

Gene Technology Regulations 2001

Statutory Rules 2001 No. 106 as amended made under the Gene Technology Act 2000

This compilation was prepared on 1 July 2007 taking into account amendments up to SLI 2007 No. 128

Schedule 1A Techniques that are not gene technology (regulation 4)

Item	Description of technique
1	Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
2	Electromagnetic radiation-induced mutagenesis.
3	Particle radiation-induced mutagenesis.
4	Chemical-induced mutagenesis.
5	Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.
6	Protoplast fusion, including fusion of plant protoplasts.
7	Embryo rescue.
8	<i>In vitro</i> fertilisation.
9	Zygote implantation.
10	A natural process, if the process does not involve genetically modified material. Examples Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

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Schedule 1 **Organisms that are not genetically modified organisms (regulation 5)**

Item	Description of organism
1	A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
2	A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.
3	Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.
6	An organism that results from an exchange of DNA if: (a) the donor species is also the host species; and (b) the vector DNA does not contain any heterologous DNA.
7	An organism that results from an exchange of DNA between the donor species and the host species if: (a) such exchange can occur by naturally occurring processes; and (b) the donor species and the host species are micro-organisms that: (i) satisfy the criteria in AS/NZS 2243.3:2002 (Safety in laboratories, Part 3: Microbiological aspects and containment facilities) jointly published by Standards Australia and Standards New Zealand, for classification as Risk Group 1; and (ii) are known to exchange nucleic acid by a natural physiological process; and (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

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Schedule 2 Dealings exempt from licensing (regulation 6)

Note Subregulation 6 (1) sets out other requirements for exempt dealings.

Part 1 Exempt dealings

Item	Description of dealing
2	A dealing with a genetically modified <i>Caenorhabditis elegans</i> , unless: <ul style="list-style-type: none">(a) an <i>advantage</i> is conferred on the animal by the genetic modification; or(b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.
3	A dealing with an animal into which genetically modified somatic cells have been introduced, if: <ul style="list-style-type: none">(a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and(b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
4	<p>(1) Subject to subitem (2), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture in each vessel containing the resultant culture.</p> <p>(2) The donor nucleic acid:</p> <ul style="list-style-type: none">(a) must satisfy either of the following requirements:<ul style="list-style-type: none">(i) it must not be derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi; or(ii) it must be characterised and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; and(b) must not code for a toxin with an LD₅₀ of less than 100 µg/kg; and(c) must not code for a toxin with an LD₅₀ of 100 µg/kg or more, if the intention is to express the toxin at high levels; and(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and(e) must not include a viral sequence unless the donor nucleic acid:<ul style="list-style-type: none">(i) is missing at least 1 gene essential for viral multiplication that:<ul style="list-style-type: none">(A) is not available in the cell into which the nucleic acid is introduced; and(B) will not become available during the dealing; and(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and(f) must not confer an oncogenic modification.
5	A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either: <ul style="list-style-type: none">(a) a pathogen; or(b) a toxin-producing organism.

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Part 2 Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	<p><i>Escherichia coli</i> K12, <i>E. coli</i> B or <i>E. coli</i> C – any derivative that does not contain:</p> <p>(a) generalised transducing phages; or</p> <p>(b) genes able to complement the conjugation defect in a non-conjugative plasmid</p> <p><i>Bacillus</i> – specified species – asporogenic strains with a reversion frequency of less than 10^{-7}:</p> <p>(a) <i>B. amyloliquefaciens</i></p> <p>(b) <i>B. licheniformis</i></p> <p>(c) <i>B. pumilus</i></p> <p>(d) <i>B. subtilis</i></p> <p>(e) <i>B. thuringiensis</i></p> <p><i>Pseudomonas putida</i> – strain KT 2440</p> <p><i>Streptomyces</i> – specified species:</p> <p>(a) <i>S. aureofaciens</i></p> <p>(b) <i>S. coelicolor</i></p> <p>(c) <i>S. cyaneus</i></p> <p>(d) <i>S. griseus</i></p> <p>(e) <i>S. lividans</i></p> <p>(f) <i>S. parvulus</i></p> <p>(g) <i>S. rimosus</i></p> <p>(h) <i>S. venezuelae</i></p> <p><i>Agrobacterium radiobacter</i></p> <p><i>Agrobacterium rhizogenes</i> — disarmed strains</p> <p><i>Agrobacterium tumefaciens</i> — disarmed strains</p> <p><i>Lactobacillus</i></p> <p><i>Oenococcus oeni</i> syn. <i>Leuconostoc oeni</i></p> <p><i>Pediococcus</i></p> <p><i>Photobacterium angustum</i></p> <p><i>Pseudoalteromonas tunicate</i></p> <p><i>Rhizobium</i> (including the genus <i>Allorhizobium</i>)</p> <p><i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas alaskensis</i></p>	<p>1. Non-conjugative plasmids</p> <p>2. Bacteriophage</p> <p>(a) lambda</p> <p>(b) lambdoid</p> <p>(c) Fd or F1 (eg M13)</p> <p>3. None (non-vector systems)</p> <p>1. Non-conjugative plasmids</p> <p>2. Plasmids and phages whose host range does not include <i>B. cereus</i>, <i>B. anthracis</i> or any other pathogenic strain of <i>Bacillus</i></p> <p>3. None (non-vector systems)</p> <p>1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264</p> <p>2. None (non-vector systems)</p> <p>1. Non-conjugative plasmids</p> <p>2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives</p> <p>3. Actinophage phi C31 and derivatives</p> <p>4. None (non-vector systems)</p> <p>1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors</p> <p>2. None (non-vector systems)</p> <p>1. Non-conjugative plasmids</p> <p>2. None (non-vector systems)</p>

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Item	Class	Host	Vector
		<i>Vibrio cholerae</i> CVD103-HgR	
2	Fungi	<i>Neurospora crassa</i> – laboratory strains <i>Pichia pastoris</i> <i>Saccharomyces cerevisiae</i> <i>Schizosaccharomyces pombe</i> <i>Kluyveromyces lactis</i> <i>Trichoderma reesei</i>	1. All vectors 2. None (non-vector systems)
3	Slime moulds	<i>Dictyostelium</i> species	1. <i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. None (non-vector systems)
4	Tissue culture	Animal or human cell cultures (including packaging cell lines)	1. Non-conjugative plasmids 2. Non-viral vectors, or defective viral vectors unable to transduce human cells 3. Avipox vectors (attenuated vaccine strains) 4. Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus 5. None (non-vector systems)
		Plant cell cultures	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in <i>Agrobacterium tumefaciens</i> , <i>Agrobacterium radiobacter</i> or <i>Agrobacterium rhizogenes</i> 2. Non-pathogenic viral vectors 3. None (non-vector systems)

Part 3 Definitions

In this Schedule:

code for, in relation to a toxin, means to specify the amino acid sequence of the toxin.

non-conjugative plasmid means a plasmid that is not self-transmissible, and includes, but is not limited to, non-conjugative forms of the following plasmids:

- (a) bacterial artificial chromosomes (BACs);
- (b) cosmids;
- (c) P1 artificial chromosomes (PACs);
- (d) yeast artificial chromosomes (YACs).

non-vector system means a system by which donor nucleic acid is introduced (for example, by electroporation or particle bombardment) into a host in the absence of a nucleic acid-based vector (for example, a plasmid, viral vector or transposon).

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Schedule 3 **Notifiable low risk dealings in relation to a GMO** **(regulations 12 and 13)**

Part 1 **Notifiable low risk dealings suitable for physical containment level 1**

Note Because of subregulation 12 (1) a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3 of this Schedule.

1.1 **Kinds of dealings**

The following kinds of notifiable low risk dealings may be conducted in physical containment level 1 facilities:

- (a) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, unless:
 - (i) an advantage is conferred on the animal by the genetic modification; or
 - (ii) because of the genetic modification, the animal is capable of secreting or producing an infectious agent;
- (b) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid confers an oncogenic modification;
- (c) a dealing involving a defective viral vector able to transduce human cells in a host mentioned in item 4 of Part 2 of Schedule 2 (animal or human cell culture), unless:
 - (i) the vector is a retroviral vector; or
 - (ii) the donor nucleic acid confers an oncogenic modification.

Part 2 **Notifiable low risk dealings suitable for physical containment level 2**

Note Because of subregulation 12 (1) a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3 of this Schedule.

2.1 **Kinds of dealings**

The following kinds of notifiable low risk dealings may be conducted in physical containment level 2 facilities:

- (a) a dealing involving whole animals (including non-vertebrates) that:
 - (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
 - (ii) does not involve any of the following:
 - (A) a genetically modified laboratory mouse;
 - (B) a genetically modified laboratory rat;
 - (C) a genetically modified *Caenorhabditis elegans*;
- (aa) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, if:
 - (i) the genetic modification confers an advantage on the animal; and
 - (ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;
- (ab) a dealing involving a genetically modified *Caenorhabditis elegans*, if:
 - (i) the genetic modification confers an advantage on the animal; and
 - (ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;
- (b) a dealing involving a genetically modified plant (including a genetically modified flowering plant), if the dealing occurs in a facility that is designed to prevent the escape from the facility of:
 - (i) pollen, seed, spores or other propagules which may be produced in the course of the dealing; and
 - (ii) invertebrates that are capable of carrying the material mentioned in subparagraph (i);

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- (ba) a dealing involving a genetically modified flowering plant, if, before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed;
- (c) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
 - (i) the host has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi; and
 - (ii) the vector has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi;
- (d) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
 - (i) either:
 - (A) the host has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or
 - (B) the vector has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; and
 - (ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector;
- (e) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:
 - (i) encodes a pathogenic determinant; or
 - (ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi;
- (f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 10 litres of GMO culture in each vessel containing the resultant culture, if:
 - (i) the dealing is undertaken in a facility that is certified by the Regulator:
 - (A) as a large scale facility; and
 - (B) to at least physical containment Level 2; and
 - (ii) the donor nucleic acid satisfies the conditions set out in item 4 of Part 1 of Schedule 2;
- (g) a dealing involving complementation of knocked-out genes, if the complementation does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of the parent organism before the genes were knocked-out;
- (h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of Schedule 2, if the donor nucleic acid is derived from either:
 - (i) a pathogen; or
 - (ii) a toxin-producing organism;
- (i) a dealing involving the introduction of a replication defective viral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2 if:
 - (i) the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions; and
 - (ii) either:
 - (A) the vector is a retroviral vector; or
 - (B) the donor nucleic acid confers an oncogenic modification.

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Part 3 Dealings that are not notifiable low risk dealings

Note 1 The following list qualifies the list in Parts 1 and 2, and is not an exhaustive list of dealings that are not notifiable low risk dealings.

Note 2 A dealing that is not a notifiable low risk dealing, or an exempt dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see Act, section 32).

3.1 Kinds of dealings

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing:

- (a) a dealing (other than a dealing mentioned in paragraph 2.1 (h) of Part 2 of this Schedule) involving cloning of nucleic acid encoding a toxin having an LD₅₀ of less than 100 µg/kg;
- (b) a dealing involving high level expression of toxin genes, even if the LD₅₀ is 100 µg/kg or more;
- (c) a dealing (other than a dealing mentioned in paragraph 2.1 (h) of Part 2 of this Schedule) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;
- (d) unless the viral vector is part of a host/vector system mentioned in Part 2 of Schedule 2 or in paragraph 1.1 (c) of Part 1 or 2.1 (i) of Part 2 of this Schedule — a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid:
 - (i) confers an oncogenic modification; or
 - (ii) encodes:
 - (A) immunomodulatory molecules; or
 - (B) cytokines; or
 - (C) growth factors, or components of a signal transduction pathway, that, when expressed, may lead to cell proliferation;
- (e) a dealing involving, as host or vector, a micro-organism that has been implicated in, or has a history of causing, disease in humans, animals, plants or fungi, unless:
 - (i) the host/vector system is a system mentioned in Part 2 of Schedule 2; or
 - (ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; or
 - (iii) the dealing is a dealing mentioned in paragraph 2.1 (g) of Part 2 of this Schedule;
- (f) a dealing involving the introduction, into a micro-organism, of nucleic acid encoding a pathogenic determinant, unless:
 - (i) the dealing is a dealing mentioned in paragraph 2.1 (g) of Part 2 of this Schedule; or
 - (ii) the micro-organism is a host mentioned in Part 2 of Schedule 2;
- (g) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products have a heightened risk of inducing an autoimmune response;
- (h) a dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility in relation to any parent or donor organism;
- (i) a dealing involving a lentiviral vector unless:
 - (i) all structural and accessory genes have been removed from the vector to render it incapable of replication or assembly into a virion without these functions being supplied *in trans*; and
 - (ii) the vector includes a deletion that results in a transcriptionally inactive vector which, even when packaging functions are supplied *in trans*, cannot be converted into full length viral RNA; and
 - (iii) the packaging cell line and packaging plasmids used contain only viral genes *gag*, *pol*, *rev* and a gene encoding an envelope protein;

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- (j) a dealing involving a genetically modified animal, plant or fungus that is capable of secreting or producing infectious agents as a result of the genetic modification;
- (k) a dealing producing, in each vessel containing the resultant GMO culture, more than 10 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f) of Part 2 of this Schedule;
- (l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council;
- (m) a dealing involving the intentional introduction of a GMO into a human being;
- (n) a dealing involving a genetically modified pathogenic organism, if the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification.