

Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005

Pursuant to sections 75 and 76 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.

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1 Title

- (1) These regulations are the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Amendment Regulations 2005.
- (2) In these regulations, the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003¹ are called “the principal regulations”.

2 Commencement

These regulations come into force on the 28th day after the date of their notification in the *Gazette*.

¹ SR 2003/152

3 Categories of low-risk genetic modification

- (1) Regulation 5(3)(b)(i) of the principal regulations is amended by omitting the word “host”, where it first appears, and substituting the words “genetically modified”.
- (2) Regulation 5(4)(a)(i) of the principal regulations is amended by inserting, after the word “humans,”, the word “animals,”.
- (3) Regulation 5(4)(a)(ii) of the principal regulations is amended by inserting, after the word “animals,”, the word “plants,”.

4 Categories of host organisms

Regulation 7(2)(b)(i)(A) of the principal regulations is amended by omitting the words “contains infectious agents”, and substituting the words “is or contains an infectious agent”.

5 Schedule amended

- (1) Clause 1(b) of the Schedule of the principal regulations is amended by omitting the words “with nucleic acid encoding for toxins”, and substituting the words “involving the expression of genes encoding toxins”.
- (2) Clause 1 of the Schedule of the principal regulations is amended by revoking paragraph (d), and substituting the following paragraph:

“(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:”.
- (3) Clause 1(j) of the Schedule of the principal regulations is amended by inserting, after the word “humans,”, the word “animals,”.

- (4) Clause 2 of the Schedule of the principal regulations is amended by omitting the definition of **risk group 3**, and substituting the following definition:

“**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.”.

- (5) Clause 2 of the Schedule of the principal regulations is amended by revoking paragraph (b) of the definition of **risk group 4**, and substituting the following paragraph:

“(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”.

Diane Morcom,

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 the 28th day after the date of their notification in the *Gazette*, amend the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 (**the principal regulations**). The amendments clarify that certain provisions in the principal regulations apply to work involving animals. They also recast clauses 1 and 2 of the Schedule of the principal regulations to refine the category specification for developments that are not low-risk genetic modifications.

Issued under the authority of the Acts and Regulations Publication Act 1989.

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