

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

NON-NOTIFIED APPLICATIONS RECEIVED

Application Code: GMC02010

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 tumours xenografts

Date Application Received: 8 October 2002

Application Code: GMD02099

Applicant: University of Auckland

Purpose: 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 with tumor tissue

Date Application Received: 8 October 2002

Application Code: S2602010

Applicant: University of Auckland

Purpose: Application to determine that *Artemia franciscana* (Kellogg 1906) is not a new organism under section 26 of the HSNO Act

Date Application Received: 22 October 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

Date Application Received: 24 October 2002

STALLED APPLICATIONS

Application Code: TNS02003

Applicant: Raytheon Polar Services (NZ) Limited

Purpose: To tranship samples from the U.S. National Science Foundation programme in the Antarctic via Christchurch to destinations outside New Zealand. Samples to be housed in MAF approved Transitional facility and processed by Raytheon Polar Services (NZ) Ltd

Date Application Received: 21 October 2002

Date Application Stalled: 22 October 2002

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

ERMA NEW ZEALAND

PO Box 131 Wellington

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

Email: info@ermanz.govt.nz

Website: www.ermanz.govt.nz

DECISIONS ON APPLICATIONS

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

This decision was published in Issue 37, with a summarised organism description. Below is the complete description as per Annex 1 in the decision. The controls have not been listed again as these were correctly published in Issue 37.

Application Code: GMD02028

Applicant: AgResearch Limited

Purpose: To develop transgenic cattle that can express functional therapeutic foreign proteins in their milk, and to develop transgenic cattle to study gene function and genetic performance

Decision: Approved with Controls

ERMA Approval Code: GMD002232

Description of the Approved Organisms:

Host organism

The host organism is *Bos taurus* Linnaeus 1758 (cattle; Family Bovidae) cells, embryos and whole animals genetically modified with material of the following type. The modifications shall meet the requirements of Category A or B experiments as described in the HSNO (Low-Risk Genetic Modification) Regulations 1998.

Vectors

The vector consists of two components – (i) the vector ‘backbone’ which shall not be introduced into the cattle genome, and (ii) the vector insert that will be introduced into the cattle genome. All components of the vector shall be characterised such that the DNA has been sequenced and there is an understanding of their function and, if relevant, the potential gene products.

(i) Vector Backbone

The vector backbone shall only contain any or all of the following elements:

- **Promoter**, operator, regulatory element binding and enhancer sequences derived from non-pathogenic bacteria
- **Selectable marker genes** that confer an ability to:
 - Be resistant against antibiotics that are not clinically significant, (that is are not used in human medicine)

- Deactivate metabolic inhibitors
- Deactivate vertebrate toxins¹
- Deactivate other selective drugs

• **Origins of replication:**

- Col E1 or pUC origins of replication derived from plasmids sourced from non-pathogenic strains of *Escherichia coli*
- Bacteriophage f1 origin of replication
- Epstein-Barr virus (EBV) origin of replication (Ori P)

(ii) Vector Insert

The vector insert shall only contain any or all of the following elements:

- **Promoter**, operator, regulatory element binding and enhancer sequences derived from yeast or mammals, or the SV40 promoter. Promoters normally associated with the permitted reporter or selectable marker genes derived from *Escherichia coli* described below may also be used with those genes.
- **Reporter genes** (genes encoding easily assayed proteins) that are not derived from bacteria (except non-pathogenic strains of *Escherichia coli*) or viruses and do not produce proteins that are pathogenic or toxic in vertebrates (have an LD50 less than 100 micrograms/kg body weight).
- **Selectable marker genes** that are not derived from viruses or bacteria (except non-pathogenic strains of *Escherichia coli*) and confer an ability to:
 - Be resistant against antibiotics that are not clinically significant in veterinary or human medicine. Genes providing resistance to beta-lactam antibiotics shall not be used.
 - Deactivate metabolic inhibitors
 - Deactivate vertebrate toxins
 - Synthesise green fluorescent protein
 - Deactivate other selective drugs

With the exception of antibiotic resistance genes the marker genes shall not be likely to provide identifiable selective advantages to micro organisms in the environment

• **Other features associated with insertion or removal of foreign genetic material or with gene or protein expression.**

Sequences not derived from bacteria or viruses (with the exception of multiple cloning sites derived from non-pathogenic strains of *Escherichia coli*), limited to the following:

- Multiple cloning sites
- Polyadenylation signals
- Splice sites
- Transcriptional activators
- Transcriptional responsive elements
- Transcriptional terminator sequences
- Secretory and targeting signals
- Intron signals that function to increase gene expression
- Homologous recombination sites and flanking sequences
- Ribosomal binding sites and/or Kozak sequences
- Insulator elements

- **Donor DNA:** The donor gene DNA will be sourced from humans (provided that the human donor DNA shall not come from Māori), mice (*Mus musculus*), cattle (*Bos taurus*), sheep (*Ovis aries*), deer (*Cervus elaphus*), or goats (*Capra hircus*). The genes will be one gene (or two genes for immunoglobulins) from the donor organisms specified and be cDNA or genomic DNA. Sequences shall be limited to genes associated with the production of therapeutic proteins in milk or study of cattle gene function.

The donor DNA shall not include:

- Known² vertebrate toxins
- Sequences that will produce particles able to infect humans, animals or plants
- Known human or animal virus receptor genes
- Known genes of allergens
- Transposons, transposable or mobile elements, genes for transposases, retrovirus long terminal repeat sequences (LTRs)
- Known genes associated with the development of transmissible spongiform encephalopathies

The Environmental Risk Management Authority reached a decision on the following application on 15 October 2002

Application Code: GMD02086

Applicant: Victoria University of Wellington

Purpose: To develop *Escherichia coli* modified with DNA from New Zealand cicada to help identify microsatellite sequences for cicada populations. The cicada microsatellites will be used to ascertain genetic variation in cicada populations and gene flow across hybrid zones

Description of Organisms: *Escherichia coli* (Migula 1895) Castellani and Chalmers 1919, strains K-12 and B, and derivatives (GMD02086) modified by non-conjugative plasmid or bacteriophage vectors containing DNA from New Zealand cicada species.

Decision: Approved with Controls

ERMA Approval Code: GMD002312

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 Chief Executive’s 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.
 - 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 Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor³ 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.

¹ Vertebrate toxins are considered to be those that have, or are suspected to have, a measurable LD50 value for any vertebrate species of less than 100 micrograms/kg body weight.

² Known means that there is published material in the peer-reviewed scientific literature indicating that the material is or may be associated with the trait.

³ An inspector appointed under the Biosecurity Act.

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

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 30 October 2002

Application Code: GMD02106

Applicant: Institute of Environmental Science and Research

Purpose: To develop genetically modified *Escherichia coli* for use in PCR assays, assay development, and as markers for monitoring micro organisms in food, water and environmental samples

Description of Organisms: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919, strains K-12 and derivatives modified by plasmid vectors containing genetic material from bacteria, viruses and protozoa isolated from environmental samples including water, food, and faeces (human, bird, animal). This includes genetic material from potentially human pathogenic bacteria such as *Campylobacter jejuni*, *Escherichia coli*, *Listeria monocytogenes*, and non-pathogenic bacteria such as species of *Bifidobacterium* and *Bacteroides*

Decision: Approved with Controls

ERMA Approval Code: GMD002312

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 Chief Executive's 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.
 - 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 Standard 154.03.02, and controls imposed by the Chief Executive.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor⁴ 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 following applications were decided by institutions acting under delegated powers from the Authority

Applicant: AgResearch, Ruakura

Institution application code: GMO02/ARR004

Purpose: To develop in containment, low risk genetically modified bacteria *Caulobacter crescentus*. Update of GMO00/ARR011

ERMA Approval code(s): Declined

Description of organism: *Caulobacter crescentus* modified with pCX-TOPO type vectors

Decision: Declined

Applicant: AgResearch, Wallaceville Animal Research Centre

Institution application code: GMO02/ARW022

Purpose: To identify genes in parasitic nematodes that are critical for normal function of the worms and that may serve as model targets for development of biological control methods. Update of GMO00/ARW015

ERMA Approval code(s): GMD002314

Description of organism: *Escherichia coli* modified with DNA sourced from the free-living nematode *Caenorhabditis elegans* or the parasitic nematodes *Trichostrongylus colubriformis*, *Trichostrongylus vitrinus*, *Trichostrongylus axei*, *Haemonchus contortus*, *Teladorsagia circumcincta*, *Teladorsagia ostertagii*, *Teladorsagia lyrata*, *Cooperia curticei*, *Cooperia oncophora*, *Nematodirus spathiger* or *Parastrongyloides trichosouri*, the jellyfish *Aequorea victoria* or from genetically disabled *Escherichia coli* strains as described in application GMO00/ARW015

Decision: Approved with controls (PC1 and PC2)

Applicant: Massey University

Institution application code: GMO01/MU009

Purpose: Analysis of genes involved in fungal infection structure development

ERMA Approval code(s): GMD002315-2316

Description of organism: *Escherichia coli* laboratory strains and *Glomerella cingulata* as modified by non-conjugative plasmids harbouring antibiotic resistance genes and characterised DNA from *Glomerella cingulata*

Decision: Approved with controls (PC2)

Applicant: University of Auckland

Institution application code: GMO02/UA012

Purpose: To use AAV vectors of different serotypes and different CAG repeats in developing strategies for the treatment of neurological disorders. Update of GMO00/UA073

ERMA Approval code(s): GMD002317-2321

Description of organism: *Escherichia coli* (non conjugative K12 and B strains), *Homo sapiens* cell lines, *Mus musculus* cell lines, *Rattus norvegicus* cell lines and *Rattus norvegicus*, modified by recombinant AAV vectors (AAV-1, AAV-2, AAV-4, AAV-5 and AAV1/2) and mouse (*Mus musculus*), rat (*Rattus norvegicus*) and human (*Homo sapiens*) genes and constructs encoding: Neurotrophins, Antiapoptotic factors, CAG trinucleotide repeat sequences, Reporter genes, Protein tags

Decision: Approved with controls (PC1 and PC2)

Applicant: University of Auckland

Institution application code: GMO02/UA017

Purpose: To enable X-ray crystallographic studies of recombinant proteins. Update of GMO00/UA050

ERMA Approval code(s): GMD002322-2328

Description of organism: *Escherichia coli*, *Cercopithecus aethiops* cell lines, *Criteculus griseus* cell lines, *Drosophila melanogaster* cell lines, *Spodoptera frugiperda* cell lines, *Pichia pastoris* and *Saccharomyces cerevisiae* modified by genes encoding proteins specified in application update from *Pseudomonas fluorescens*, *Homo sapiens*, *Trichosurus vulpecula*, *Legionella*

pneumophila, *Rhodobacter capsulatus*, *Discosoma coral*, *Helicobacter pylori*, *Plasmodium falciparum*, *Bacillus amyloliquefaciens*, *Porphyromonas gingivalis*, *Prevotella strain RS2* and Influenza virus

Decision: Approved with controls (PC1 and PC2)

Applicant: University of Otago

Institution application code: GMO02/UO024

Purpose: To understand metabolism, and in particular photosynthesis, in cyanobacteria

ERMA Approval code(s): GMD002332-2336

Description of organism: *Anabaena PCC 7120* and *Nostoc punctiforme* Nostoc PCC73102 modified with mobiliser and helper plasmids pRK2013 and pRL528, and related plasmids, pRL1063 and derivatives of pRL271 as donor plasmids; genes encoding resistance to antibiotics including erythromycin, chloramphenicol, kanamycin, gentamicin, neomycin, spectinomycin and streptomycin; standard reporter genes including luciferase, beta-glucuronidase and green fluorescent protein; genes related to photosynthesis and growth from non-native plant species including *Arabidopsis thaliana*, *Chlamydomonas reinhardtii*, *Hydrastis canadensis* (goldenseal), *Panax ginseng* (Korean ginseng), *Panax quinquefolius* (American ginseng), *Pisum sativum* (pea), *Oryza sativa* (rice), *Spinacia oleracea* (spinach), *Nicotiana tabacum* (tobacco) and *Zea mays* (maize)

Synechococcus PCC7002 and *Synechocystis PCC 6803* modified with pUC-based plasmids such as pUC18, pUC19, pBluescript and pGEM; genes encoding resistance to antibiotics including erythromycin, chloramphenicol, kanamycin, gentamicin, neomycin, spectinomycin and streptomycin; standard reporter genes including luciferase, beta-glucuronidase and green fluorescent protein; genes related to photosynthesis and growth from non-native plant species including *Arabidopsis thaliana*, *Chlamydomonas reinhardtii*, *Hydrastis canadensis* (goldenseal), *Panax ginseng* (Korean ginseng), *Panax quinquefolius* (American ginseng), *Pisum sativum* (pea), *Oryza sativa* (rice), *Spinacia oleracea* (spinach), *Nicotiana tabacum* (tobacco) and *Zea mays* (maize)

⁴ An inspector appointed under the Biosecurity Act.

Synechococcus PCC 7942 modified with pPUC303 and pAM1044; genes encoding resistance to antibiotics including erythromycin, chloramphenicol, kanamycin, gentamicin, neomycin, spectinomycin and streptomycin; standard reporter genes including luciferase, beta-glucuronidase and green fluorescent protein; genes related to photosynthesis and growth from non-native plant species including *Arabidopsis thaliana*, *Chlamydomonas reinhardtii*, *Hydrastis canadensis* (goldenseal), *Panax ginseng* (Korean ginseng), *Panax quinquefolius* (American ginseng), *Pisum sativum* (pea), *Oryza sativa* (rice), *Spinacia oleracea* (spinach), *Nicotiana tabacum* (tobacco) and *Zea mays* (maize)

Decision: Approved with controls (PC2)

Applicant: University of Otago

Institution application code: GMO02/UO025

Purpose: To construct mutants in *Lactobacillus reuteri* (DSM 20016) through homologous recombination using two recently developed plasmids pTRK669 and pORI28. Update of GMO00/UO080

ERMA Approval code(s): GMD002337-2338

Description of organism: *Escherichia coli* K12 derivatives modified with non-conjugative plasmids pTRK669 and pORI28; chromosomal DNA from *Lactobacillus reuteri* (DSM 20016)

Lactobacillus reuteri (DSM 20016) modified with non-conjugative plasmids pTRK669 and pORI28; chromosomal DNA from *Lactobacillus reuteri* (DSM 20016)

Decision: Approved with controls (PC1 and PC2)

Applicant: University of Otago

Institution application code: GMO02/UO019

Purpose: To find sequences within the zif-zooA intergenic region from *Streptococcus equi* subspecies zooepidemicus are essential for expression of the associated reporter genes and to determine conditions of cellular growth for the expression of genes in host. Update of GMO02/UO001

ERMA Approval code(s): GMD002329-2331

Description of organism: *Escherichia coli* K12, *Streptococcus equi* and *Streptococcus gordonii* modified with non-conjugative plasmid cloning vectors such as pJG12 and pTV1-OK and related vectors containing fragments of the zif-zooA intergenic region from *Streptococcus equi* subspecies zooepidemicus

Decision: Approved with controls (PC1 and PC2)

HAZARDOUS SUBSTANCES

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

Application Code: HSR02046

Applicant: Osmose New Zealand

Purpose: To import Bistar, an insecticide containing bifenthrin for the treatment of timber and wood products

Date Application Received: 16 October 2002

Date Publicly Notified: 16 October 2002

Date Submissions Close: 27 November 2002

Application Code: HSR02007

Applicant: Reckitt Benckiser (NZ) Limited

Purpose: To import Reckitt Product 1, RB-2-107 and RB-2-108 as household insecticides

Date Application Received: 1 August 2002

Date Publicly Notified: 24 October 2002

Date Submissions Close: 6 December 2002

NON NOTIFIED APPLICATIONS RECEIVED

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

Date Application Received: 27 September 2002

Application Code: HSC02005

Applicant: DuPont (NZ) Limited

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

Date Application Received: 21 October 2002

Application Code: HSC02012

Applicant: BASF New Zealand

Purpose: To import into containment BNZ001/02 and BNZ002/02 to conduct field trials to assess the efficacy of the substances in certain crops

Date Application Received: 24 October 2002

Application Code: HSR02050

Applicant: Taranaki Nuchem Limited

Purpose: This application is for the manufacture and release of Taratek GC, a water soluble antispain product.

Date Application Received: 29 October 2002

Application Code: HSR02051

Applicant: Yates New Zealand Limited

Purpose: To import Pyganic for use as an insecticide on New Zealand crops

Date Application Received: 30 October 2002

Application Code: HSR02043

Applicant: Agrenz Limited

Purpose: To import Aquabac xt, a biological larvicide, formulated as an aqueous suspension containing *Bacillus thuringiensis* var. israelensis (Bti) for control of mosquito larvae

Date Application Received: 31 October 2002

Application Code: HSR02044

Applicant: Grosafe Chemicals Limited

Purpose: To import Bactur 48 LC containing *Bacillus thuringiensis* var. kurstaki (Btk) for control of insect pests such as tussock moth, gypsy moth and painted apple moth

Date Application Received: 31 October 2002

DECISIONS ON APPLICATIONS

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

Application code: HSR02029

Applicant: Virbac Laboratories NZ Limited

Purpose: To import for release an endectocide (VBPOC) for use on production animals

Description of Substances: VBPOC

Classifications: Classification: 3.1B, 6.1B, 6.1D, 6.3B, 6.4A, 6.8B, 6.9A, 9.1A, 9.2B, 9.3A, 9.4A

Decision: Approved with Controls

ERMA Approval Code: HSR000023

Controls:

Control Code ⁵	Regulation ⁶	Explanation ⁷
Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001 – Flammable Property Controls		
F1	Regulation 7	General test certification requirements for VBPOC
F2, T7, E8	Regulations 8, 10	General public transportation restrictions and requirements for VBPOC
F3	Regulation 55	General limits on VBPOC
F4	Regulation 56	Certain flammable substances to be under the control of an approved handler
F5	Regulations 58 – 59	Requirements regarding hazardous atmosphere zones for VBPOC
F6	Regulations 60 – 70	Requirements to prevent unintended ignition of VBPOC
F11	Regulation 76	Segregation of incompatible substances
F12	Regulations 77 – 78	General requirement for hazardous substance locations for VBPOC
F14	Regulation 81	Test certification requirements for facilities where VBPOC is present
F16	Regulation 83	Controls on transit depots where VBPOC is present
F17	Regulations 84 – 85	Requirements to control adverse effects of intended ignition of VBPOC, including requirements for protective equipment and clothing
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T2	Regulations 29, 30	Controlling exposure in places of work
T4	Regulation 7	Requirements for equipment used to handle VBPOC
T5	Regulation 8	Requirements for protective clothing and equipment
T6	Regulation 9	Approved handler requirements
T8	Regulation 28	Controls on Vertebrate Poisons
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls		
E1	Regulations 32 – 45	Limiting exposure to ecotoxic substances
E2	Regulations 46 – 48	Restrictions on use within application area
E6	Regulation 7	Requirements for equipment used to handle VBPOC

⁵ Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from ERMA New Zealand and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

⁶ 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.

⁷ These explanations are for guidance only. Refer to the cited regulations for the formal specification, and for definitions and exemptions.

E7	Regulation 9	Approved handler requirements
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, 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information
I3, I5, I8	Regulation 9, 11, 13	Priority identifiers for VBPOC
I9, I11, I13, I16	Regulation 18, 20, 22, 25	Secondary identifiers for VBPOC
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 – VBPOC 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 VBPOC
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	Regulation 41, 43, 46	Specific documentation requirements for VBPOC
I29	Regulations 51 – 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising VBPOC
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 VBPOC Regulation 8 – Compatibility
P3, P5, P13, P15	Regulation 9, 11, 19, 21	Packaging requirements for VBPOC
PG2	Schedule 2	This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 2 correlate to the packaging requirements of UN Packaging Group II.
Hazardous Substances (Disposal) Regulations 2001		
D2, D4, D5	Regulation 6, 8, 9	Disposal requirements for VBPOC
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, EM4, EM6, EM7	Regulations 6, 7, 8(c), 8(e), 8(f), 9 – 11	Level 1 emergency management information: General requirements
EM8	Regulations 12 – 16, 18 – 20	Level 2 emergency management information requirements
EM9	Regulation 17	Extra content for VBPOC
EM10	Regulations 21 – 24	Fire extinguishers
EM11	Regulations 25 – 34	Level 3 emergency management requirements – emergency response plans
EM12	Regulations 35 – 41	Level 3 emergency management requirements – secondary containment
EM13	Regulation 42	Level 3 emergency management requirements – signage
Hazardous Substances (Personnel Qualification) Regulations 2001		
AH1	Regulations 4 – 6	Approved Handler requirements (including test certificate and qualification requirements)

The Environmental Risk Management Authority reached a decision on the following application on 9 October 2002

Application code: HSC02006

Applicant: Syngenta Crop Protection Limited

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

Description of Substances: A12705J, A12705L, A12705N, A13363B, A13918A

Decision: Approved with Controls

ERMA Approval Code: HSC000012-HSC000016

Controls:

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

- 1.1 The substances will only be used on wheat crops.
- 1.2 The trial sites will be small parts of larger commercial facilities. The trials will involve no more than 16 sites at any one time and may continue for 3 seasons. Each trial site will be a maximum of 0.2 hectares. Access to the trial site(s) will be by permission of the Trial Director or owner of the property on which it is located.

- 1.3 The trial sites will be chosen so as to prevent any of the substances entering any water source.
- 1.4 All trial sites must be at least 50 metres from buildings where people live or work (commercial and research glasshouses being an exception).
- 1.5 The properties containing the trial sites will be secured by stock proof fencing at the boundaries of the property.
- 1.6 The trial site boundaries will be clearly marked and distinctly visible from outside the trial site throughout the life of the trial(s). The existence of the trial will be clearly marked to avoid accidental/incidental access and harvesting of treated crop.
- 1.7 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.
- 1.8 The transportation of the substances will comply with *The Land Transport Rule: Dangerous Goods 1999*.
- 1.9 Storage will be in accordance with the *Code of Practice for the Management of Agrichemicals NZS8409:1999*.

- 1.10 The substances will be diluted prior to use (spray volume 200 L/ha) and applied by way of hand-held spray-boom application equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment.
- 1.11 The new azoxystrobin formulations will be applied once per season at 150 to 200 g ai/ha 80-100+ days prior to harvest.
- 1.12 The new adjuvants will be applied once per season 80-100+ days prior to harvest.
- 1.13 Spraying must be in accord with Section 5 of *NZS8409:1999 Code of Practice for the Management of Agrichemicals*.
- 1.14 Solid waste will be disposed of by either ploughing in or mulching at the trial facility or disposed of at an appropriate local authority operated landfill.
- 1.15 No treated produce shall be consumed by people or animals or offered for sale.
- 1.16 Any portion of the substances surplus to requirements will be disposed of by one of the following methods:
 - Returned to Syngenta.
 - Disposed in an appropriate local authority landfill (pre-treatment at a hazardous waste facility may be required).
 - Diluted with water or soil and spread over a designated non-crop, non-grazed waste area at the trial site.

2. To exclude organisms

- 2.1 Grazing animals will be excluded from all trial sites for the duration of the trial period by the provision of stock-proof fencing.

3. To exclude unauthorised people

- 3.1 There will be a sign situated at the edge of the trial site closest to the entry point into the field where the trial site is situated 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.

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 at the storage facility so as to be sufficient for the application to the designated plots.
- 4.2 The mixing of the substances will comply with section 5.5 of the *Code of Practice for the Management of Agrichemicals NZS8409: 1999*.

- 4.3 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. This dispensing will take place prior to transportation to each trial site for application, and will not be carried out on the trial site.
- 4.4 Any surplus mixed product will 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 will be rinsed after use with fresh water and appropriate cleaning fluid such as detergent or chlorine based decontaminant, and the rinsate disposed of at the trial site(s) 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 substance

- 5.1 Any accidental spillage of the unmixed substances 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 substances, the container labels or MSDS will 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) will be observed.

6. Inspection and monitoring requirements

- 6.1 The Trial Director or nominated researcher will keep track of all use of the substance as per section 5.9.1 of *Code of Practice for the Management of Agrichemicals NZS8409: 1999*.
- 6.2 Occupational Safety & Health⁸ (OSH) and ERMA New Zealand are to 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 will notify OSH and ERMA New Zealand immediately the event is noticed (and at least 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.

⁸ Head Office, Attention HSNO Project Manager (or equivalent position)

6.5 The applicant shall provide a completion report to ERMA New Zealand and OSH within one month of the end of the trials.

6.6 This approval is for three years from the date at 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 Syngenta 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 9 October 2002

Application code: HSC02007

Applicant: Syngenta Crop Protection Limited

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

Description of Substances: A12724C, A13821B, A13959A, A13974A, A13975A, A13976A, A13977A, A13979A, A13980A

Decision: Approved with Controls

ERMA Approval Code: HSC000017-HSC000025

Controls:

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

1.1 The substances will only be used on wheat crops.

1.2 The trial sites will be small parts of larger commercial facilities. The trials will involve no more than 16 sites at any one time and may continue for three seasons. Each trial site will be a maximum of 0.2 hectares. Access to the trial site(s) will be by permission of the Trial Director or owner of the property on which it is located.

1.3 The trial sites will be chosen so as to prevent any of the substances entering any water source.

1.4 All trial sites must be at least 50 metres from buildings where people live or work (commercial and research glasshouses being an exception).

1.5 The properties containing the trial sites will be secured by stock proof fencing at the boundaries of the property.

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

1.7 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.

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

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

1.10 The substances will be diluted prior to use (spray volume 200 L/ha) and applied by way of hand-held spray-boom application equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment.

1.11 The new azoxystrobin formulations will be applied once per season at 150 to 200 g ai/ha 80-100+ days prior to harvest.

1.12 The new adjuvants will be applied once per season 80-100+ days prior to harvest.

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

1.14 Solid waste will be disposed of by either ploughing in or mulching at the trial facility or disposed of at an appropriate local authority operated landfill.

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

1.16 Any portion of the substances surplus to requirements will be disposed of by one of the following methods:

- Returned to Syngenta.
- Disposed in an appropriate local authority landfill (pre-treatment at a hazardous waste facility may be required).
- Diluted with water or soil and spread over a designated non-crop, non-grazed waste area at the trial site.

2. To exclude organisms

2.1 Grazing animals will be excluded from all trial sites for the duration of the trial period by the provision of stock-proof fencing.

3. To exclude unauthorised people

3.1 There will be a sign situated at the edge of the trial site closest to the entry point into the field where the trial site is situated 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.

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 at the storage facility so as to be sufficient for the application to the designated plots.

4.2 The mixing of the substances will comply with section 5.5 of the *Code of Practice for the Management of Agrichemicals NZS8409: 1999*.

4.3 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. This dispensing will take place prior to transportation to each trial site for application, and will not be carried out on the trial site.

4.4 Any surplus mixed product will 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 will be rinsed after use with fresh water and appropriate cleaning fluid such as detergent or chlorine based decontaminant, and the rinsate disposed of at the trial site(s) 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 substance

5.1 Any accidental spillage of the unmixed substances 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 substances, the container labels or MSDS will 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) will be observed.

6. Inspection and monitoring requirements

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

6.2 Occupational Safety & Health⁹ (OSH) and ERMA New Zealand are to 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 will notify OSH and ERMA New Zealand immediately the event is noticed (and at least 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.

6.5 The applicant shall provide a completion report to ERMA New Zealand and OSH within one month of the end of the trials.

6.6 This approval is for three years from the date at 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 Syngenta 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 10 October 2002

Application code: HSR02030

Applicant: Parnell Laboratories New Zealand Limited

Purpose: To import Aquafol a Prescription Animal Remedy intended for use as an anaesthetic agent in dogs and cats. The active ingredient is propofol 1%, an agent that is widely used in human medicine for anaesthesia and sedation

Description of Substances: Aquafol

Classifications: 6.4A, 6.5B, 6.8B

Decision: Approved with Controls

ERMA Approval Code: HSR000024

⁹ Head Office, Attention HSNO Project Manager (or equivalent position)

Controls:

Control Code ¹⁰	Regulation ¹¹	Explanation ¹²
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	Regulation 7	Requirements for equipment used to handle substances
T5	Regulation 8	Requirements for protective clothing and equipment
T7	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
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, 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information
I9	Regulation 18	Secondary identifiers for all hazardous substances
I16	Regulation 25	Secondary identifiers for toxic substances
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Requirements for using concentration ranges
I19	Regulations 29 – 31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported
I21	Regulations 37 – 39, 47 – 50	Documentation required in places of work
I28	Regulation 46	Specific documentation requirements for toxic substances
Hazardous Substances (Packaging) Regulations 2001		
P1	Regulations 5, 6, 7 (1), 8	General packaging requirements
P3	Regulation 9	Packaging requirements for substances packed in limited quantities
P13	Regulation 19	Packaging requirements for toxic substances
PG3	Schedule 3	This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 3 correlate to the packaging requirements of UN Packaging Group III.
Hazardous Substances (Disposal) Regulations 2001		
D4	Regulation 8	Disposal requirements for toxic and corrosive substances
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Information requirements

¹⁰ Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from ERMA New Zealand and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

¹¹ These regulations form the controls applicable to this substance. Refer to the cited regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

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

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	Regulation 8(e)	Information requirements for toxic 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

The Environmental Risk Management Authority reached a decision on the following application on 24 October 2002

Application code: HSR02026

Applicant: Bomac Laboratories Limited

Purpose: To import Multicide, a disinfectant with antibacterial and antiviral effects against several bacteria and viruses of importance to livestock

Description of Substances: Multicide

Classifications: 6.1E, 6.3A, 8.3A, 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000025

Controls:

Control Code ¹³	Regulation ¹⁴	Explanation ¹⁵
Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 – Toxic and Ecotoxic Property Controls		
T4, E6	Regulation 7	Requirements for equipment used to handle substances
T5	Regulation 8	Requirements for protective clothing and equipment
T7, E8	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
T8	Regulation 28	Controls on Vertebrate Poisons
Hazardous Substances (Identification) Regulations 2001		
I1	Regulations 6, 7, 32 – 35, 36 (1) – (7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1) – (7) – Comprehensibility, Clarity and Durability of information
I2, I8	Regulation 8, 14	Priority identifiers for Multicide
I9, I10, I11, I16	Regulation 18, 19, 20, 25	Secondary identifiers for Multicide
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Requirements for using concentration ranges

¹³ Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from ERMA New Zealand and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

¹⁴ These regulations form the controls applicable to this substance. Refer to the cited regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

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

I19	Regulations 29 – 31	Alternative information in certain cases Regulation 29 – Multicide 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 Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 47 – Information not included in approval Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request
I22, I28	Regulation 40, 46	Specific documentation requirements for Multicide
I29	Regulations 51 – 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising Multicide
Hazardous Substances (Packaging) Regulations 2001		
P1, P3, P13, P14	Regulations 5, 6, 7(1), 8, 9, 19, 20	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing Multicide Regulation 8 – Compatibility
PG3	Schedule 3	Packaging requirements equivalent to UN PGIII
Hazardous Substances (Disposal) Regulations 2001		
D4, D5	Regulation 8, 9	Disposal requirements for Multicide
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, EM2, EM6, EM7	Regulations 6, 7, 8(a), 8(e), 8(f), 9, 10, 11	Emergency management information requirements for Multicide
EM8	Regulations 12 – 16, 18 – 20	Level 2 emergency management information requirements
EM11	Regulations 25 – 34	Level 3 emergency management requirements – emergency response plans
EM13	Regulation 42	Level 3 emergency management requirements – signage

TEST CERTIFIERS

The Chief Executive of the Environmental Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following application on 10 September 2002

This application was incorrectly published in Issue 37

Application Code: TST02016

Applicant: Nicola Cuff

Address: 16 Nephin Place
Howick
Auckland

Decision: Approved with Controls

ERMA Approval Code: TST000010

Requirements for which a test certificate may be issued, and limitations

Approved handlers in control of:

Handlers in control of substances of classes 2.1.1A, 2.1.2A, 3.1A, 3.1B, 4.3A, 4.3B, 5.1.1, 5.1.2, 5.2, 6, 8 and 9 in manufacturing and distribution facilities.

DECISIONS WITH FUTURE GENERAL IMPLICATIONS; SELECTED CASE STUDIES

Māori membership of institutional biological safety committees (IBSCs)

Preamble

1. The policy set out below is based on the approach to Māori membership of IBSCs recommended by the Royal Commission on Genetic Modification and agreed to by the Government. This approach is that IBSCs include at least one Māori member, appointed on the nomination of the hapū or iwi with manuhenua in the locality covered by an application. The policy sets out the practical steps for achieving this.

Principal policy requirements

2. The principal requirement is that there should be at least one Māori member appointed to each IBSC on the nomination of the hapū or iwi with manuhenua in the location of the IBSC. Thus [if an institution has regionally based stations with their own IBSCs, it is the locality of the particular IBSC that should determine which hapū or iwi should have the right to nominate. This policy will automatically apply unless the institution seeks and is granted an exemption from the Authority.

Exemptions and variations from the principal policy requirement

- Institutions may apply for an exemption. Applications for an exemption must be made in writing to the Chief Executive of ERMA New Zealand. Requirements for applications will be separately promulgated. Decisions will be made by the full Authority, in consultation with Ngā Kaihautū. Until or unless an exemption is granted, the requirement set out in (2) above will apply. If the requirement is unable to be met or until it is met, the IBSC will not have an operable delegation, ie all applications must either be referred to ERMA New Zealand or referred to an IBSC which does have an operable delegation.
- The Authority will be especially reluctant to grant exemptions if the IBSC intends to consider applications which involve endemic¹ flora and fauna, ie organisms which can only be found in New Zealand. If cases like this are put forward the Authority reserves the right to exclude endemic flora and fauna from the scope of the delegation.
- In considering whether or not to grant an exemption the Authority will consider the extent to which 'every reasonable endeavour' has been made to secure a nomination. Reasonable endeavours in this regard should extend to endeavours toward face to face consultation with the potentially involved hapū and iwi over a period of time, ie not just a single attempt. An exemption will be considered if, despite every reasonable endeavour:
 - the local Māori community does not wish to or does not take any action toward, nominating a Māori meeting the criteria; or
 - there is a dispute within the Māori community over who has manuhenua or who has mandate. It is for the Māori community itself to resolve issues of this sort
- In the event that reasonable endeavours are not successful, other action will still be expected as an alternative and this may include:
 - The appointment of a Māori at the initiative of the institution, but having regard to the criteria and those views that have been expressed by local hapū and iwi;
 - The establishment of other relationships with the local Māori community that will provide a similar level and quality of input.

¹ In this document and elsewhere, the following definitions apply.

'Endemic' means a species that is only found in New Zealand. Thus Kiwi are endemic to New Zealand.

'Native' (synonymous to indigenous) means originating in New Zealand, or present at the time of first human occupation, as opposed to exotic or introduced. Thus silvereyes or waxeyes are native to New Zealand, but are not endemic, because they also occur in Australia.

This might include a direct consultative relationship with all interested hapū and iwi, or the establishment of a consultative committee on which hapū and iwi are represented.

7. It is recognised that particular difficulties arise if the research requiring an IBSC approval is to be done in one location, ie at the institution, but involves native flora and fauna which come from another location or with even greater difficulty from throughout New Zealand. In cases like this it is not required, but still desirable that the IBSC contain Māori members who are nominated from both points of view. However, it would be sufficient for the Māori member to be that nominated by the iwi and hapū in the locality of the IBSC, but for input from other Māori affected to be gathered through the process of consultation. The latter is the responsibility of the applicant and the IBSC, and not specifically of the nominated Māori member.

IBSCs – Requirements for consultation with the Māori community on rapid assessment applications

Introduction

1. The policy set out below applies to all GMO development applications made under s35 of the Act, ie applications which conform with the low risk criteria in the Low Risk Regulations.
2. Such applications may be made to either an institutional biological safety committee (IBSC) or to the Chief Executive of ERMA New Zealand, provided that the Authority has made a delegation for this purpose. The IBSC or the Chief Executive are referred to as the ‘decision-maker’ in the text below. The requirements for consultation are the same for applications considered by either decision-maker.

Requirements for consultation

3. In terms of this policy, ‘consultation’ is defined as:
‘a process of genuine and informed dialogue intended to create understanding and knowledge of the views of the parties on a particular subject’.
4. The obligation to consult rests primarily with the applicant. If consultation is not in conformity with the guidelines then the decision-maker should either decline the application or return it to the applicant for further work to make good the deficiency, ie the applicant should be allowed to withdraw the application and resubmit.

5. Consultation is a two way (at least) process. The obligation to consult requires that every reasonable endeavour is made to do so. Reasonable endeavours require multiple, not single, attempts to establish a dialogue. Reasonable endeavours require attempts at face to face meetings, not just written correspondence. However, it is accepted that on occasion reasonable endeavours will not succeed and, under those circumstances, the obligation shall be considered to have been discharged. However, the circumstances of such attempts must be documented so they are available for audit.

Circumstances under which the requirement to consult is waived

6. The requirement to consult on individual applications is waived if there is agreement and understanding, between the institution and the relevant local Māori community, on what type of work is not of concern. However, any such agreement must be documented, eg in the form of an MOU, and will be subject to audit by the parties and by ERMA New Zealand
7. The need to consult may also be waived if the IBSC has a member, or has in other ways formally involved Māori individuals who are mandated to speak on behalf of the relevant local Māori community. Wider consultation with the Māori community will only be necessary if advised by the mandated individual.

Circumstances requiring mandatory consultation if a waiver does not apply

8. Under the following circumstances, consultation must occur with the Māori community prior to a decision being made on an application to an IBSC or to the Chief Executive.
 - (a) Work that involves DNA from native flora and fauna.
 - (b) The use of human DNA of any origin, including DNA from an individual person irrespective of whether or not informed consent has been given, DNA from anonymous sources such as gene libraries, widely used cell lines, or synthesised DNA.

Notes:

1. This requirement applies to the use of a human cell as the host (which is unlikely to occur under HSNO), or more commonly to the use of human DNA as the donor material. It does not apply to the use of human cells that are not genetically modified, because such cells are not in themselves subject to the HSNO Act.

2. In this policy, the term ‘native’ is used to refer to flora and fauna that have originated in New Zealand or were present at the time of first human occupation, ie are not exotic or introduced, but are not necessarily endemic to New Zealand.
9. Consultation is also mandatory when DNA from traditional varieties of taonga tuku iho or DNA that is from other valued species are involved, where the following additional criteria are met.
 - (a) the species that are deemed to be taonga tuku iho or valued have been agreed between the applicant institution and the relevant Māori community, through a proper process of consultation;
 - (b) this agreement is documented to the satisfaction of the parties and the documentation is provided to the decision-maker.

Circumstances under which dialogue that is less formal than consultation may be appropriate

10. The difference between informal dialogue as set out in this section and formal consultation, is that in the former case the provisions of paragraph 15 do not apply.
11. There must be at least informal dialogue with the local Māori community on the use of DNA from microorganisms, unless it can be clearly established that the micro organisms are introduced and not native. This dialogue should be directed towards determining one of the following positions:
 - (a) the local Māori community has no interest in the specified micro organisms, for any application;
 - (b) there may be interest in regard to particular applications so informal dialogue should continue to occur;
 - (c) the micro organisms are to be given ‘valued’ status so formal consultation is required on applications.
12. There are a wide variety of other situations in which informal dialogue may be appropriate. Dialogue may be particularly appropriate if the Māori community has an interest in GMO development work but is not fully aware of the ‘low risk’ nature of work covered by rapid assessment and what this means in practice, or wishes to have more information on the implications of and rationale for the research more generally. Applicant institutions are encouraged to be as open as possible in this regard, and to be inclusive in their approach.

Who should be consulted?

13. Consultation may be locally based, not nationally based. Thus unless special circumstances apply, such as the sourcing of DNA from throughout New Zealand, there is no requirement to undertake national consultation for low risk GMO development applications.
14. Consultation should occur with the hapū or iwi with mana whenua for the locality where the research is based. If material involving DNA from organisms found naturally in New Zealand, whether used as the host or as donor DNA, is sourced from localities other than where the research is based, consultation must also occur with mana whenua in those other locations.

Dealing with the results of consultation

15. The results of formal consultation must be dealt with as follows
 - (a) Where Māori want special conditions to be imposed for cultural reasons, then as far as is judged practicable by the decision-maker those requests should be complied with. The question of what is practicable will vary from case to case.
 - (b) If Māori object to the work following consultation, including proposals to apply certain conditions designed to meet those objections and provided that the objection is not a general objection to genetic modification, then the decision-maker must either decline the application or refer it to the Authority for a full assessment.

Impacts on Transitional Substances when a ‘same as’ Part V application is received

An interesting issue that the Authority has to consider arises when it makes a decision on an application for a new substance under Part V of the HSNO Act yet there are existing substances in the transitional provisions of the Act that are the ‘same as’ the new substance. This particularly applies to pesticides, where registered pesticides in the transitional provisions of the Act are personal to the registrant and another person wishes to import or manufacture that substance.

The decision made on Part V applications in this situation will have a number of implications on the substances in transition that are considered to be the ‘same as’ the substance proposed in the application (whether the application is approved or declined). There may also be impacts on the Part V substance. These implications can be both legal and practical.

Firstly, it needs to be established that the transitional substance is in fact the 'same' as the Part V substance, ie, that the substance definition and hazard classification of the registered pesticide is the same, such that it will be covered by the Part V approval.

Potential impacts if Part V substance is approved

If the Part V application is approved, legal advice is that any existing substances in transition considered the 'same' as the Part V substance can either adopt the Part V approval controls, or continue with the existing controls from their transitional approval. In practice this means that existing controls will continue, particularly if the Part V controls are stricter than the transitional controls.

In the situation where the 'same as' transitional substances which have few substantive differences in controls, the Authority has decided that it will leave the substance as it is (ie, not even transfer) so that at the end of the transitional period they will automatically 'adopt' the Part V controls. Registrants of affected transitional substances of the Part V application will be notified and informed of the implications, ie, that when the transitional period expires, their substances would be covered by the controls from that Part V application.

Where there are significant differences in controls (eg requirement for tracking and approved handlers) the Authority has decided to review the registration of the transitional substance under section 168 (when resources permit) to bring them into line with the Part V products through varying the terms and conditions of the registration. However, it is recognized that these measures will only be taken if the Authority (after considering any representations or submissions made by or on behalf of the proprietor) is satisfied that the continued use of the registered pesticide is likely to have a significant adverse effect on human health or the environment [s168(3)]. This is a reasonably stiff test, eg the Authority would be hard put to justify this if there was no history of the substance causing harm.

Potential impacts if Part V substance is declined

In the event that a Part V application is declined the Authority has decided that it will review the registration of the 'same as' transitional substance under section 168 to bring them into line with the Part V decision through revocation of the registration or if warranted proceeding with a reassessment. However, again these measures may only be taken if the Authority (after considering any representations or submissions made by or on behalf of the proprietor) is satisfied that the continued use of the registered pesticide is likely to have a significant adverse effect on human health or the environment [s168(3)].

Dealing with substances that are not quite similar

An interesting situation arises for substances that are not the same, but have similar controls to the 'similar' transitional substances and a similar or worse hazard/risk profile. If the 'similar' substances have their controls revised, how about the next group? The issue here is that changing controls at one point could have a domino effect on a range of other substances.

ERMA New Zealand staff have been made conscious of this issue so that domino implications are not overlooked. However, any actions taken in response would need to be on a case by case basis, and only if there was a serious systemic concern. Otherwise the situation could become very difficult to manage.
