

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: GMC03001

Applicant: University of Otago

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

Date Application Received: 4 February 2003

Application Code: GMD03013

Applicant: University of Canterbury

Purpose: To develop novel genetic markers that will be used to help better conserve and manage the critically endangered kaki or Black Stilt (*Himantopus novaeseelandiae*)

Date Application Received: 20 February 2003

DECISIONS ON APPLICATIONS

There have been no applications decided in this period.

DELEGATED AUTHORITY

Applicant: AgResearch, Ruakura

ERMA Approval Code: GMD002514 — 2515

Institution Code: GMO02/ARR003

Purpose: To add recombinant protein to the heart muscle of sheep

Description of Organism: *Escherichia coli* and *Ovis aries* both modified with pcDNA3 plasmid carrying IGF or MGF gene

Decision: Approved with controls / PC1 and PC2

Applicant: HortResearch, Auckland

ERMA Approval Code: GMD002517 — 2519

Institution Code: GMO02/HRA068

Purpose: The use of novel selectable antibiotic resistance genes for genetic modification of the apple scab fungus. Update of GMO99/HRA022 and GMO00/HRA030

Description of Organism: *Escherichia coli* K12 or B strains and *Agrobacterium tumefaciens* (non-tumorigenic) and *Venturia inaequalis* all modified by plasmid and lambda vectors containing DNA from *Aspergillus nidulans*, *Escherichia coli*, *Botrytis cinerea*, *Venturia inaequalis* and *Streptomyces noursei*.

Decision: Approved with controls / PC1 and PC2

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

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



Applicant: HortResearch, Auckland

ERMA Approval Code: GMD002520 — 2539

Institution Code: GMO02/HRA069

Purpose: Update of GMO02/HRA059 involving a minor modification of the purpose by including studies on the defence of plants against non-native fungal and bacterial pathogens

Description of Organism: *Escherichia coli* K12 and B approved non-conjugative hosts and *Agrobacterium tumefaciens* (non-tumorigenic, disarmed) strains containing binary plasmids suitable for transient expression of proteins in *Arabidopsis thaliana* leaves, *Nicotiana benthamiana* leaves, *Nicotiana tabacum* leaves, *Nicotiana clevelandii* leaves, *Nicotiana glutinosa* leaves, *Lycopersicon esculentum* leaves, *Actinidia deliciosa* leaves, *Actinidia chinensis* leaves, *Actinidia arguta* leaves, *Actinidia eriantha* leaves, *Vaccinium corymbosum* leaves, *Vaccinium ashei* leaves, *Vaccinium angustifolium* leaves, *Vaccinium macrocarpon* leaves, *Malus domestica* leaves, *Cyphomandra betacea* leaves, *Petunia hybrida* leaves and *Vitis vinifera* leaves.

Decision: Approved with controls / PC1 and PC2

Applicant: HortResearch, Auckland

ERMA Approval Code: GMD002540

Institution Code: GMO02/HRA070

Purpose: To construct libraries of plant genes in suitable vectors for subsequent analysis by high throughput sequencing and for later use in programs aimed at functional analysis of the plant genes.
Update of GMO02/HRA066 and GMO00/HRA036

Description of Organism: *Escherichia coli* K12 and B approved non-conjugative hosts and non-approved hosts (containing F and no traD mutation) modified by plasmid and lambda vectors (ZAP II, ZAP Express, ZAP-CMV, DASH II, FIX II, ZIPLOX, pSport, pCMVSPORT, pGEM, pBluescript, pLitmus, pUC, pKK223-3, pDONR, pENTR, pBK-CMV) or derivatives, modified by adding plant DNA from: *Abies* species including fir tree, *Acinus* species including thyme, *Actinidia* species including kiwifruit, *Aesculus* species including chestnut, *Allium*

species including onion, *Aloe* species including *Aloe vera*, *Amomum* species including cardamom, *Amygdalus* species including almond, *Anacardium* species including cashew nut, *Ananas* species including pineapple, *Anethum* species including dill, *Annona* species including custard apple, *Anthemis* species including chamomile, *Antirrhinum* species including snapdragon, *Apium* species including celery, *Apocynum* species including hemp, *Arachis* species including peanut, *Aniba* species including rosewood, *Arnica* species including arnica, *Artemisia* species including tarragon, *Asimina* species including cherimoya, *Asparagus* species including asparagus, *Bellis* species including common daisy, *Beta* species including beetroot, *Boronia* species including boronia, *Boswellia* species including frankincense, *Brassica* species including canola, *Camellia* species including camellia, *Capsicum* species including capsicum pepper, *Cardamine* species including hairy bittercress, *Carica* species including papaya, *Chenopodium* species including arrach, *Chicory* species including chicory, *Chrysanthemum* species including pyrethrum, *Chrysophyllum* species including star apple, *Cicuta* species including hemlock, *Cinnamomum* species including camphor, *Citrus* species including orange, *Cocos* species including coconut, *Coffea* species including coffee, *Commiphora* species including myrrh, *Conium* species including hemlock, *Cenothera* species including evening primrose, *Corylus* species including hazelnut, *Crocus* species including saffron, *Cucumis* species including cantelope melon, *Cucurbita* species including cucumber, *Cupressus* species including cypress, *Cycas* species including cycad, *Cyclamen* species including cyclamen, *Cymbidium* species including cymbidium orchid, *Cyphomandra* species including tamarillo, *Datura* species including Purple Angel's Trumpet, *Daucus* species including carrot, *Delphinium* species including larkspur, *Dianthus* species including carnation, *Digitalis* species including foxglove, *Diospyros* species including date palm and persimmon, *Dryobalanops* species including camphor tree, *Durio* species including durian, *Echinacea* species including pale purple coneflower, *Eucalyptus* species including gum tree, *Eustoma* species including lisianthus, *Feijoa* species including pineapple

guava, *Festuca* species including fescue, *Ficus* species including rubber, *Foeniculum* species including fennel, *Fragaria* species including strawberry, *Freesia* species including freesia, *Garamia* species including mangosteen, *Ginko* species including rosehip, *Glycine* species including soybean, *Glycyrrhiza* species including liquorice, *Gossypium* species including cotton, *Helianthus* species including sunflower, *Hevea* species including para rubber, *Holcus* species including yorkshire fog, *Hordeum* species including barley, *Humulus* species including hop, *Hyacinthus* species including hyacinth, *Jasminum* species including jasmine, *Juglans* species including walnut, *Juniperus* species including juniper, *Lavandula* species including lavender, *Leptospermum* species including laevagutum, *Litchi* species including lychee, *Lolium* species including ryegrass, *Lotus* species including lotus, *Lycopersicon* species including tomato, *Nerium* species including oleander, *Macadamia* species including macadamia, *Malus* species including apple, *Mangifera* species including mango, *Medicago* species including alfalfa, *Mentha* species including peppermint, *Mimosa* species including sensitive plant, *Morinda* species including noni, *Musa* species including banana, *Myristica* species including nutmeg, *Narcissus* species including daffodil, *Ocimum* species including basil, *Olea* species including olive, *Orchis* species including orchids, *Origanum* species including margoram, *Oryza* species including rice, *Panax* species including ginseng, *Papaver* species including poppy, *Passiflora* including passionfruit, *Pastinaca* species including parsnip, *Pelargonium* species including geranium, *Persea* species including avocado, *Phaseolus* species including bean, *Phoenix* species including date palm, *Picea* species including norway spruce, *Pimenta* species including allspice, *Pimpinella* species including anise, *Pinus* species including Monterey pine tree, *Piper* species including pepper, *Pisum* species including peas, *Plantago* species including plantain, *Plumeira* species including frangipani, *Pogostemon* species including patchouli, *Polygonum* species including coriander, *Populus* species including poplar, *Prunus* species including apricot, *Punica* species including pomegranate, *Pyrola* species including wintergreen, *Pyrus* species

including pear, *Quercus* species including oak, *Ribes* species including currant, *Ricinus* species including castor oil plant, *Rosa* species including rose, *Rosmarinus* species including rosemary, *Rubus* species including raspberry, *Saccharum* species including sugarcane, *Salix* species including pacific willow, *Salvia* species including sage, *Sandersonia* species including sandersonia, *Santalum* species including sandalwood, *Sarracenia* species including pitcher plant, *Sesamum* species including sesame, *Solanum* species including potato, *Spinacia* species including spinach, *Symphytum* species including comfrey, *Thea* species including tea plant, *Theobroma* species including cacao, *Thymus* species including common thyme, *Trifolium* species including clover, *Triticum* species including wheat, *Vaccinium* species including blueberry, *Valeriana* species including valerian, *Vanilla* species including vanilla, *Veronica* species including speedwell, *Viola* species including violet, *Vitis* species including grapevine, *Verbena* species including vervain, *Wisteria* species including wisteria, *Zea* species including corn, *Zingiber* species including ginger, and excluding any species native to New Zealand, and excluding any species subject to CITES and excluding genes known to code for toxins for vertebrates.

Decision: Approved with controls / PC1 and PC2

Applicant: HortResearch, Auckland

ERMA Approval Code: GMD002544

Institution Code: GMO02/HRA072

Purpose: To maintain plant DNA clones in *Escherichia coli* in containment for extraction of DNA and to produce proteins for preliminary tests of their function.
Update of GMO00/HRA040

Description of Organism: *Escherichia coli* K12 or B approved non-conjugative host strains modified with plant DNA from the following species: apple (*Malus domestica*), and kiwifruit (*Actinidia deliciosa*, *Actinidia arguta*, *Actinidia chinensis*, *Actinidia eriantha*), Thale Cress (*Arabidopsis thaliana*), Mung bean (*Vigna radiata*), Barley (*Hordeum vulgare*), Pea (*Pisum sativum*), Maize (*Zea mays*), Wheat (*Triticum* spp.), Squash (*Cucurbita maxima*), Spinach (*Spinacia oleracea*), Blueberry (*Vaccinium*

corybosum, *Vaccinium ashei*, *Vaccinium angustifolium*, *Vaccinium macrocarpon*) Citrus (*Citrus limon*, *Citrus maxima*, *Citrus unshui*, *Citrus sinensis*), Potato (*Solanum tuberosum*), Sugar cane (*Saccharum* spp.), Pine (*Pinus radiata*), Poplar (*Populus alba*), Eucalyptus (*Eucalyptus grandis*), Snapdragon (*Antirrhinum majus*), Tobacco (*Nicotiana tabacum*, *Nicotiana benthamiana*) and Tomato (*Lycopersicon esculentum*) and the following commercially available plasmid vectors pET-Blue1, pET-Blue2, pET30-Xa/LIC, pET32 Xa/LIC, pET35, pBAD derivatives, pMAL derivatives and pSPORT derivatives eg pSP19g10L.

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002541

Institution Code: GMO02/UO041

Purpose: The study of nucleotide sequences in mammalian (rat, mouse, sheep, cow, deer) genomes that are involved in the regulation of the expression of individual genes

Description of Organism: *Escherichia coli* K12 and B strains modified with non-conjugative cloning vectors such as PCR-Script, pUC series, pBluescript, and pLitmus plasmids; fragments of mammalian genomic DNA derived from tissue or from cell lines of mouse (*Mus musculus*), rat (*Rattus norvegicus*), sheep (*Ovis aries*), cow (*Bos taurus*, *Bos indicus*), and deer (*Cervus elephas*) either directly, after fragmentation with restriction nucleases, or by polymerase chain reaction copying

Decision: Approved with controls / PC1

Applicant: University of Otago

ERMA Approval Code: GMD002542 — 2543

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 non-conjugative plasmid vectors such as pBeloBAC11 and pEG597, or similar; DNA fragments from uncharacterised bacteria in the gut microflora

of specific-pathogen-free HLA-B27/beta2 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. *Bacillus subtilis* MT119 trpC2 leuB6 or similar auxotrophic strains modified with non-conjugative plasmid vectors such as pHV1432 and pEG597, or similar; DNA fragments from uncharacterised bacteria in the gut microflora of specific-pathogen-free HLA-B27/beta2 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

AMENDMENTS TO APPROVALS

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

The following amendments dates were incorrectly published in previous *Bulletins*. Below is a list of the correct dates for these amendments:

Application Code: GMF98001

Applicant: PPL Therapeutics (NZ) Limited

Purpose: To field test (maintain a manufacturing flock of) transgenic sheep, for the purpose of producing a biopharmaceutical (human alpha-1-antitrypsin, hAAT), in the Waikato region

Date Amendment Signed: 19 November 2002

Previous Bulletin: 33 and 39

Application Code: GMF98007

Applicant: Crop & Food Research Ltd

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

Date Amendment Signed: 10 June 2002

Previous Bulletin: 36

Application Code: GMF98008

Applicant: Crop & Food Research Ltd

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

Date Amendment Signed: 10 June 2002

Previous Bulletin: 36

Application Code: GMF98009

Applicant: AgResearch Limited

Purpose: To field test, in Waikato, genetically modified cattle with extra bovine genes, the insertion of the human myelin basic protein gene, and the deletion of the bovine β -lactoglobulin gene. Genes will be expressed in the milk of the cattle

Date Amendment Signed: 27 March 2002

Previous Bulletin: 22

Application Code: GMF99004

Applicant: AgResearch Limited

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

Date Amendment Signed: 27 March 2002

Previous Bulletin: 36

Application Code: NOC98004

Applicant: Malaghan Institute of Medical Research

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

Date Amendment Signed: 8 April 2002

Previous Bulletin: 36

Application Code: NOC98005

Applicant: Tasmanian Institute of Agricultural Research

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

Date Amendment Signed: 27 March 2002

Previous Bulletin: 36

Application Code: NOC99005

Applicant: University of Otago

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

Date Amendment Signed: 27 March 2002

Previous Bulletin: 36

Application Code: NOC99023

Applicant: Landcare Research Institute

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

Date Amendment Signed: 27 March 2002

Previous Bulletin: 36

Application Code: NOC01006

Applicant: Forest Research Institute Limited

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

Date Amendment Signed: 27 March 2002

Previous Bulletin: 36

The following amendment to the controls was made by the Authority on 11 June 2002 (2nd amendment)

Application Code: NOC00005

Applicant: Landcare Research

Purpose: To import into containment soil/substrate samples from which unknown nematodes and associated soil microfauna will be extracted. The samples will relate to various research programmes concerned with ecosystem processes, biodiversity and environmental quality

Original Control

- 1.6 Organisms other than those fixed on slides for keeping, shall be disposed of by autoclaving. All other biological material, including soil, associated with the samples shall also be disposed of by autoclaving.

Amended Control

- 1.6 Organisms other than those fixed for keeping, shall be disposed of by autoclaving. All other biological material, including soil, associated with the samples shall also be disposed of by autoclaving.
-

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: HSR03002

Applicant: Reckitt Benckiser (NZ) Limited

Purpose: To import RB-2-109, a pest control product containing pyrethroid actives which is used as a domestic use insecticide aerosol spray. It is manufactured in Australia and packed into shipping cartons and will be imported into New Zealand ready for sale

Date Application Received: 14 February 2003

Date Publicly Notified: 24 February 2003

Date Submissions Close: 4 April 2003

Application Code: HSR03006

Applicant: Rentokil Initial Limited

Purpose: To import Pygo, an insecticide for use against flying and crawling insects in domestic and industrial situations by professional pest controllers.

Date Application Received: 17 February 2003

Date Publicly Notified: 28 February 2003

Date Submissions Close: 11 April 2003

Application Code: HSR02061

Applicant: Fort Dodge New Zealand Limited

Purpose: To import Moxidectin/Praziquantel Equine Gel which is intended for use as a broad-spectrum anthelmintic in horses

Date Application Received: 25 February 2003

(yet to be verified before it is publicly notified)

Application Code: HSR03001**Applicant: Reckitt Benckiser (NZ) Limited**

Purpose: To import RB-2-110, a pest control product containing pyrethroid actives which is used as an insecticide aerosol spray. It is manufactured in Australia and packed into shipping cartons and will be imported into New Zealand ready for sale

Date Application Received: 26 February 2003

(yet to be verified before it is publicly notified)

Application Code: HSR03005**Applicant: Fort Dodge New Zealand Limited**

Purpose: To import CYDECTIN Plus Fluke which is intended for use as a broad-spectrum anthelmintic for use on production animals (sheep). The product triggers the HSNO thresholds for acute toxicity, irritation, sensitisation and ecotoxicity

Date Application Received: 27 February 2003

(yet to be verified before it is publicly notified)

NON NOTIFIED APPLICATIONS RECEIVED AND STALLED**Application Code: HSR02055****Applicant: Certis Australia Pty Limited**

Purpose: To import Thuricide 48LV Biological Insecticide, a highly selective biological insecticide for control of pest caterpillars in a broad range of situations.

Date Application Received: 11 February 2003**Date Stalled:** 12 February 2003

Reason Stalled: Under Section 52 of the HSNO Act the Authority considers that the applicant is able to provide further relevant information

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following application on 12 February 2003

Application code: HSR02046**Applicant: Osmose New Zealand**

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

Description of Substances:

Bistar® Timber Insecticide

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

Decision: Approved with Controls**ERMA Approval Code: HSR000043****Controls:**

Control Code ¹	Regulation ²	Explanation ³
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T3	Regulations 5(1), 6	Requirements for keeping records of use
T4, E6	Regulation 7	Requirements for equipment used to handle Bistar® Timber Insecticide
T5	Regulation 8	Requirements for protective clothing and equipment
T7, E8	Regulation 10	Restrictions on the carriage of Bistar® Timber Insecticide on passenger service vehicles
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
E3	Regulation 49	Controls relating to protection of terrestrial invertebrates eg beneficial insects

¹ 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.

² 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.

³ These explanations are for guidance only. Refer to the cited regulations for the formal specification, and for definitions and exemptions.

E4	Regulations 50 — 51	Controls relating to protection of terrestrial vertebrates
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 Bistar® Timber Insecticide
I9, I11, I16	Regulations 18, 20, 25	Secondary identifiers for Bistar® Timber Insecticide
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 – Bistar® Timber Insecticide in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when Bistar® Timber Insecticide is imported
I20	Regulation 36(8)	Durability of information for Bistar® Timber Insecticide
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 Bistar® Timber Insecticide
I29	Regulations 51 — 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising Bistar® Timber Insecticide
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, PG3	Regulations 9, 19, 21	Packaging requirements for Bistar® Timber Insecticide
Hazardous Substances (Disposal) Regulations 2001		
D4, D5	Regulations 8, 9	Disposal requirements for Bistar® Timber Insecticide

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, EM6, EM7	Regulations 6, 7, 8(e), 8(f), 9 — 11	Level 1 emergency management information: Recommended 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

DELEGATED AUTHORITY

There have been no delegated decisions decided in this period.

TEST CERTIFIERS

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

RECENT POLICY DECISIONS

REVISED APPROACH TO ADVISING ON THE STATUS OF SUBSTANCES IN TRANSITION

The Authority has revisited its approach to the advice we give in relation to the status of notified toxic substances (NOTS) under the Act’s transitional provisions. Our preferred interpretation of the Act has been that substances that were notified as toxic substances under the Toxic Substances Act (NOTS) can continue to be imported by any person (ie not just by the notifier) if that substance was properly notified, and was lawfully used prior to the Act commencing in July 2001.

The interpretation that the substance must have been lawfully used prior to commencement is legally arguable as the Act is not clear on this point, but has some substance. It is consistent with good risk management outcomes as it recognised that some substances appear to have been notified without having been imported or manufactured here before the Act

commenced, and thus that any future introduction of such (perhaps quite hazardous) substances may occur without any controls applying to them.

However, it has become clear that our interpretation poses real difficulties for those companies that wish to establish whether the substance they wish to import or manufacture is covered by the transitional provisions. We are responding to a steady stream of enquiries from companies wanting to know if their substance matches one that has been notified. Where we can establish a match with a similar NOTS, we advise the enquirer, accordingly. However because the notifications are confidential we cannot release details, and the enquirer has no practical way of establishing whether the substance was in lawful use.

The Authority has agreed to amend our policy on NOTS so we no longer state that in order to be covered by the transitional provisions the notified substance must also have been legally imported or manufactured prior to July 2001. We would still be in the situation of giving advice to applicants rather than giving a formal determination. There is no provision in the Act for making such determinations, and the ambiguous provisions in the Act remain. Prospective applicants would thus still be in the position of making their own decision, and living with the consequences. In this respect our advice continues to be that if prospective applicants were uncertain, they should play safe by making a Part V application.

However, a corollary is that we will be keeping a careful watch to identify cases where the introduction of new substances under the transitional provisions could pose significant risks because of the lack of effective controls. Where such cases are identified we will immediately add the substances concerned to our priority list for reassessment.

EXEMPTIONS TO TRANSITIONAL CONTROLS

Most hazardous substances that were legally in use before the commencement of the HSNO Act are subject to the transitional provisions of the Act. They must thus comply with the regulations that existed at the commencement date until they are transferred to the HSNO regime. These regulations include those that apply to pesticides, toxic substances, dangerous goods and explosives. On transfer a set of HSNO controls will attach to the substances.

The Act anticipates that circumstances may arise during the transitional period when HSNO controls may be more appropriate for a substance than the existing regulations, and it allows the Authority to grant exemptions from regulations where it can be satisfied that the HSNO requirements can be met.

An example is where a company seeks to revise its product labels, and wishes to do so in a manner that will meet the HSNO controls. This can be an issue when the current requirements are not consistent with the HSNO controls, and the exemption means that a further revision is not required at the time of transfer.

The Authority has agreed to establish processes for such exemptions to be processed. Applications forms and guidance will be posted on our website as soon as it is prepared. In the meantime, any Companies wishing to take advantage of this opportunity should contact us for further advice and guidance.

CONSULTATION ON PROPOSED POLICY

CONFIDENTIAL INFORMATION AND INFORMATION FOR PUBLIC RELEASE

A key issue for hazardous substance applicants and interested parties is that of how much information the Authority should release in order to meet public information requirements and in the light of this, what information can be held to be confidential. Although there are already informal guidelines (in the User Guide for applicants especially) experience has indicated that these guidelines should be formalised. Applicants will then be clearer about expectations, and ERMA New Zealand staff will be able to give more definite advice. Accordingly, the attached policy statement has been prepared by the Authority. This statement is a proposal and will not be adopted formally until stakeholders have had an opportunity to comment.

The statement relates primarily to the validity of confidential information as presented in an application, ie whether particular information must be able to be released or whether it can validly be kept confidential.

However, it also relates to derived information, eg on hazards and risks, which may be contained in Evaluation & Review reports and decisions, and which may be obtained from sources other than the application.

Section A Information which will be held as confidential

Commercially sensitive information which does not comprise the information set out in Section B of this policy will not be publicly released.

Information supplied to the Authority before an application is lodged is not covered by the Official Information Act (OIA) 1982, which means that another person cannot request this information under the OIA.

Once the application has been lodged, the OIA applies, and anyone can ask for copies of information held by the Authority. The OIA works on a presumption that all information can be made available unless there is good reason to withhold it. Section 9(2)(b) of the OIA provides that there is good reason for withholding information:

‘...if, and only if, the withholding of the information is necessary to –

- (b) Protect information where the making available of that information –
 - (i) Would disclose a trade secret; or
 - (ii) Would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information;...

Section 57(1) of the HSNO Act provides that information which could be withheld under section 9(2)(b) of the OIA is not to be released when an application is publicly notified.

Sections 57(2) to (4) of the HSNO Act set out a process for the Authority to follow if a request is made under the OIA for information that may be commercially sensitive. The Authority will advise the person who supplied the information that a request has been made to release it under the OIA.

The person who supplied the information then has 10 working days to respond and give justification as to why the information should be kept confidential. The Authority has 20 working days to respond to the request to release the information. The decision about whether the information meets the criteria for withholding under the OIA rests solely with the Authority. However, the Authority is very conscious of the importance of confidentiality to commercial applicants and will uphold legitimate confidentiality very strongly.

If an application that is subject to an OIA request is withdrawn, the application will be returned to the applicant and the OIA request will not be actioned.

It is the responsibility of the applicant to clearly identify information they consider to be commercially sensitive and to supply this information as an appendix.

A non-confidential summary of the information, clearly cross-referenced, should appear in the main application. Applicants should also justify why the information should be kept confidential.

Section B Information which the Authority may require to be publicly released

The following information contained in any application will not generally be treated as confidential:

- (1) A unique identifier for the substance (this should include the name by which the substance is intended by the applicant to be known to users or the public).
- (2) The name of the manufacturer/importer and applicant.
- (3) A summary of information on the hazardous properties of the substance as a whole, including:
 - HSNO Hazard classifications;
 - Summary of physicochemical data such as physical state, melting/boiling point, density, vapour pressure, flash point, water solubility;
 - Summary of toxic and ecotoxic properties;
- (4) A summary of the lifecycle of the substance including its uses, and disposal information for rendering the substance harmless.
- (5) A summary of the assessment of risks, costs and benefits.
- (6) Information on recommended methods and precautions concerning manufacture (if in NZ), handling, storage, transport, safety and emergency measures.

It should be noted that items (3), (4) and (5) specifically ask for summaries, which allows applicants some discretion as to the level of detail of the non-confidential information, while also allowing the Authority flexibility as to the level of the detail considered acceptable.

Information provided in the 'Summary of Public Information' section of the application form is, by definition, not confidential.

In preparing the Evaluation and Review report on an application, the executive of the Authority will often obtain and present additional and derived information pertinent to the application, particularly in relation to the matters covered in points (3) to (6) of paragraph 8.

The same approach to determining confidential and non-confidential information as for the publication of the application will apply. That is, in the case of confidential information, the matters listed in paragraph 8 would normally be presented in the body of the report in summary form, with the details contained in a confidential appendix. This information may include information on the assessment of risks and benefits, which has been sourced by the Authority's executive and not provided by the applicant.

The Decision on an application will often also contain additional or derived information, particularly in relation to the controls that will apply to the substance. These controls are largely regulatory requirements and as such are considered to be non-confidential. Where there is potential for confidential information to be released via the description of a control, this matter will be discussed with the applicant and, if appropriate, the description will be worded so as to retain confidentiality while still addressing the regulatory requirement.

Where there is the potential for information that the applicant may consider to be confidential to be released and this information lies outside the boundary of information that this policy determines shall be released, the matter will be discussed with the applicant. In general, if the Authority is satisfied that publication of these additional matters relating to the substance could reasonably be expected to prejudice the commercial interests of the applicant, and this prejudice outweighs the public interest in the publication of those particulars, then those matters will be treated as confidential. Otherwise, information will be treated as non-confidential.

If an applicant insists on maintaining confidentiality to a greater degree than the Authority is prepared to accept, then the Authority may determine that some of the information needs to be released in any case. Under such circumstances, the applicant has the option of withdrawing their application. In this case, all information will be returned to the applicant and no information will be released. It is stressed that maintaining confidentiality is not expected to be a problem in the vast majority of cases. The Authority will be sensitive to the need to respect confidentiality where there is justification for doing so.

Comments are thus sought on the proposed policy, which is also available on our website at www.ermanz.govt.nz/consultation/index.cfm

Please send us your submissions by **17 April 2003** to:

Consultation on Proposed Policy on Confidential Information, ERMA New Zealand, PO Box 131, Wellington
Email: info@ermanz.govt.nz