1998/216

HAZARDOUS SUBSTANCES AND NEW ORGANISMS (LOW-RISK GENETIC MODIFICATION) REGULATIONS 1998

MICHAEL HARDIE BOYS, Governor-General

ORDER IN COUNCIL

At Wellington this 27th day of July 1998

Present:

THE RIGHT HON JENNY SHIPLEY PRESIDING IN COUNCIL

PURSUANT to section 41 (c) of the Hazardous Substances and New Organisms Act 1996, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, makes the following regulations.

ANALYSIS

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

(2) These regulations come into force on 29 July 1998.

2. Interpretation—In these regulations, unless the context otherwise requires,—

"The Act" means the Hazardous Substances and New Organisms Act 1996:

"PC conditions" means physical containment conditions as set out in the conditions of standard microbiological laboratory practice specified in the current Australian/New Zealand Standard 2243.3 for "Safety in Laboratories, Part 3: Microbiology" (AS/NZ 2243.3):

"PC1 (physical containment conditions 1)" means conditions for the physical containment of organisms as set out in sections 3.2.2 and 3.4 of the current Australian/New Zealand Standard 2243.3 for "Safety in Laboratories, Part 3: Microbiology" (AS/NZ 2243.3):

"PC2 (physical containment conditions 2)" means conditions for the physical containment of organisms as set out in sections 3.2.3 and 3.5 of the current Australian/New Zealand Standard 2243.3 for "Safety in Laboratories, Part 3: Microbiology" (AS/NZ 2243.3).

3. Classification of genetic modification experiments—Genetic modification of an organism is as categorised in Schedule 1.

4. Approved host/vector systems—The approved host/vector systems are set out in Schedule 2.

5. Low-risk genetic modification—Genetic modification of an organism carried out in the circumstances described in categories A or B is low-risk genetic modification, except as provided by regulation 6.

6. Experiments that are not low risk—An experiment is not low risk if the genetic modification of an organism is—

(a) Carried out in the circumstances described in category C, as set out in Schedule 1; or

(b) Falls into both categories B and C, as set out in Schedule 1.

SCHEDULE 1

Reg. 3

CATEGORY A

Category A experiments are experiments carried out under PC1 containment conditions and that are either—

(a) Experiments involving the approved host/vector systems set out in Schedule 2 if the donor nucleic acid—

(i) Is not derived from micro-organisms able to cause disease in humans, animals, or plants; and

(ii) Does not code for a toxin for vertebrates and is not an oncogene; and

(iii) Does not comprise or represent more than two-thirds of the genome of a virus; and

(iv) Is not being used in an experiment in which the genetic material missing from the viral genome, and essential for producing infection, is available in the cell into which the incomplete genome is introduced, or is made available by subsequent breeding processes; or

(b) Shot gun cloning of nucleic acid from the approved host/vector systems of the non-pathogenic organisms (prokaryotic or eukaryotic, including mammalian) set out in Schedule 2.

Reg. 3

CATEGORY B

Category B experiments are experiments that—

(a) Are carried out under—

(i) PC1 conditions if the host organism is described in column 2 of Schedule 2; or

(ii) PC2 conditions for other host organisms; or

(iii) PC2 conditions if the modification is carried out in plant houses, animal houses, insectaries, bird houses, or aquaria; and

(b) Either—

(i) Do not generate an organism with a higher level of risk to the laboratory personnel, the community, or the environment than the parent organism; or

(ii) Are genetic modification experiments involving whole animals (including non-vertebrates, but excluding micro-organisms) of the following types:

(A) Somatic cells of animals *in vivo*:

(B) The production or use of mice in which the genetic modification involves the deletion or inactivation of a specific gene, whether or not the mice also carry a selectable marker gene:

(C) The genetic modification of the oocyte, zygote, or early embryo by any means to produce a novel whole organism, except experiments specified in category C, paragraph (g) of this schedule:

(D) Injection of naked nucleic acids into animals; or

(iii) Are genetic modification experiments involving the production of modified whole plants; or

(iv) Are experiments with any host/vector system where the host or vector either—

(A) Does not cause disease in plants, humans, or animals; or

SCHEDULE 1—*continued*

CATEGORY B—*continued*

(B) Is able to cause disease in plants, humans, or animals but the nucleic acid to be introduced is fully characterised and will not increase the virulence of the host or vector; or

(v) Are experiments with the approved host/vector systems set out in Schedule 2, where the gene inserted is—

(A) A pathogenic determinant:

(B) Uncharacterised nucleic acid from micro-organisms able to cause disease in humans, animals, or plants:

(C) Nucleic acid that encodes a toxin for vertebrates with an LD_{50} of more than 100μg/kg, if the experiment does not involve the high-level expression of the toxin:

(D) An oncogene; or

(vi) Are experiments using as a host or vector, micro-organisms which are able to cause disease in plants, humans, or animals, and—

(A) Which are micro-organisms listed as approved hosts or vectors in Schedule 2; or

(B) Where the nucleic acid to be introduced is fully characterised and will not affect the virulence of the host or vector.

CATEGORY C Reg. 3

Category C experiments are—

(a) Experiments with nucleic acid encoding a toxin for vertebrates having an LD_{50} of less than 100μg/kg:

(b) Experiments involving toxin genes at levels higher than that occurring in the parent organism even if the LD_{50} is greater than 100μg/kg, including experiments with uncharacterised nucleic acid which may include toxin sequences from non-toxin producing organisms, but excluding experiments with nucleic acid which has been characterised, and shown not to code for a toxin, from a toxin-producing organism as donor:

(c) Experiments involving viral vectors whose host range includes human cells and that contain 1 or more inserted nucleic acid sequences coding for a product known to play a role in the regulation of mammalian cellular growth or to be toxic to mammalian cells:

(d) Experiments using, as host or vector, micro-organisms which are able to cause disease in plants, humans, or animals, which use defective vector/helper virus combinations which have the potential to regenerate non-defective recombinant virus:

(e) Introduction of genes determining pathogenicity into micro-organisms other than the approved hosts set out in Schedule 2:

(f) Cloning or transfer of complete viral genomes, viroids, or fragments of a genome capable of giving rise to infectious particles pathogenic to humans, animals, or plants, excluding experiments involving—

(i) Cloning of less than two-thirds of a complete viral genome; and

SCHEDULE 1—*continued*

CATEGORY C—*continued*

(ii) Cloning of a viral genome lacking activity for a vital component of replication or packaging not supplied by the experimental system:

(g) Experiments involving recombinations between whole viral genomes, viroids, or complementary fragments of such genomes, where 1 or more fragments contain virulence or pathogenic determinants (including experiments which alter host ranges of pathogens or which may increase their virulence or infectivity):

(h) Experiments involving the injection of a fragment or the whole of a genome of a virus into an embryo to produce a transgenic animal secreting or producing infectious viral particles.

SCHEDULE 2

LIST OF APPROVED HOST/VECTOR SYSTEMS

Organism	**Host**	**Vector**
Bacteria	*Escherichia coli* K12 or *E.Coli* B derivatives that do not contain conjugative plasmids or generalised transducing phages.	Non-conjugative plasmids. Bacteriophage: lambda, lambdoid, Ff (eg M13).
	Bacillus subtilis or *Bacillus licheniformis.* Asporogenic strains with a reversion frequency of less than 10^{-7}.	Indigenous *Bacillus* plasmids and phages whose host range does not include *Bacillus cereus* or *Bacillus anthracis.*
	Pseudomonas putida strain KT 2440 or similar plasmids.	Certified plasmids: pKT 262, pKT 263, pKT 264.
	Streptomyces specified species: *Streptomyces coelicolor, Streptomyces lividans, Streptomyces parvulus, Streptomyces griseus.*	Certified plasmids: SCP2, SLP1, SLP2, PIJ101, and derivatives. Actinophage phi C31 and derivatives or similar plasmids.
Fungi	*Neurospora crassa,* laboratory strains. *Saccharomyces cerevisiae.*	Any vector.

SCHEDULE 2—*continued*

LIST OF APPROVED HOST/VECTOR SYSTEMS—*continued*

Organism	Host	Vector
Slime moulds	*Dictyostelium* species.	*Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2.
Tissue culture	Mammalian (including human) cells.	Non-viral vectors or defective viral vectors (including retrovirus or retroviral-helper combinations) that cannot infect human cells.
Avian cells		Avipox vectors.
In vitro plant culture		Non-tumorigenic Ti plasmid vectors in *Agrobacterium tumefaciens* and non-pathogenic viral vectors. *Agrobacterium rhizogenes.*
Insect cell culture	Such as *Spodoptera frugiperda.* Insect cell lines.	Baculovirus (*Autographa californica* nuclear polyhedrosis virus). Non-conjugative plasmids.

MARIE SHROFF,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on 29 July 1998, specify the circumstances in which genetic modification of an organism is low-risk genetic modification.

Regulation 3 divides various types of genetic modification experiments into 3 separate categories. These are set out in Schedule 1.

Regulation 4 provides for an approved host/vector system. This is set out in Schedule 2.

Regulation 5 prescribes which categories of experiment are low-risk genetic modifications for the purpose of section 42 (2) of the Hazardous Substances and New Organisms Act 1996.

Regulation 6 provides that experiments that fall into category C or both categories B and C are not to be regarded as low-risk genetic modifications.

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These regulations are administered in the Ministry for the Environment.