HSNO (Low Risk Genetic Modification) Regulations 2003

Explanatory Statement

The revised HSNO (Low Risk Genetic Modification) Regulations 2003 came into force on 31 July 2003. They contain substantial changes to how low risk genetic modifications are determined and classified.
Key Changes include:

- Previous Category C modifications are now specified in the Schedule of the Regulations as "Developments that are not low risk genetic modifications". In addition, three new classes of modifications have been added to this Schedule as not low-risk. Note: none of the modifications that were previously considered Category C have moved into Category A or B.

- A number of new concepts are introduced to describe the properties of the host organism because the prescriptive list of Approved Host/Vector Systems has been removed from the Regulation. Interpretation of the Regulations will now require a determination as to whether the modification involves category 1 or 2 host organisms, as defines in the 2003 Regulations. This determination requires an assessment of the biological characteristic of the host organism and also factors in the level of containment.

- The concept of risk group is introduced when determining whether a micro-organism is a Category 2 host organism or constitutes a no low risk development. Risk groups 1, 2, 3, and 4 are defined in the Regulations and do not refer to any particular Biosafety Standard.

A number of GMOs will change classification from Category B given in previous 1998 Regulations to Category A and thus, containment requirements will shift from PC2 to PC1. For example, modifications of disarmed non-pathogenic strains of *Agrobacterium tumefaciens* and *Pichia pastoris* will move from Category B to A as long as the modification "does not increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment; and does not result in the genetically modified organism having a greater ability to escape from containment that the unmodified host organism." In addition, genetic modification of a whole plant may be considered Category A instead of B if is does not contain a reproductive structure and is kept in a closed container.

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REGULATIONS

Note: *These regulations which come into force on 31 July 2003 specify the circumstances in which genetic modification of an organism is a low-risk genetic modification.*

1. Title
These regulations are the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003.

2. Commencement
These regulations come into force on 31 July 2003.

3. Interpretation.
In these regulations, unless the context otherwise requires –
AS/NZ containment standard means Australian and New Zealand containment standard.

MAF Biosecurity Authority containment standard mean Ministry of Agriculture and Forestry Biosecurity Authority containment standard.

PC1 containment means

a) the conditions for the physical containment of organisms described as Physical Containment Level 1 (PC1) in AS/NZ containment standard 2243.3: 2002 (Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities); and
b) the modification referred to in the following MAF Biosecurity Authority containment standards:
   i) 154.03.02 (31 October 2002) (Containment facilities for micro-organisms):
   ii) 154.03.03 (31 October 2002) (Containment facilities for vertebrate laboratory animals):
   iii) 154.02.08 (31 October 2002) (Transitional and containment facilities for invertebrates):
   iv) 155.04.09 (24 March 2003) (containment facilities for new organisms, including genetically modified organisms, of plant species).

PC2 containment means

a) the conditions for the physical containment of organisms described as Physical Containment Level 2 (PC2) in AS/NZ containment standard 2243.3: 2002 (Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities); and

b) the modification referred to in the following MAF Biosecurity Authority containment standards:

i) 154.03.02 (31 October 2002) (Containment facilities for micro-organisms):

ii) 154.03.03 (31 October 2002) (Containment facilities for vertebrate laboratory animals):

iii) 154.02.08 (31 October 2002) (Transitional and containment facilities for invertebrates):

iv) 155.04.09 (24 March 2003) (containment facilities for new organisms, including genetically modified organisms, of plant species).

4. Low risk genetic modification. Genetic modification of an organisms a low risk genetic modification is the modification-

a) does not involve any of the developments specified in the Schedule; and

b) is either

i) a category A genetic modification, as defined in regulation 5(1); or

ii) a category B genetic modification, as defined in regulation 5(2).

5. Categories of low-risk genetic modification

(1) A **category A genetic modification is** a modification that-

a) involves a category 1 host organisms, as defines in regulation 7(1)

b) is carried out under a minimum of PC1 containment; and

c) does not increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment; and

d) does not result in the genetically modified organism having a greater ability to escape from containment than the unmodified host organism.

(2) A **category B genetic modification** is a modification that is carried out under a minimum of PC2 containment and involves either -

a) a category 1 host organism, as defined in regulation 7(1), that satisfies the requirements of subclause (3); or

b) a category 2 host organism, as defined in regulation 7(2), that satisfies the requirements of subclause (4).

(3) If a category 1 host organism is used,-

a) the nucleic acid that is introduced must be characterised to the extent that –

i) its sequence is known; or

ii) its gene function is understood; and

b) the modification must not –

i) result in a genetically modified organism that is more pathogenic, virulent, or infectious to laboratory personnel, the community, or the environment than a category 2 host organism; and

ii) result in the genetically modified organism having a greater ability to escape from containment that the unmodified organisms.

(4) If a category 2 host organism is used,-

a) the modification must involve either

i) a host organism that is not normally able to cause disease in humans, animals, plants, or fungi; or

ii) a host organism that is normally able to cause disease in humans, animals, plants or fungi provided that the nucleic acid that is introduced is characterised to the extent that –

b) the modification must not –

i) increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment; and

ii) result in the genetically modified organism having a greater ability to escape from containment than the unmodified host organism.

6. Host organisms involved in low-risk genetic modification

(1) A host organism involved in low-risk genetic modification must be either -

a) a category 1 host organism, as defined in regulation 7(1); or

b) a category 2 host organism, as defines in regulation 7(2).

(2) If a host organism may be characterised as both a category 1 host organism and a category 2 host organism, the organism must be classified as a category 2 host organism for the purposes of the low-risk genetic modification.

7 Categories of host organisms

(1) A **Category 1 host organism** is an organism that -

a) is clearly identifiable and classifiable according to genus, species, and strain or other sub-specific category as appropriate; and

b) is not normally able to cause disease in humans, animals, plants, or fungi; and
c) does not contain infectious agents normally able to cause disease in humans, animals, plants, or fungi; and
d) does not produce desiccation-resistant structures, such as spores or cysts, that can normally be disseminated in the air; and
e) is characterised to the extent that its main biological characteristics are known; and
f) does not normally infect, colonise, or establish is humans.

(2) A **Category 2 host organism** is an organism that –
a) is clearly identifiable and classifiable according to genus, species, and strain or other sub-specific category as appropriate; and
b) is –
i) a micro-organism of risk group 1 or risk group 2 that-
A) is an infectious agent or contains infectious agents pathogenic to humans, animals, plants, or fungi; or
B) produces desiccation-resistant structures, such as spores or cysts, that may normally be disseminated in the air; or
C) is not characterised to the extent that its main biological characteristics are known; or
D) normally infects, colonises, or establishes in humans; or
ii) a mammalian cell line containing active viruses or infectious agents normally able to cause disease in human; or
iii) a whole animal, vertebrate or invertebrate, including oocytes, zygotes, early embryos, and other cells able to grow without human intervention into a whole animal; or
iv) a whole plant
A) with a reproductive structure and that is not kept in a closed container; or
B) with a reproductive structure and that is kept in a closed container; or
C) without a reproductive structure and that is not kept in a closed container.

(3) For the purposes of subclause (2)(b)(i)
risk group 1 means micro-organisms that are unlikely to cause disease in humans, animals, plants, or fungi
risk group 2 means micro-organisms that
a) may cause disease in humans, animals, plants or fungi but are unlikely to be a serious hazard to laboratory personnel, the community, animals or the environment; and
b) have effective treatment and preventative measures with respect to any infections that they may cause; and
c) present a limited risk of the spread of infection

8 Special requirements for certain category 1 host organisms
If a category 1 host organism is a whole plant or plant tissue, it –
a) must not be allowed to develop reproductive structures; and
b) must be kept in a closed container.

9 Revocation
The Hazardous substances and New Organisms (Low Risk Genetic Modification) Regulations 1998 (SR1998/216) are revoked.

Schedule
Developments that are not low-risk genetic modifications

1. The following developments are not low-risk genetic modification:
a) developments involving host organisms that are micro-organism of risk group 3 or 4:
b) developments involving the expression of genes encoding toxins that have an oral or dermal vertebrate LD50 of less that 100μg/kg:
c) developments involving production of pharmacologically active forms of other biologically active molecules that have an oral or dermal vertebrate LD50 of less that 100μg/kg:
d) developments involving the expression of genes encoding toxins at levels higher than that occurring in the organism from which they are derived, but excluding developments involving expression of genes that are –
(i) from a toxin-producing organism as donor; and
(ii) shown not to encode a substance toxic to vertebrates
e) developments involving viral vectors whose host range includes human cells and that contain 1 or more inserted nucleic acid sequences coding for a product that can lead to uncontrolled mammalian cellular proliferation or be toxic to mammalian cells, or both:

f) developments involving or resulting in viral genomes, viroids, or fragments of a genome capable, in the host/vector system used, of giving rise to particles naturally infectious and normally able to cause disease in humans, animals, plants, or fungi other than those that satisfy the requirements of a category A or category B genetic modification:

g) developments using micro-organisms as a host or vector that are normally able to cause disease in humans, animals, plants, or fungi and that use defective vector/helper virus combinations with the potential to regenerate a non-defective recombinant virus other than those that satisfy the requirements of a category A or B genetic modification:

h) developments involving recombinations between whole viral genomes, viroids, or complementary fragments of those genomes, where 1 or more fragments contain 1 or more virulence determinants that can alter the host range of a pathogen or that increase the virulence or infectivity of the virus.:

i) developments involving the introduction of genes determining pathogenicity into micro-organisms other than category 1 host organisms involved in category A genetic modification:

j) developments involving micro-organisms that are capable of causing disease in humans, animals, plants, or fungi unless the developments only involve cloning genetic material that is well characterised and is known not to increase the virulence or infectivity of the host:

k) developments involving modifications to pathogenic micro-organisms that result in resistance to antibiotics used for clinical or veterinary treatment of infections caused by that micro-organism.

2. For the purposes of clause 1-

LD50 means the median lethal dose, being a statistically derived single dose of a substance that can be expected to cause disease in 50% of animals.

risk group 3 means micro-organisms that are pathogens that –

a) that usually cause serious human, animal, or plant disease and may present a serious hazard to laboratory personnel; and

b) that could present a risk if spread in the community or the environment; and

c) in respect of which effective preventive measures or treatments are usually available

risk group 4 means micro-organisms that are pathogens –

a) that usually cause life-threatening human or animal disease and present a serious hazard to laboratory personnel; and

b) that are readily transmissible from –

(i) an individual human to another human or to an animal

(ii) an individual animal to another animal or to a human; and

c) in respect of which effective treatment and preventative measures are not usually available.