EXPOSURE DRAFT

Gene Technology Amendment (2017 Measures No. 1) Regulations 2017

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 2017

Peter Cosgrove
Governor-General

By His Excellency's Command

Dr David Gillespie **[DRAFT ONLY—NOT FOR SIGNATURE]**
Assistant Minister for Health
Parliamentary Secretary to the Minister for Health

Contents

EXPOSURE DRAFT

1 Name

This instrument is the *Gene Technology Amendment (2017 Measures No. 1) Regulations 2017*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after the end of the period of 6 months beginning on the day this instrument is registered.	
2. Schedule 1	The day after the end of the period of 6 months beginning on the day this instrument is registered.	
3. Schedule 2	The day after the end of the period of 18 months beginning on the day this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Gene Technology Act 2000*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments commencing 6 months after registration

Gene Technology Regulations 2001

1 Regulation 3 (definition of *characterised*)

Repeal the definition, substitute:

characterised means:

(a) in relation to a nucleic acid—the nucleic acid has been sequenced and there is an understanding of potential gene products or potential functions of the nucleic acid; or

(b) in relation to a genetic modification—the gene or genomic region which is modified has been sequenced and there is an understanding of:

(i) potential gene products or potential functions of the gene or genomic region; and

(ii) the likely effect of the genetic modification on the gene products or functions.

2 Regulation 3

Insert:

host/vector system has a meaning affected by subclause 2.1(3) of Schedule 2.

3 Regulation 3 (definition of *non-vector system*)

Repeal the definition, substitute:

non-vector system has the meaning given in Part 3 of Schedule 2.

4 Regulation 3 (definition of *toxin-producing organism*)

Omit "100 μg/kg", substitute "100 micrograms per kilogram".

5 Regulation 3 (note)

Omit "• GM product".

6 Regulation 4

Omit "section 10", substitute "subsection 10(1)".

7 After regulation 4

Insert:

4A Organisms that are genetically modified organisms

For the purposes of paragraph (c) of the definition of ***genetically modified organism*** in subsection 10(1) of the Act, an organism mentioned in Schedule 1B is a genetically modified organism.

8 Regulation 5

Omit "section 10", substitute "subsection 10(1)".

9 Paragraph 9(f)

Repeal the paragraph, substitute:

(f) that part of the Department known as the Therapeutic Goods Administration.

10 Paragraph 12(1)(a)

Repeal the paragraph, substitute:

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

(aa) it is not a dealing of a kind mentioned in Part 3 of Schedule 3; and

11 Paragraph 13(1)(b)

Repeal the paragraph, substitute:

(b) the Institutional Biosafety Committee has assessed the dealing to be a kind of dealing mentioned in Part 1 or 2 of Schedule 3, and not mentioned in Part 3 of Schedule 3; and

12 Paragraph 13(1)(d)

Repeal the paragraph, substitute:

(d) the dealing is only undertaken no later than the day 5 years after the date of the assessment; and

13 Paragraph 13(1)(e)

After "is mentioned in", insert ", or is in a class of persons mentioned in,".

14 Paragraph 13(1)(f)

Repeal the paragraph, substitute:

(f) subject to subregulation (3), the dealing is undertaken in facilities that:

(i) are mentioned in, or are in a class of facilities mentioned in, the Institutional Biosafety Committee's record of assessment as being appropriate for the dealing; and

(ii) are facilities in which subregulation (2) permits the dealing to be undertaken; and

15 Paragraph 13(1)(h)

Omit "dealing; and", substitute "dealing.".

16 Paragraph 13(1)(i)

Repeal the paragraph.

17 Subregulation 13(1) (note)

Repeal the note.

18 Subregulation 13(3)

Repeal the subregulation, substitute:

(3) If a notifiable low risk dealing involves the transportation, storage or disposal of a GMO, the transportation, storage or disposal may happen outside a facility that complies with paragraph (1)(f) and subregulation (2), if it is conducted in accordance with:

(a) the *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force from time to time, that have been issued by the Regulator under paragraph 27(d) of the Act; or

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

(3A) For the purposes of subparagraph (2)(b)(ii), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent micro-organism satisfies those criteria.

19 Regulation 13A

Repeal the regulation.

20 Subparagraph 13B(a)(i)

Omit "proposing to undertake the dealing", substitute "that submitted the proposal".

21 Subparagraphs 13B(a)(iii) and (iv)

Repeal the subparagraphs, substitute:

(iii) its assessment whether the dealing is a kind of dealing mentioned in Part 1 or 2 of Schedule 3, and not mentioned in Part 3 of Schedule 3;

(iv) if the Committee has assessed the dealing as being a kind of dealing mentioned in Part 1 or 2 of Schedule 3 (and not mentioned in Part 3 of Schedule 3)—which kind of dealing in those Parts that the dealing is;

22 Subparagraph 13B(a)(vii)

After "dealing", insert ", having regard to the requirements of subregulation 13(2)".

23 Subparagraph 13B(a)(x)

Omit "the name of the person or accredited organisation", substitute "the person or persons".

24 Subregulations 13C(1) and (2)

Repeal the subregulations, substitute:

(1) A person or accredited organisation that has been given a copy of a record of assessment by an Institutional Biosafety Committee under paragraph 13B(b) must, if the dealing has been assessed by the Committee as a notifiable low risk dealing:

(a) for an accredited organisation that is required, as a condition of accreditation, to give an annual report to the Regulator—include a record of the dealing in the organisation's annual report for the year in which the Institutional Biosafety Committee made the assessment; and

(b) in any other case—give to the Regulator collated records of all such dealings assessed in a single financial year.

(2) A record of a dealing for the purposes of subregulation (1) must include:

(a) the particulars, prescribed under regulation 39 in relation to the dealing, to be included in the Record of GMO 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 dealing to the Committee for assessment.

(2A) For the purposes of paragraph (1)(b), the collated records must be given to the Regulator:

(a) in a form approved by the Regulator; and

(b) as soon as practicable after the end of the financial year and no later than 30 September in the following financial year.

25 Subregulation 13C(3)

After "Institutional Biosafety Committee", insert "under paragraph 13B(b)".

26 Subregulation 21(2) (note)

Omit all the words after "section 27B of that Act".

27 Paragraph 26(1)(b)

Omit "to whom paragraph 100(7A)(a) or (b) of the Act applies", substitute "who is also a member of the Ethics and Community Committee".

28 Paragraph 32(c)

Repeal the paragraph, substitute:

(c) the reference in paragraph 26(1)(b) to the Ethics and Community Committee were a reference to the Gene Technology Technical Advisory Committee or the Australian Health Ethics Committee; and

29 Regulation 39

Repeal the regulation, substitute:

39 Record of GMO Dealings

For the purposes of subsection 138(4) of the Act, the following particulars are prescribed in relation to a notifiable low risk dealing that is notified to the Regulator:

(a) the person or persons that proposed to undertake the dealing, as recorded by the Institutional Biosafety Committee that assessed the dealing as a notifiable low risk dealing;

(b) the kind of notifiable low risk dealing, in terms of Part 1 or 2 of Schedule 3;

(c) the identifying name given to the dealing by the person or accredited organisation that submitted the dealing to the Institutional Biosafety Committee for assessment;

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

30 Schedule 1A (at the end of the table)

Add:

11	Introduction of RNA into an organism, if: (a) the RNA cannot be translated into a polypeptide; and (b) the introduction of the RNA cannot result in an alteration of the organism's genome sequence; and

(c) the introduction of the RNA cannot give rise to an infectious agent.

31 After Schedule 1A

Insert:

Schedule 1B—Organisms that are genetically modified organisms

Note: See regulation 4A.

1.1 Genetically modified organisms

For the purposes of regulation 4A, organisms mentioned in the following table are genetically modified organisms.

Organisms that are genetically modified organisms

Item	Description of organism
1	An organism that has had its genome modified by oligonucleotide-directed mutagenesis
2	An organism modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was added to guide homology-directed repair

32 Schedule 1 (after table item 3)

Insert:

4	An organism modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was not added to guide homology-directed repair.

33 Schedule 1 (at the end of the table)

Add:

8	An organism that is descended from a genetically modified organism (the ***initial organism***), but which has not inherited any traits that occurred in the initial organism because of gene technology.
9	An organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present.
10	*Agrobacterium radiobacter* strain K1026 (known as NoGall).
11	*Pasteurella multocida* strain PMP1 (known as Vaxsafe PM).

34 Part 1 of Schedule 2 (table item 4, column headed "Description of dealing", subparagraph (2)(a)(ii))

Omit "harm;", substitute "harm; and".

35 Part 1 of Schedule 2 (table item 4, column headed "Description of dealing", example)

Omit "transmissibility; and", substitute "transmissibility.".

36 Part 1 of Schedule 2 (table item 4, column headed "Description of dealing", paragraphs (2)(b) and (c))

Omit "100 μg/kg", substitute "100 micrograms per kilogram".

37 Part 1 of Schedule 2 (table item 4, column headed "Description of dealing", subparagraph (2)(e)(i))

Repeal the subparagraph, substitute:

(i) cannot give rise to virions or infections agents when introduced into a host as part of the dealing, without additional genes or gene products that are not available in the host cell and that will not become available during the dealing; and

38 Part 1 of Schedule 2 (table item 5, column headed "Description of dealing")

Omit "item 1 of", substitute "items 1 to 6 of the table in".

39 Part 2 of Schedule 2

Repeal the Part, substitute:

Part 2—Host/vector systems for exempt dealings

2.1 Hosts and vectors

(1) A reference to a host mentioned in this Part is a reference to a host mentioned in column 2 of an item of the table in this clause.

(2) A reference to a vector mentioned in this Part is a reference to a vector mentioned in column 3 of an item of the table in this clause.

(3) A reference to a ***host/vector system*** mentioned in this Part is a reference to any of the following:

(a) a system involving a host mentioned in column 2 of an item of the table in this clause and a vector mentioned in column 3 of the same item;

(b) a non-vector system involving a host mentioned in column 2 of an item of the table;

(c) a system involving a GMO mentioned as a vector in column 3 of an item of the table (except item 7), without a host.

Note: Column 1 of the table is included for information only.

Hosts and vectors

	Column 1	Column 2	Column 3
Item	**Host class**	**Hosts**	**Vectors**
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	Any of the following: (a) non-conjugative plasmids; (b) lambda bacteriophage; (c) lambdoid bacteriophage; (d) Fd, F1 or M13 bacteriophage

Schedule 1 Amendments commencing 6 months after registration

Hosts and vectors

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
		non-conjugative plasmid	
2	Bacteria	*Bacillus*—asporogenic strains of the following species with a reversion frequency of less than 10^{-7}: (a) *B. amyloliquefaciens*; (b) *B. licheniformis*; (c) *B. pumilus*; (d) *B. subtilis*; (e) *B. thuringiensis*	Any of the following: (a) non-conjugative plasmids; (b) other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus*
3	Bacteria	*Pseudomonas putida* strain KT2440	Non-conjugative plasmids
4	Bacteria	The following *Streptomyces* 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*	Any of the following: (a) non-conjugative plasmids; (b) plasmids SCP2, SLP1, SLP2, pIJ101 and derivatives; (c) actinophage phi C31 and derivatives
5	Bacteria	Any of the following: (a) *Agrobacterium radiobacter*; (b) *Agrobacterium rhizogenes* (disarmed strains only); (c) *Agrobacterium tumefaciens* (disarmed strains only)	Ri plasmids or non-tumorigenic disarmed Ti plasmids
6	Bacteria	Any of the following: (a) *Allorhizobium* species; (b) *Corynebacterium glutamicum*; (c) *Lactobacillus* species; (d) *Lactococcus lactis*; (e) *Oenococcus oeni* syn. *Leuconostoc oeni*; (f) *Pediococcus* species; (g) *Photobacterium angustum*; (h) *Pseudoalteromonas tunicata*; (i) *Rhizobium* species; (j) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis*; (k) *Streptococcus thermophilus*; (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102; (m) *Synechocystis* species strain PCC 6803;	Non-conjugative plasmids

Hosts and vectors			
	Column 1	**Column 2**	**Column 3**
Item	**Host class**	**Hosts**	**Vectors**
		(n) *Vibrio cholerae* CVD103-HgR; (o) *Zymomonas mobilis*	
7	Fungi	Any of the following: (a) *Kluyveromyces lactis*; (b) *Neurospora crassa* (laboratory strains); (c) *Pichia pastoris*; (d) *Saccharomyces cerevisiae*; (e) *Schizosaccharomyces pombe*; (f) *Trichoderma reesei*; (g) *Yarrowia lipolytica*	All vectors
8	Slime moulds	*Dictyostelium* species	*Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
9	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*	Any of the following: (a) plasmids; (b) replication defective viral vectors unable to transduce human cells; (c) polyhedrin minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV)
10	Tissue culture	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	Any of the following: (a) Ri plasmids, or non-tumorigenic disarmed Ti plasmids, in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes* (disarmed strains only) or *Agrobacterium tumefaciens* (disarmed strains only); (b) non-pathogenic viral vectors

40 Clause 1.1 of Schedule 3

Omit "13(3)(b)", substitute "subregulation 13(3)".

41 Paragraph 1.1(c) of Schedule 3

Repeal the paragraph, substitute:

(c) a dealing involving virions of a replication defective vector derived from *Human adenovirus* or from *Adeno-associated virus*, either without a host or with a host mentioned in item 9 of Part 2 of Schedule 2, if the donor nucleic acid:

(i) cannot restore replication competence to the vector; and

(ii) does not confer an oncogenic modification or immunomodulatory effect in humans.

42 Clause 2.1 of Schedule 3

Omit "13(3)(b)", substitute "subregulation 13(3)".

43 Paragraph 2.1(d) of Schedule 3

Omit "host and vector not mentioned as a host/vector system", substitute "host/vector system not mentioned".

44 Subparagraphs 2.1(d)(ii) and (iii) of Schedule 3

Omit "donor nucleic acid", substitute "genetic modification".

45 Paragraph 2.1(d) of Schedule 3 (example)

Omit "Donor nucleic acid", substitute "A genetic modification".

46 Subparagraph 2.1(e)(i) of Schedule 3

Repeal the subparagraph, substitute:

(i) is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; or

47 Paragraph 2.1(h) of Schedule 3

Omit "item 1 of", substitute "items 1 to 6 of the table in".

48 Paragraph 2.1(i) of Schedule 3

Omit "the introduction", substitute "virions".

49 Paragraph 2.1(i) of Schedule 3

Omit "into", substitute "and".

50 Paragraph 2.1(j) of Schedule 3

Repeal the paragraph, substitute:

(j) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid cannot restore replication competence to the vector; and

(ii) the dealing is not a dealing mentioned in paragraph 1.1(c);

51 Paragraph 2.1(k) of Schedule 3

Omit "the introduction", substitute "virions".

52 Paragraph 2.1(k) of Schedule 3

Omit "into", substitute "and".

53 Subparagraph 2.1(k)(ii) of Schedule 3

Repeal the subparagraph, substitute:

(ii) the donor nucleic acid does not confer an oncogenic modification or immunomodulatory effect in humans;

54 Paragraph 2.1(l) of Schedule 3

Omit all the words before subparagraph (i), substitute:

(l) a dealing involving virions of a replication defective retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

55 Subparagraph 2.1(l)(i) of Schedule 3

Omit "into a virion", substitute "new virions".

56 Paragraph 2.1(m) of Schedule 3

Omit "the introduction", substitute "virions".

57 Paragraph 2.1(m) of Schedule 3

Omit "into a host", substitute "and a host".

58 Subparagraph 2.1(m)(i) of Schedule 3

Repeal the subparagraph, substitute:

(i) the donor nucleic acids does not confer an oncogenic modification or immunomodulatory effect in humans; and

59 Subparagraph 2.1(m)(ii) of Schedule 3

Omit "into a virion", substitute "new virions".

60 Clause 2.2 of Schedule 3

Before "Any", insert "(1)".

61 Clause 2.2 of Schedule 3

Omit "(3)(b)", substitute "subregulation 13(3)".

62 At the end of clause 2.2 of Schedule 3

Add:

(2) For the purposes of subclause (1), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent micro-organism satisfies those criteria.

63 Clause 3.1 of Schedule 3

Before "A dealing", insert "(1)".

64 Paragraphs 3.1(a) and (b) of Schedule 3

Omit "100 μg/kg", substitute "100 micrograms per kilogram".

65 Paragraph 3.1(d) of Schedule 3

Repeal the paragraph, substitute:

(d) a dealing involving virions of a replication defective viral vector and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid confers an oncogenic modification or immunomodulatory effect in humans; and

(ii) the dealing is not a dealing mentioned in paragraph 2.1(i);

66 Paragraph 3.1(e) of Schedule 3

Omit all the words after "if the", substitute "genetic modification confers an oncogenic modification or immunomodulatory effect in humans;".

67 Sub-subparagraph 3.1(f)(ii)(B) of Schedule 3

Omit "donor nucleic acid", substitute "genetic modification".

68 Subparagraph 3.1(f)(ii) of Schedule 3 (example)

Omit "Donor nucleic acid", substitute "A genetic modification".

69 At the end of clause 3.1 of Schedule 3

Add:

; (q) a dealing involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 and that is not undertaken:

(i) in a facility that is certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or

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

(r) a dealing involving a GMO capable of sexual reproduction, the sexual progeny of which are, as a result of the genetic modification, more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism);

(s) a dealing involving a viral vector that can modify an organism capable of sexual reproduction, so that the sexual progeny of the organism are more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism).

Note: A modification that increases the likelihood of inheritance of a nucleotide sequence or sequences, as described in paragraphs (r) and (s), is generally known as an engineered gene drive.

(2) For the purposes of paragraph (1)(p), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4 if the unmodified parent micro-organism satisfies those criteria.

(3) For the purposes of paragraph (1)(q), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent micro-organism satisfies those criteria.

Schedule 2—Amendments commencing 18 months after registration

Gene Technology Regulations 2001

1 Schedule 1 (table item 1)

Repeal the item.