crops

Description of Substances: WRS-X-A1

Decision: Approved with Controls

ERMA Approval Code: HSC000035

Controls:

1. To limit the likelihood of escape of any contained hazardous substances or contamination by hazardous substances

1.1 The trials shall be undertaken in accordance with the Aminosulfone Analogues Project Plan and Waireka Management Plan, which accompanied the application except where the following controls direct otherwise. 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.

1.2 The substance shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO_2 or air on plots specifically designated and marked for each treatment.

1.3 The trial sites shall be chosen so as to prevent any of the substance entering any surface water or groundwater system.

1.4 All trial sites shall be at least 50 metres from buildings where people live or work (commercial and research glasshouses and buildings on research stations where the trial is being conducted being exceptions).

1.5 Spraying shall be in accord with Section 5 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

1.6 Sprayed produce shall be disposed of by either ploughing in, mulching or at an appropriate local authority operated landfill.

1.7 No sprayed produce shall be consumed by people or animals or offered for sale.

1.8 Access to the trial site(s) shall be by permission of the Trial Director or owner of the property on which it is located. The trial site(s) shall be secured by stock proof fencing and all potential 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.

1.9 The substance shall be securely packed in containers that meet international regulations or comply with The Land Transport Rule: Dangerous Goods 1999, and that are identified in accordance with the Hazardous Substances (Identification) Regulations 2001.

1.10 The transportation of the substance shall comply with The Land Transport Rule: Dangerous Goods 1999.

1.11 Storage of the substance shall be in accordance with the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

1.12 Any portion of the substance (undiluted) surplus to requirements shall be disposed of by the following method:

Returning it to Dow AgroSciences New Zealand Ltd.

1.13 The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trial(s). The existence of the trial shall be clearly marked to avoid accidental/incidental access and harvesting of treated crop or produce.

2. To exclude organisms or control organisms

2.1 Grazing animals shall be excluded from all trial sites, including buffer zones, by stock proof fencing for the duration of the trial period. The trial period means the period of the date of initial application of the substance to the date of site close-off in accordance with Control 6.6. (See also control 1.8)

2.2 Crops shall not be treated during flowering or when bees are foraging.

3. To exclude unauthorised people

3.1 Access to each trial site(s) shall be by permission of the Trial Director or owner of the property on which it is located. The trial facility or site(s) shall be secured by stock proof fencing and all potential access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops or produce should not be removed or disturbed.

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

4.1 The amount of the substance taken into each trial site shall be pre-measured so as to be sufficient for the application to the designated site.

4.2 The dispensing of the substance from the original imported container will be in a controlled environment (for example, storage area) to minimise inadvertent release, spillage, and unnecessary exposure. Dispensing will take place prior to transportation to each trial site for application if possible.

4.3 The mixing and dilution of the substance will comply with section 5.5 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

4.4 Any surplus spray mix shall be disposed of at the trial site(s) by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site.

4.5 The equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate similarly disposed of at the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.

5. To control the effects of any accidental release of the substances

5.1 Any accidental spillage of the unmixed substance or spray mix shall be either diluted with water, sand or earth, and then spread over a marked and designated non-crop and non-grazed area at the trial site, or taken to an approved landfill.

5.2 To minimise the effects of any accidental release of the substance, the container label shall carry appropriate safety precautions and relevant first aid measures for immediate action pending medical attention.

5.3 Should an accidental release and exposure occur, normal precautions (such as the careful washing of hands, face, clothing, and equipment) shall be observed.

6. Inspection and monitoring requirements

6.1 The Trial Director shall keep track of all use of the substance as per section 5.9.1 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

6.2 Occupational Safety & Health, Head Office [Attn: HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the locations, start, and completion of the field trials.

6.3 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.

6.4 The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time in accordance with the Management Plan.

6.5 This approval is for 3 years from the date at which Dow AgroSciences New Zealand Ltd notify ERMA New Zealand of the trial's commencement.

6.6 Site Close off – The Trial Director shall ensure that at the trial site residue levels for components A and B shall be below international cut-off levels for toxicological or ecotoxicological concern, or show that the environmental fate of these components is such that they are not readily available and will not move off the site. This includes any areas used for the preparation or disposal of the spray mix.

7. Qualifications required of the person responsible for implementing the controls

7.1 The personnel applying the substance to the crops shall be GROWSAFE certified.

The Environmental Risk Management Authority reached a decision on the following application on 29 January 2003

Application code: HSC02009

Applicant: Dow AgroSciences Limited

Purpose: To import for field testing the toxic and ecotoxic spinosad analogues formulated as WRS-X-S1 and WRS-X-S2 to assess their ability to control plant damaging insects in various fruit and vegetable crops

Description of Substances: WRS-X-S1 and WRS-X-S2

Decision: Approved with Controls

ERMA Approval Code: HSC000033 — 000034

Controls:

1. To limit the likelihood of escape of any contained hazardous substances or contamination by hazardous substances

1.1 The trials shall be undertaken in accordance with the Spinosad Analogues Project Plan and Waireka Management Plan, which accompanied the application except where the following controls direct otherwise. 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.

1.2 The substances shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO_2 or air on plots specifically designated and marked for each treatment.

1.3 The trial sites shall be chosen so as to prevent any of the substances entering any surface water or groundwater system.

1.4 All trial sites shall be at least 50 metres from buildings where people live or work (commercial and research glasshouses and buildings on research stations where the trial is being conducted being exceptions).

1.5 Spraying shall be in accord with Section 5 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

1.6 Sprayed produce shall be disposed of by either ploughing in or mulching at the trial site, or at an appropriate landfill.

1.7 No sprayed produce shall be consumed by people or animals or offered for sale.

1.8 Access to the trial site(s) shall be by permission of the Trial Director or owner of the property on which it is located. The trial facility or site(s) shall be secured by stock proof fencing and all potential 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.

1.9 The substance WRS-X-S2 shall be securely packed in containers that meet international regulations or comply with The Land Transport Rule: Dangerous Goods 1999, and that are identified in accordance with the Hazardous Substances (Identification) Regulations 2001.

1.10 The substance WRS-X-S1 shall be securely packed in containers that meet the requirements of Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001, and which appropriately identify the substance, and provide warning of the hazard profile of the substance.

1.11 The transportation of the substances shall comply with The Land Transport Rule: Dangerous Goods 1999.

1.12 Storage of the substances shall be in accordance with the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

1.13 Any portion of the substances (undiluted) surplus to requirements shall be disposed of by the following method:

Returning it to Dow AgroSciences New Zealand Ltd.

1.14 The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trial(s). The existence of the trial shall be clearly marked to avoid accidental/incidental access and harvesting of treated crop or produce.

2. To exclude organisms or control organisms

2.1 Grazing animals shall be excluded from all trial sites, including buffer zones, by stock proof fencing for the duration of the trial period. The trial period means the period of the date of initial application of the substance to the date of site close-off in accordance with Control 6.6. (See also Control 1.8.)

2.2 Crops shall not be treated during flowering or when bees are foraging.

3. To exclude unauthorised people

3.1 Access to each trial site(s) shall be by permission of the Trial Director or owner of the property on which it is located. The trial facility or site(s) shall be secured by stock proof fencing and all potential access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops or produce should not be removed or disturbed.

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

4.1 The amount of the substances taken into each trial site shall be pre-measured so as to be sufficient for the application to the designated site.

4.2 The dispensing of the substances from the original imported container will be in a controlled environment (for example, storage area) to minimise inadvertent release, spillage, and unnecessary exposure. Dispensing will take place prior to transportation to each trial site for application if possible.

4.3 The mixing and dilution of the substances will comply with section 5.5 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

4.4 Any surplus spray mix shall be disposed of at the trial site(s) by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site.

4.5 The equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate similarly disposed of at the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.

5. To control the effects of any accidental release of the substances

5.1 Any accidental spillage of the unmixed substance or spray mix shall be either diluted with water, sand or earth, and then spread over a marked and designated non-crop and non-grazed area at the trial site, or taken to an approved landfill.

5.2 To minimise the effects of any accidental release of the substance, the container label shall carry appropriate safety precautions and relevant first aid measures for immediate action pending medical attention.

5.3 Should an accidental release and exposure occur, normal precautions (such as the careful washing of hands, face, clothing, and equipment) shall be observed.

6. Inspection and monitoring requirements

6.1 The Trial Director shall keep track of all use of the substances as per section 5.9.1 of the Code of Practice for the Management of Agrichemicals NZS8409: 1999.

6.2 Occupational Safety & Health, Head Office [Attn: HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the locations, start, and completion of the field trials.

6.3 If a breach of containment occurs, the Trial Director shall notify OSH and ERMA New Zealand within 24 hours of the breach being detected.

6.4 The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time in accordance with the Management Plan.

6.5 This approval is for 3 years from the date at which Dow AgroSciences New Zealand Ltd notify ERMA New Zealand of the trial's commencement.

6.6 Site Close off – The Trial Director shall ensure that at the trial site residue levels for Component A (WRS-X-S1) and Components A and B (WRS-X-S2) shall be below international cut-off levels for toxicological or ecotoxicological concern, or show that the environmental fate of these components is such that they are not readily available and will not move off the site. This includes any areas used for the preparation or disposal of the spray mix.

7. Qualifications required of the person responsible for implementing the controls

7.1 The personnel applying the substance to the crops shall be GROWSAFE certified.

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 December 2002

Application code: HSR02054

Applicant: SACOA Pty Limited

Purpose: This application is for the importation and release of SACOA BIOPEST Paraffinic Oil in New Zealand to be used in pest management programs in a variety of commercial crops

Description of Substances: SACOA BIOPEST Paraffinic Oil

Classifications: 6.1E, 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000033

Controls:

Control Code[21]	Regulation [22]	Explanation[23]
	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

21 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/publications/) and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations.*

22 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.

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

T8	Regulation 28	Controls on Vertebrate Poisons
	Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls	
E2	Regulations 46 — 48	Restrictions on use within application area
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)	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
I8	Regulation 14	Priority identifiers for certain toxic substances
I9, I11, I16	Regulation 18, 20, 25	Secondary identifiers
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
I21, I28	Regulations 37 — 39, 46 — 50	Documentation required in places of work
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, P3, P13	Regulations 5, 6, 7(1), 8, 9, 19	Packaging requirements
	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
	Hazardous Substances (Emergency Management) Regulations 2001	
EM1	Regulations 6, 7, 9 — 11	Level 1 emergency management information: General requirements
EM6, EM7	Regulation 8(e), 8(f)	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 Chief Executive of the Environment Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following application on 10 December 2002

Application code: HSR02057

Applicant: Elliott Chemicals Limited

Purpose: To import Contans® WG, a biological plant protection agent based on *Coniothyrium minitans*

Description of Substances: Contans® WG

Classifications: 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000034

Controls:

Control Code[24]	Regulation[25]	Explanation[26]
	Hazardous Substances (Identification) Regulations 2001	
I1	Regulations 6, 7, 32 — 35, 36(1) — (7)	General identification requirements Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) — (7) – Comprehensibility, Clarity and Durability of information
I9, I11	Regulation 18, 20	Secondary identifiers
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
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
	Hazardous Substances (Disposal) Regulations 2001	
D5	Regulations 9	Disposal requirements for ecotoxic substances
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements

24 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/publications/) and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations.*

25 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.

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

D8	Regulations 13, 14	**Documentation requirements**
	Hazardous Substances (Emergency Management) Regulations 2001	
EM8	Regulations 12 — 16, 18 — 20	**Level 2 emergency management information requirements**
EM13	Regulation 42	**Level 3 emergency management requirements – signage**

TEST CERTIFIERS

There have been no test certifier applications decided in this period.