Gene Technology Amendment Regulations 2011 (No. 1)[1]

Select Legislative Instrument 2011 No. 73

I, PROFESSOR MARIE BASHIR, AC, CVO, Administrator of the Government of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Gene Technology Act 2000*.

Dated 2 June 2011

MARIE BASHIR
Administrator

By Her Excellency's Command

CATHERINE KING
Parliamentary Secretary for Health and Ageing

Federal Register of Legislative Instruments F2011L00933

1 Name of Regulations

These Regulations are the *Gene Technology Amendment Regulations 2011 (No. 1)*.

2 Commencement

These Regulations commence on 1 September 2011.

3 Amendment of *Gene Technology Regulations 2001*

Schedule 1 amends the *Gene Technology Regulations 2001*.

4 Transitional

(1) The first purpose of this regulation is to provide the opportunity to apply for a licence to a person who was undertaking 1 of the following kinds of dealings before 1 September 2011 that now requires a licence:

(a) an exempt dealing;

(b) a notifiable low risk dealing.

(2) Subject to subregulation (3), despite the amendments made to Schedules 2 and 3 by these Regulations:

(a) a dealing that was an exempt dealing immediately before 1 September 2011 continues to be an exempt dealing under the Act if the dealing is undertaken by the same person; and

(b) a dealing that was a notifiable low risk dealing immediately before 1 September 2011 continues to be a notifiable low risk dealing under Division 2 of Part 6 of the Act if the dealing is undertaken by the same person.

(3) Subregulation (2) ceases to apply on the earlier of:

(a) the day on which a licence is issued to the person for the dealing; and

(b) 1 September 2012.

(4) The second purpose of this regulation is to provide the opportunity to a person who was undertaking a dealing before 1 September 2011, that was then an exempt dealing but that is now likely to be a notifiable low risk dealing, to have a proposal assessed by an Institutional Biosafety Committee as to whether the dealing is a notifiable low risk dealing.

(5) Subject to subregulation (6), despite the amendments made to Schedules 2 and 3 by these Regulations, a dealing mentioned in subregulation (4) that was an exempt dealing immediately before 1 September 2011 continues to be an exempt dealing under the Act if the dealing is undertaken by the same person.

(6) Subregulation (5) ceases to apply on the earlier of:

(a) the day on which an Institutional Biosafety Committee assesses the dealing; and

(b) 1 September 2012.

(7) In this regulation:

Act means the *Gene Technology Act 2000*.

exempt dealing has the meaning given by subsection 32 (3) of the Act.

licence means a licence under Part 5 of the Act.

notifiable low risk dealing means a dealing under Division 2 of Part 3 of the *Gene Technology Regulations 2001*.

Schedule 1 Amendments

(regulation 3)

[1] Regulation 3, after definition of *animal*

insert

AS/NZS 2243.3:2010 means the Australian/New Zealand Standard *Safety in laboratories Part 3: Microbiological safety and containment*, jointly published by Standards Australia and Standards New Zealand, as in force on 1 September 2011.

[2] Regulation 3, after definition of *expert adviser*

insert

genetically modified laboratory guinea pig means a laboratory strain of guinea pig of the species *Cavia porcellus* that has been modified by gene technology.

[3] Regulation 3, after definition of *genetically modified laboratory mouse*

insert

genetically modified laboratory rabbit means a laboratory strain of rabbit of the species *Oryctolagus cuniculus* that has been modified by gene technology.

[4] Regulation 3, after definition of *infectious agent*

insert

inspector means a person appointed by the Regulator under section 150 of the Act as an inspector.

[5] Regulation 3, definition of *oncogenic modification*

substitute

oncogenic modification means a genetic modification capable of contributing to tumour formation, including modifications that cause at least 1 of the following:

(a) defects in DNA proofreading and repair;

(b) defects in chromosome maintenance;

(c) defects in cell cycle checkpoint mechanisms;

(d) uncontrolled cell proliferation;

(e) resistance to apoptosis;

(f) cellular immortalisation.

[6] Regulation 5A

omit

making available inspectors appointed under section 150 of the Act

insert

making inspectors available

[7] Paragraph 6 (1) (d)

omit

environment; and

insert

environment.

[8] Paragraph 6 (1) (e)

omit

[9] Regulation 11A

substitute

11A Time limit for deciding variation application

(1) For subsection 71 (7) of the Act, the Regulator must vary the licence, or refuse to vary the licence, within 90 days after the day an application for a variation of the licence is received by the Regulator.

(2) For the period mentioned in subregulation (1), the following days are not counted:

(a) a Saturday, a Sunday or a public holiday in the Australian Capital Territory;

(b) a day on which the Regulator cannot proceed with the decision-making process, or a related function, because the Regulator is waiting for information that the applicant has been asked, in writing, to give.

[10] Paragraph 12 (1) (a)

substitute

(a) it is a dealing of a kind mentioned in Part 1 or 2 of Schedule 3 (other than a dealing also mentioned in Part 3 of Schedule 3); and

[11] Regulation 13

substitute

13 Requirements for undertaking notifiable low risk dealings

(1) A person may undertake a notifiable low risk dealing only if:

(a) a person or an accredited organisation has prepared and submitted a written proposal for an Institutional Biosafety Committee to assess whether the dealing is a notifiable low risk dealing; and

(b) the Institutional Biosafety Committee has assessed the dealing to be a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3; and

(c) the dealing undertaken is the dealing described in the Institutional Biosafety Committee's record of assessment of the proposal; and

(d) the dealing is only undertaken before the day mentioned in regulation 13A for the dealing; and

(e) the person is mentioned in the Institutional Biosafety Committee's record of assessment as having the appropriate training and experience to undertake the dealing; and

(f) the dealing is undertaken in facilities mentioned in the Institutional Biosafety Committee's record of assessment as being appropriate for the dealing; and

(g) the person keeps or can give, on request, a copy of the Institutional Biosafety Committee's record of assessment to an inspector; and

(h) the person does not compromise the containment of a GMO involved in the dealing; and

(i) the person undertakes the dealing in accordance with subregulations (2) and (3).

Note A person complies with paragraph (e) if the person is in a class of persons that an Institutional Biosafety Committee has included in the record of assessment as having the appropriate training and experience to undertake the dealing. Similarly, a person complies with paragraph (f) if the facility in which the person undertakes the dealing is in a class of facilities that an Institutional Biosafety Committee has included in the record of assessment as being appropriate for the dealing.

(2) A notifiable low risk dealing must be undertaken:

(a) for a kind of dealing mentioned in Part 1 of Schedule 3 — in a facility certified by the Regulator to at least physical containment level 1 and that is appropriate for the dealing; or

(b) for a kind of dealing mentioned in Part 2 of Schedule 3:

(i) that is not a dealing mentioned in subparagraph (ii) — in a facility certified by the Regulator to at least physical containment level 2 and that is appropriate for the dealing; or

(ii) that involves a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 — in a facility certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or

(c) in a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken.

(3) However, if a notifiable low risk dealing involves the transportation, storage or disposal of a GMO, the transportation, storage or disposal:

(a) may only be undertaken before the day mentioned in regulation 13A as being the day on or before which the dealing must stop being undertaken; and

(b) may happen outside a facility mentioned in subregulation (2), but in that case must be conducted in accordance with:

(i) the *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force on 1 September 2011, that have been issued by the Regulator for this purpose under paragraph 27 (d) of the Act; or

(ii) transportation, storage or disposal requirements that the Regulator has agreed in writing are appropriate for the containment of the GMO.

(4) For paragraph (2) (c), the Regulator must consider the capacity of a facility to contain GMOs before deciding whether to agree, in writing, to a facility.

[12] Regulation 13A

substitute

13A Time limits for stopping notifiable low risk dealings

For paragraph 13 (1) (d), the day on or before which the dealing described in the record of assessment of the dealing must stop being undertaken is:

(a) the day 5 years after the date of assessment, if the dealing is assessed by an Institutional Biosafety Committee on or after 1 September 2011; and

(b) 31 August 2016, if the dealing is assessed by an Institutional Biosafety Committee in the period 31 March 2008 to 31 August 2011 (inclusive); and

(c) 31 March 2015, if the dealing is assessed by an Institutional Biosafety Committee before 31 March 2008.

Note A person will have to apply for, and obtain, a new assessment of the dealing as a notifiable low risk dealing from an Institutional Biosafety Committee to continue to undertake the dealing after the applicable day mentioned in this regulation.

13B Requirements for Institutional Biosafety Committees about records of assessments of notifiable low risk dealing proposals

An Institutional Biosafety Committee that has assessed a proposal as to whether a dealing is a notifiable low risk dealing must:

(a) make a record of its assessment, in a form approved by the Regulator, that includes the following:

(i) the identifying name of the dealing to be undertaken that was given to the dealing by the person or accredited organisation proposing to undertake the dealing;

(ii) a description of the dealing to be undertaken;

(iii) its assessment whether the dealing is a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3;

(iv) if the Committee has assessed the dealing as being a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3, the kind of notifiable low risk dealing that the dealing is, in terms of those Parts;

(v) the date of the Committee's assessment of the dealing;

(vi) the persons or classes of persons considered by the Committee to have the appropriate training and experience to undertake the dealing;

(vii) the facilities or classes of facilities the Committee considers to be of the appropriate physical containment level and type for the dealing;

(viii) the name of the Committee that assessed the proposal;

(ix) the name of the person or accredited organisation that submitted the proposal;

(x) the name of the person or accredited organisation proposing to undertake the dealing; and

(b) give a copy of the record of assessment to the person or accredited organisation that submitted the proposal to the Committee.

13C Information to be kept or given to the Regulator by persons or accredited organisations

(1) A person or an accredited organisation that has been given a copy of a record of assessment by an Institutional Biosafety Committee must, if the dealing has been assessed by the Committee as a notifiable low risk dealing, give the Regulator a record of the proposed dealing, in the form approved by the Regulator, that includes:

(a) the particulars, prescribed under regulation 39 (1) in relation to the dealing, to be included in the Record of GMO and GM Product Dealings; and

(b) the name of the Committee that assessed the dealing; and

(c) the name of the person or accredited organisation that submitted the proposal for assessment of the dealing to the Committee.

(2) The record of the proposed dealing mentioned in subregulation (1) must be given to the Regulator in the financial year in which the Institutional Biosafety Committee made the assessment:

(a) by an accredited organisation — in the annual report for the financial year to be given by the organisation to the Regulator; or

(b) by any other person — in a report for the financial year to be given by the person to the Regulator, in the form approved by the Regulator.

(3) A person or accredited organisation given a copy of a record of assessment by an Institutional Biosafety Committee must keep a copy of the Committee's record of assessment for 8 years after the date of the assessment.

(4) The Regulator may at any time, by written notice, require from the following persons or organisations further information about how a notifiable low risk dealing is being undertaken, including information about a GMO being dealt with:

(a) the person or accredited organisation that submitted the proposal for assessment of the dealing;

(b) any other person involved with undertaking the dealing.

(5) A person or organisation given a notice under subregulation (4) must, by the end of the period mentioned in the notice, give the Regulator the information required by the notice.

[13] Paragraph 39 (1) (b)

after

Part 1

insert

or 2

[14] Paragraph 39 (1) (d)

substitute

(d) the date of assessment by an Institutional Biosafety Committee that the dealing is a notifiable low risk dealing.

[15] Schedule 1, item 7, subparagraph (b) (i)

omit

AS/NZS 2243.3:2002 (Safety in laboratories, Part 3: Microbiological aspects and containment facilities) jointly published by Standards Australia and Standards New Zealand

insert

AS/NZS 2243.3:2010

[16] Schedule 2, Part 1, after item 3

insert

3A A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if:

(a) the *in vivo* 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.

[17] Schedule 2, Part 1, subitem 4 (1)

omit

10

insert

25

[18] Schedule 2, Part 1, subitem 4 (2)

substitute

(2) The donor nucleic acid:

(a) must meet either of the following requirements:

(i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy:

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi;

(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;

Example

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:

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility; and

(b) must not code for a toxin with an LD_{50} of less than 100 μg/kg; and

(c) must not code for a toxin with an LD_{50} 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:

(i) is missing at least 1 gene essential for viral multiplication that:

(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) cannot restore replication competence to the vector.

[19] Schedule 2, Part 2

substitute

Part 2 Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	*Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917 — any derivative that does not contain: (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1. Non-conjugative plasmids 2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3. None (non-vector systems)
		Bacillus — specified species — asporogenic strains with a reversion frequency of less than 10^{-7}: (a) *B. amyloliquefaciens* (b) *B. licheniformis* (c) *B. pumilus* (d) *B. subtilis* (e) *B. thuringiensis*	1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus* 3. None (non-vector systems)

Item	Class	Host	Vector
		Pseudomonas putida — strain KT 2440	1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2. None (non-vector systems)
		Streptomyces — specified species: (a) *S. aureofaciens* (b) *S. coelicolor* (c) *S. cyaneus* (d) *S. griseus* (e) *S. lividans* (f) *S. parvulus* (g) *S. rimosus* (h) *S. venezuelae*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. None (non-vector systems)
		Agrobacterium radiobacter *Agrobacterium rhizogenes* — disarmed strains *Agrobacterium tumefaciens* — disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. None (non-vector systems)
		Lactobacillus *Lactococcus lactis* *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicata* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Streptococcus thermophilus*	1. Non-conjugative plasmids 2. None (non-vector systems)

Item	Class	Host	Vector
		Synechococcus — specified strains: (a) PCC 7002 (b) PCC 7942 (c) WH 8102 *Synechocystis* species — strain PCC 6803 *Vibrio cholerae* CVD103-HgR	
2	Fungi	*Kluyveromyces lactis* *Neurospora crassa* — laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei* *Yarrowia lipolytica*	1. All vectors 2. None (non-vector systems)
3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* 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 *in vitro*	1. Non-conjugative plasmids 2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells 3. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems)

Item	Class	Host	Vector
		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-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens*, *Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. None (non-vector systems)

[20] Schedule 2, Part 3, definition of *non-vector system*

substitute

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.

[21] Schedule 3

substitute

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

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.

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;

(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;

(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 LD_{50} of less than 100 μg/kg;

(b) a dealing involving high level expression of toxin genes, even if the LD_{50} 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;

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(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.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au.