

Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003

(SR 2003/152)

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

Contents

	Page
1 Title	1
2 Commencement	2
3 Interpretation	2
4 Low-risk genetic modification	3
5 Categories of low-risk genetic modification	3
6 Host organisms involved in low-risk genetic modification	5
7 Categories of host organisms	5
8 Special requirements for certain category 1 host organisms	7
9 Revocation	7
Schedule	7

Developments that are not low-risk genetic modifications

1 Title

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

Note

These regulations are administered in the Ministry for the Environment.

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 means Ministry of Agriculture and Forestry Biosecurity Authority containment standard

PCI containment means—

- (a) the conditions for the physical containment of organisms described as Physical Containment Level 1 (PC 1) in AS/NZ containment standard 2243.3:2002 (Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities); and
- (b) the modifications 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 modifications 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 organism is a low-risk genetic modification if 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 organism, as defined in regulation 7(1); and
 - (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 than the unmodified host organism.
- (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—
 - (A) its sequence is known; and
 - (B) its gene function is understood; and
 - (C) its potential gene products are understood; and
 - (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.

Subclause (3)(b)(i) was amended, as from 1 September 2005, by regulation 3(1) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221) by substituting the words “genetically modified” for the word “host” where it first appeared.

Subclause (4)(a)(i) was amended, as from 1 September 2005, by regulation 3(2) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221) by inserting the expression “animals,” after the expression “humans,”.

Subclause (4)(a)(ii) was amended, as from 1 September 2005, by regulation 3(3) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221) by inserting the expression “plants,” after the expression “animals,”.

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 defined 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 in 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
(A) is or contains an infectious agent 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 humans; 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 preventive measures with respect to any infections that they may cause; and
 - (c) present a limited risk of the spread of infection.

Subclause (2)(b)(i)(A) was amended, as from 1 September 2005, by regulation 4 Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221) by substituting the words “is or contains an infectious agent” for the words “contains infectious agents”.

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 (SR 1998/216) are revoked.

Schedule

r 4(3)

**Developments that are not low-risk
genetic modifications**

1

The following developments are not low-risk genetic modifications:

- (a) developments involving host organisms that are micro-organisms of risk group 3 or risk group 4;
- (b) developments involving the expression of genes encoding toxins that have an oral or dermal vertebrate LD₅₀ of less than 100 µg/kg;
- (c) developments involving production of pharmacologically active forms of other biologically active molecules that have an oral or dermal vertebrate LD₅₀ of less than 100 µg/kg;
- (d) developments involving the expression of genes that encode a substance toxic to vertebrates at levels higher than the level occurring in the organism from which they are derived—
 - (i) including, despite paragraph (b), genes that encode a substance toxic to vertebrates that have an oral or dermal LD₅₀ greater than 100 µg/kg; but
 - (ii) excluding developments involving the expression of genes that are—

- (A) from a toxin-producing organism as donor; and
- (B) 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 category B genetic modification:
- (h) developments involving recombinations between whole viral genomes, viroids, or complementary fragments of these genomes, where 1 or more fragments contain 1 or more virulence determinants or pathogenic determinants, including developments 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.

Paragraph (b) was amended, as from 1 September 2005, by regulation 5(1) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221) by substituting the words “involving the expression of genes encoding toxins” for the words “with nucleic acid encoding for toxins”.

Paragraph (d) was substituted, as from 1 September 2005, by regulation 5(2) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221).

Paragraph (j) was amended, as from 1 September 2005, by regulation 5(3) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221) by substituting the expression “animals,” after the expression “humans,”.

2 For the purposes of clause 1(a),—

risk group 3 means micro-organisms that are pathogens—

- (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 preventative measures or treatments are usually available.

risk group 3: this definition was substituted, as from 1 September 2005, by regulation 5(4) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221).

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; or
 - (ii) an individual animal to another animal or to a human; and
- (c) in respect of which effective treatment and preventive measures are not usually available.

risk group 4: paragraph (b) of this definition was substituted, as from 1 September 2005, by regulation 5(5) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005 (SR 2005/221).

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 31 July 2003, specify the circumstances in which genetic modification of an organism is a low-risk genetic modification. These regulations replace the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette*: 3 July 2003.
