



Gene Technology Regulations 2001

Statutory Rules 2001 No. 106 as amended

made under the

Gene Technology Act 2000

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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.

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 2243.3:2010 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.

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: (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: (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.
3A	A dealing with an animal whose somatic cells have been genetically modified <i>in vivo</i> by a replication defective viral vector, if: (a) the <i>in vivo</i> modification occurred as part of a previous dealing; and (b) the replication defective viral vector is no longer in the animal; and (c) no germ line cells have been genetically modified; and (d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and (e) the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.

Item	Description of dealing
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 25 litres of GMO culture in each vessel containing the resultant culture.</p> <p>(2) The donor nucleic acid:</p> <p>(a) must meet either of the following requirements:</p> <p>(i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy:</p> <p>(A) human beings; or</p> <p>(B) animals; or</p> <p>(C) plants; or</p> <p>(D) fungi;</p> <p>(ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm;</p> <p><i>Example</i></p> <p>Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it:</p> <p>(a) provides an advantage; or</p> <p>(b) adds a potential host species or mode of transmission; or</p> <p>(c) increases its virulence, pathogenicity or transmissibility; and</p> <p>(b) must not code for a toxin with an LD₅₀ of less than 100 µg/kg; and</p> <p>(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</p> <p>(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and</p> <p>(e) must not include a viral sequence, unless the donor nucleic acid:</p> <p>(i) is missing at least 1 gene essential for viral multiplication that:</p> <p>(A) is not available in the cell into which the nucleic acid is introduced; and</p> <p>(B) will not become available during the dealing; and</p> <p>(ii) cannot restore replication competence to the vector.</p>

Item	Description of dealing
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: <ol style="list-style-type: none"> (a) a pathogen; or (b) a toxin-producing organism.

Part 2 Host/vector systems for exempt dealsings

Item	Class	Host	Vector
1	Bacteria	<p><i>Escherichia coli</i> K12, <i>E. coli</i> B, <i>E. coli</i> C or <i>E. coli</i> Nissle 1917 — any derivative that does not contain:</p> <ol style="list-style-type: none"> (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid <p><i>Bacillus</i> — specified species — asporogenic strains with a reversion frequency of less than 10^{-7}:</p> <ol style="list-style-type: none"> (a) <i>B. amyloliquefaciens</i> (b) <i>B. licheniformis</i> (c) <i>B. pumilus</i> (d) <i>B. subtilis</i> (e) <i>B. thuringiensis</i> <p><i>Pseudomonas putida</i> — strain KT 2440</p>	<ol style="list-style-type: none"> 1. Non-conjugative plasmids 2. Bacteriophage <ol style="list-style-type: none"> (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3. None (non-vector systems) <ol style="list-style-type: none"> 1. Non-conjugative plasmids 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> 3. None (non-vector systems) <ol style="list-style-type: none"> 1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2. None (non-vector systems)

Item	Class	Host	Vector
		<i>Streptomyces</i> — specified species:	1. Non-conjugative plasmids
		(a) <i>S. aureofaciens</i>	2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives
		(b) <i>S. coelicolor</i>	
		(c) <i>S. cyaneus</i>	3. Actinophage phi C31 and derivatives
		(d) <i>S. griseus</i>	
		(e) <i>S. lividans</i>	4. None (non-vector systems)
		(f) <i>S. parvulus</i>	
		(g) <i>S. rimosus</i>	
		(h) <i>S. venezuelae</i>	
		<i>Agrobacterium radiobacter</i>	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors
		<i>Agrobacterium rhizogenes</i> — disarmed strains	
		<i>Agrobacterium tumefaciens</i> — disarmed strains	2. None (non-vector systems)
		<i>Lactobacillus</i>	1. Non-conjugative plasmids
		<i>Lactococcus lactis</i>	2. None (non-vector systems)
		<i>Oenococcus oeni</i> syn.	
		<i>Leuconostoc oeni</i>	
		<i>Pediococcus</i>	
		<i>Photobacterium angustum</i>	
		<i>Pseudoalteromonas tunicata</i>	
		<i>Rhizobium</i> (including the genus <i>Allorhizobium</i>)	
		<i>Sphingopyxis alaskensis</i> syn.	
		<i>Sphingomonas alaskensis</i>	
		<i>Streptococcus thermophilus</i>	
		<i>Synechococcus</i> — specified strains:	
		(a) PCC 7002	
		(b) PCC 7942	
		(c) WH 8102	
		<i>Synechocystis</i> species — strain PCC 6803	
		<i>Vibrio cholerae</i> CVD103-HgR	

Item	Class	Host	Vector
2	Fungi	<i>Kluyveromyces lactis</i> <i>Neurospora crassa</i> — laboratory strains <i>Pichia pastoris</i> <i>Saccharomyces cerevisiae</i> <i>Schizosaccharomyces pombe</i> <i>Trichoderma reesei</i> <i>Yarrowia lipolytica</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	Any of the following if they cannot spontaneously generate a whole animal: (a) animal or human cell cultures (including packaging cell lines); (b) isolated cells, isolated tissues or isolated organs, whether animal or human; (c) early non-human mammalian embryos cultured <i>in vitro</i> Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures; (b) isolated plant tissues or organs	1. Non-conjugative plasmids 2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells 3. Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems) 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 in which donor nucleic acid is or was introduced into a host cell:

- (a) in the absence of a nucleic acid-based vector; or
- (b) using a nucleic acid-based vector in the course of a previous dealing and the vector is:
 - (i) no longer present; or
 - (ii) present but cannot be remobilised from a host cell.

Example 1

A system mentioned in paragraph (a) might involve the use of electroporation or particle bombardment.

Example 2

A system mentioned in paragraph (b) might involve cells that were transduced with a replication defective retroviral vector in which no vector particles remain.

Schedule 3 Notifiable low risk dealings in relation to a GMO

(regulations 12 and 13)

Part 1 Notifiable low risk dealings suitable for at least physical containment level 1

<p><i>Note</i> 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.</p>
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1.1 Kinds of dealings suitable for at least physical containment level 1

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13 (2) (c) or 13 (3) (b) applies, in facilities certified to at least physical containment level 1 and that are appropriate for the dealings:

- (a) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit or a genetically modified laboratory rat, unless:
 - (i) an advantage is conferred on the animal by the genetic modification; or
 - (ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification;
- (c) a dealing involving a replication defective vector derived from *Human adenovirus* or *Adeno associated virus* in a host mentioned in item 4 of Part 2 of Schedule 2, if the donor nucleic acid:
 - (i) cannot restore replication competence to the vector; and
 - (ii) does not:
 - (A) confer an oncogenic modification in humans; or

- (B) encode a protein with immunomodulatory activity in humans.

Part 2 Notifiable low risk dealings suitable for at least physical containment level 2 or 3

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.

2.1 Kinds of dealings suitable for at least physical containment level 2

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13 (2) (c) or 13 (3) (b) applies, in facilities certified to at least physical containment level 2 and that are appropriate for the dealings:

- (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 guinea pig;
 - (B) a genetically modified laboratory mouse;
 - (C) a genetically modified laboratory rabbit;
 - (D) a genetically modified laboratory rat;
 - (E) a genetically modified *Caenorhabditis elegans*;
- (aa) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat or 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;

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- (b) a dealing involving a genetically modified plant;
 - (c) a dealing involving a host/vector system not mentioned in paragraph 1.1 (c) or Part 2 of Schedule 2, if neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:
 - (i) human beings; or
 - (ii) animals; or
 - (iii) plants; or
 - (iv) fungi;
 - (d) a dealing involving a host and vector not mentioned as a host/vector system in Part 2 of Schedule 2, if:
 - (i) the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy:
 - (A) human beings; or
 - (B) animals; or
 - (C) plants; or
 - (D) fungi; and
 - (ii) the donor nucleic acid is characterised; and
 - (iii) the characterisation of the donor nucleic acid shows that it is unlikely to increase the capacity of the host or vector to cause harm;

Example

Donor nucleic acid would not comply with subparagraph (iii) if, in relation to the capacity of the host or vector to cause harm, it:

- (a) provides an advantage; or
 - (b) adds a potential host species or mode of transmission; or
 - (c) increases its virulence, pathogenicity or transmissibility.
- (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 otherwise healthy:
 - (A) human beings; or
 - (B) animals; or
 - (C) plants; or

- (D) fungi;
- (f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 25 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 as a large scale facility; and
 - (ii) the donor nucleic acid satisfies the conditions set out in subitem 4 (2) of Part 1 of Schedule 2;
- (g) a dealing involving complementation of knocked-out genes, if the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out;

Example

A dealing would not comply with paragraph (g) if it involved complementation that, in relation to the parent organism:

- (a) provides an advantage; or
 - (b) adds a potential host species or mode of transmission; or
 - (c) increases its virulence, pathogenicity or transmissibility.
- (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 unable to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;
- (j) a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells, other than a dealing mentioned in paragraph 1.1 (c), into a host mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;

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- (k) a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if:
 - (i) the donor nucleic acid cannot restore replication competence to the vector; and
 - (ii) the donor nucleic acid does not:
 - (A) confer an oncogenic modification in humans; or
 - (B) encode a protein with immunomodulatory activity in humans;
 - (l) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2, if:
 - (i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied *in trans*; and
 - (ii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and
 - (iii) either:
 - (A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or
 - (B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;
 - (m) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if:
 - (i) the donor nucleic acid does not:
 - (A) confer an oncogenic modification in humans; or

- (B) encode a protein with immunomodulatory activity in humans; and
- (ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied *in trans*; and
- (iii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and
- (iv) either:
 - (A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or
 - (B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these.

2.2 Kinds of dealings suitable for at least physical containment level 3

Any kind of dealing mentioned in this Part involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 must be undertaken, unless paragraph 13 (2) (c) or (3) (b) applies, in facilities that are:

- (a) certified to at least physical containment level 3; and
- (b) appropriate for the dealing.

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 only be undertaken 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)) 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)) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;
- (d) a dealing involving the introduction of a replication defective viral vector into a host not mentioned in Part 2 of Schedule 2, other than a dealing mentioned in paragraph 2.1 (i), if the donor nucleic acid:
 - (i) confers an oncogenic modification in humans; or
 - (ii) encodes a protein with immunomodulatory activity in humans;
- (e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the donor nucleic acid:
 - (i) confers an oncogenic modification in humans; or
 - (ii) encodes a protein with immunomodulatory activity in humans;
- (f) a dealing involving, as host or vector, a micro-organism, if:
 - (i) the micro-organism has been implicated in, or has a history of causing, disease in otherwise healthy:

- (A) human beings; or
- (B) animals; or
- (C) plants; or
- (D) fungi; and

(ii) none of the following sub-subparagraphs apply:

- (A) the host/vector system is a system mentioned in Part 2 of Schedule 2;
- (B) the donor nucleic acid is characterised and its characterisation shows that it is unlikely to increase the capacity of the host or vector to cause harm;
- (C) the dealing is a dealing mentioned in paragraph 2.1 (g);

Example

Donor nucleic acid would not comply with sub-subparagraph (B) if, in relation to the capacity of the host or vector to cause harm, it:

- (a) provides an advantage; or
- (b) adds a potential host species or mode of transmission; or
- (c) increases its virulence, pathogenicity or transmissibility.

- (g) 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); or
 - (ii) the micro-organism is a host mentioned in Part 2 of Schedule 2;
- (h) 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 are likely to increase the capacity of the micro-organisms to induce an autoimmune response;
- (i) 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 an increased capacity to cause harm compared to the capacity of the parent or donor organism;

Example

A dealing would comply with paragraph (i) if it produces a novel replication competent virus that has a higher capacity to cause harm to any potential host species than the parent organism because the new virus has:

- (a) an advantage; or
 - (b) a new potential host species or mode of transmissibility; or
 - (c) increased virulence, pathogenicity or transmissibility.
- (j) a dealing, other than a dealing mentioned in paragraph 2.1 (l) or (m), with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells;
 - (k) 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;
 - (l) a dealing producing, in each vessel containing the resultant GMO culture, more than 25 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f);
 - (m) a dealing that is inconsistent with a policy principle issued by the Ministerial Council;
 - (n) a dealing involving the intentional introduction of a GMO into a human being, unless the GMO:
 - (i) is a human somatic cell; and
 - (ii) cannot secrete or produce infectious agents as a result of the genetic modification; and
 - (iii) if it was generated using viral vectors:
 - (A) has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells; and
 - (B) the testing did not detect a virus mentioned in sub-subparagraph (A); and
 - (C) the viral vector used to generate the GMO as part of a previous dealing is no longer present in the somatic cells;
 - (o) 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;

- (p) a dealing involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4.