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South Australia

Gene Technology Variation Regulations 2019

under the *Gene Technology Act 2001*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Gene Technology Variation Regulations 2019*.

2—Commencement

(1) Subject to this regulation, these regulations come into operation on 8 October 2019.

(2) Part 3 of these regulations come into operation on 1 July 2020.

(3) Part 4 of these regulations come into operation on 8 October 2020.

3—Variation provisions

In these regulations, a provision under a heading referring to the variation of specified regulations varies the regulations so specified.

Part 2—Variation of *Gene Technology Regulations 2017* (commencing on 8 October 2019)

4—Variation of regulation 3—Definitions

(1) Regulation 3, definition of ***characterised***—delete the definition and 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—after definition of ***genetically modified laboratory rat*** insert:

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

(3) Regulation 3, definition of ***non-vector system***—delete the definition and substitute:

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

(4) Regulation 3, definition of ***toxin-producing organism***—delete "µg/kg" and substitute:

micrograms per kilogram

(5) Regulation 3, note, dot point 7—delete dot point 7

5—Revocation of regulation 3B

Regulation 3B—delete the regulation

6—Variation of regulation 4—Techniques not consisting gene technology

Regulation 4—delete "section 10" and substitute:

subsection 10(1)

7—Insertion of regulation 4A

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 is a genetically modified organism if an item in Schedule 1B applies to the organism.

8—Substitution of regulation 5

Regulation 5—delete the regulation and substitute:

5—Organisms that are not genetically modified organisms

For the purposes of paragraph (e) of the definition of ***genetically modified organism*** in subsection 10(1) of the Act, an organism is not a genetically modified organism if—

(a) one or more items in Schedule 1 applies to the organism; and

(b) the organism has not been modified by gene technology except for any modifications described in those items; and

(c) the organism has not inherited any traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology, except as described in item 9 in Schedule 1; and

(d) none of the items in Schedule 1B applies to the organism.

9—Variation of regulation 9—Prescribed authorities

Regulation 9(f)—delete paragraph (f) and substitute:

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

10—Variation of regulation 11A—Time limit for deciding variation application

Regulation 11A(2)(b)—delete ", will not be counted"

11—Variation of regulation 12—Notifiable low risk dealings

Regulation 12(1)(a)—delete paragraph (a) and 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

12—Variation of regulation 13—Requirements for undertaking notifiable low risk dealings

(1) Regulation 13(1)(d)—delete paragraph (d) and substitute:

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

(2) Regulation 13(1)(e)—after "in" insert:

, or is in a class of persons mentioned in,

(3) Regulation 13(1)(f)—delete paragraph (f) and substitute:

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

(a) 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

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

(4) Regulation 13(1)(h)—delete "dealing; and" and substitute:

dealing.

(5) Regulation 13(1)(i)—delete paragraph (i)

(6) Regulation 13(1), note—delete the note

(7) Regulation 13(2)(b)—delete paragraph (b) and substitute:

(b) for a kind of dealing mentioned in clause 2.1 of Schedule 3 (but not clause 2.2)—in a facility certified by the Regulator to at least physical containment level 2 and that is appropriate for the dealing; or

(ba) for a kind of dealing mentioned in clause 2.2 of Schedule 3—in a facility certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or

(8) Regulation 13(3)—delete subregulation (3) and 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.

13—Revocation of regulation 13A

Regulation 13A—delete the regulation

14—Insertion of Part 8

After Part 7 insert:

Part 8—Application and transitional provisions

Division 1—Amendments made by the *Gene Technology Variation Regulations 2019*

41—Changed requirements for dealings

Former exempt dealings

(1) If—

(a) a person was undertaking a dealing before the amending day; and

(b) the dealing was an exempt dealing under the old regulations; and

(c) the dealing is not (apart from this provision) an exempt dealing under the new regulations,

then, despite the amendments, the dealing is an exempt dealing when undertaken by the person.

(2) Subregulation (1) applies until—

(a) the dealing is assessed, under the new regulations, as a notifiable low risk dealing by an Institutional Biosafety Committee; or

(b) the person is issued a GMO licence for the dealing; or

(c) 1 year after the amending day if neither of the events in paragraphs (a) and (b) occurs before then.

Former notifiable low risk dealings

(3) If—

(a) a person was undertaking a dealing before the amending day; and

(b) the dealing was a notifiable low risk dealing under the old regulations; and

(c) the dealing—

(i) is not (apart from this provision) a notifiable low risk dealing under the new regulations; and

(ii) is not an exempt dealing,

then, despite the amendments, the dealing is a notifiable low risk dealing when undertaken by the person.

(4) Subregulation (3) applies until—

(a) the person is issued a GMO licence for the dealing; or

(b) 1 year after the amending day if the person is not issued a GMO licence before then.

Changed requirements for notifiable low risk dealings

(5) If a person was undertaking a notifiable low risk dealing before the amending day, the dealing is, for the purposes of section 37 of the Act, undertaken in accordance with the regulations if—

(a) it is undertaken in accordance with the old regulations; or

(b) it is undertaken in accordance with the new regulations.

(6) Subregulation (5) ceases to be in force 1 year after the amending day.

Definitions

(7) In this regulation—

amending day means the day that Part 2 of the amending regulations commences;

amending regulations means the *Gene Technology Variation Regulations 2019*;

new regulations means these regulations as amended by the amending regulations;

old regulations means these regulations as in force immediately before the amending day.

15—Variation of Schedule 1A—Techniques that are not gene technology

Schedule 1A, Table of Particulars—delete the table and substitute:

Item	Description of technique
1	Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
2	Electromagnetic radiation-induced mutagenesis.

Item	Description of technique
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	*In vitro* 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.
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.

16—Insertion of Schedule 1B

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, an organism is a genetically modified organism if an item in the following table applies to the organism.

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.

17—Variation of Schedule 1—Organisms that are not genetically modified organisms

Schedule 1, Table of Particulars—delete the table and substitute:

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.
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.
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.
8	An organism that is descended from a genetically modified organism (the ***initial organism***), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology.
9	An organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology, if— (a) the initial organism was not a genetically modified organism (because of the application of regulation 5); or (b) all such inherited traits are traits that occurred in the initial organism as a result of a modification described in an item in this Schedule.
10	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.
11	*Agrobacterium radiobacter* strain K1026.
12	*Pasteurella multocida* strain PMP1.

18—Variation of Schedule 2—Dealings exempt from licensing

Schedule 2, Parts 1 and 2—delete the parts and substitute:

Part 1—Exempt dealings

Item		Description of dealing
2		A dealing with a genetically modified *Caenorhabditis elegans*, unless— (a) an advantage 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 *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.
4	(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.
	(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;

Item	Description of dealing

(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; and

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.

(b) must not code for a toxin with an LD_{50} of less than 100 micrograms per kilogram; and

(c) must not code for a toxin with an LD_{50} of 100 micrograms per kilogram 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) if the donor nucleic acid includes a viral sequence—cannot give rise to infectious agents when introduced into any potential host species, without additional non-host genes or gene products that—

(i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and

(ii) will not become available during the dealing; and

(f) if the donor nucleic acid includes a viral sequence—cannot restore replication competence to the vector.

5 A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in Part 2 of this Schedule, if the donor nucleic acid is not derived from either—

(a) a pathogen; or

(b) a toxin-producing organism.

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.

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

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
3	Bacteria	*Pseudomonas putida* strain KT 2440.	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).	Disarmed Ri or 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*;	Non-conjugative plasmids.

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
		(k) *Streptococcus thermophilus*; (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102; (m) *Synechocystis* species strain PCC 6803; (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).

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
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) Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes* (disarmed strains only) or *Agrobacterium tumefaciens* (disarmed strains only); (b) non-pathogenic viral vectors.

19—Variation of Schedule 3—Notifiable low risk dealings in relation to a GMO

(1) Schedule 3, Part 1, clause 1.1—delete "13(3)(b)" and substitute:

13(3)

(2) Schedule 3, Part 1, clauses 1.1(c)—delete paragraph (c) and 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—

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

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

(3) Schedule 3, Part 2, clause 2.1—delete "13(3)(b)" and substitute:

13(3)

(4) Schedule 3, Part 2, clause 2.1(d)—delete "host and vector not mentioned as a host/vector system" and substitute:

host/vector system not mentioned

(5) Schedule 3, Part 2, clause 2.1(d)(ii)—delete "donor nucleic acid" and substitute:

genetic modification

(6) Schedule 3, Part 2, clause 2.1(d)(iii)—delete "donor nucleic acid" and substitute:

genetic modification

(7) Schedule 3, Part 2, clause 2.1(d)(iii), example—delete "Donor nucleic acid" and substitute:

A genetic modification

(8) Schedule 3, Part 2, clause 2.1(e)(i)—delete subparagraph (i) and substitute:

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

(9) Schedule 3, Part 2, clause 2.1(h)—delete "item 1 of" and substitute:

items 1 to 6 of the table in

(10) Schedule 3, Part 2, clause 2.1(i)—delete "the introduction" and substitute:

virions

(11) Schedule 3, Part 2, clause 2.1(i)—delete "into" and substitute:

and

(12) Schedule 3, Part 2, clause 2.1(j)—delete paragraph (j) and 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—

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

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

(13) Schedule 3, Part 2, clause 2.1(k)—delete "the introduction" and substitute:

virions

(14) Schedule 3, Part 2, clause 2.1(k)—delete "into" and substitute:

and

(15) Schedule 3, Part 2, clause 2.1(k)(ii)—delete subparagraph (ii) and substitute:

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

(16) Schedule 3, Part 2, clause 2.1(l)—delete "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" and substitute:

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

(17) Schedule 3, Part 2, clause 2.1(l)(i)—delete "into a virion" and substitute:

new virions

(18) Schedule 3, Part 2, clause 2.1(m)—delete "the introduction" and substitute:

virions

(19) Schedule 3, Part 2, clause 2.1(m)—delete "into" and substitute:

and

(20) Schedule 3, Part 2, clause 2.1(m)(i)—delete subparagraph (i) and substitute:

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

(21) Schedule 3, Part 2, clause 2.1(m)(ii)—delete "into a virion" and substitute:

new virions

(22) Schedule 3, Part 2, clause 2.2—delete clause 2.2 and substitute:

2.2—Kinds of dealing suitable for at least physical containment level 3

(1) A kind of dealing that—

(a) is a kind mentioned in clause 2.1; and

(b) involves 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 subregulation 13(3) applies, in facilities certified to at least physical containment level 3 and that are appropriate for the dealings.

(2) For the purposes of paragraph (1)(b), 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.

(3) However, subclause (2) does not apply in relation to a replication defective retroviral vector that meets the criteria in paragraph 2.1(l) or (m).

(23) Schedule 3, Part 3, heading, note 2—delete note 2 and substitute:

Note 2—

If a dealing is not a notifiable low risk dealing, or an exempt dealing, as provided by these Regulations, a person undertaking the dealing must be authorised by a GMO licence unless the dealing is within one of the other exceptions to licensing provided by the Act: see section 32 of the Act.

(24) Schedule 3, Part 3, clause 3.1(a)—delete "µg/kg" and substitute:

micrograms per kilogram

(25) Schedule 3, Part 3, clause 3.1(b)—delete "µg/kg" and substitute:

micrograms per kilogram

(26) Schedule 3, Part 3, clause 3.1(d) and (e)—delete paragraphs (d) and (e) and 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);

(e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the genetic modification confers an oncogenic modification or immunomodulatory effect in humans;

(27) Schedule 3, Part 3, clause 3.1(f)(ii)(B)—delete "donor nucleic acid" and substitute:

genetic modification

(28) Schedule 3, Part 3, clause 3.1(f)(ii), example—delete "Donor nucleic acid" and substitute:

A genetic modification

(29) Schedule 3, Part 3, clause 3.1—after paragraph (p) insert:

(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.

(30) Schedule 3, Part 3, clause 3.1—after its present contents (now to be designated subclause (1)) insert:

(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.

(4) However, subclause (3) does not apply in relation to a replication defective retroviral vector that meets the criteria in paragraph 2.1(l) or (m).

Part 3—Variation of *Gene Technology Regulations 2017* (commencing on 1 July 2020)

20—Variation of regulation 13—Requirements for undertaking notifiable low risk dealings

Regulation 13(1)(b)—delete paragraph (b) and 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

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

(1) Regulation 13B(a)(i)—delete "proposing to undertake the dealing" and substitute:

that submitted the proposal

(2) Regulation 13B(a)(iii) and (iv)—delete subparagraphs (iii) and (iv) and 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;

(3) Regulation 13B(a)(vii)—after "dealing" insert:

, having regard to the requirements of subregulation 13(2)

(4) Regulation 13B(a)(x)—delete "the name of the person or accredited organisation" and substitute:

the person or persons

22—Variation of regulation 13C—Information to be kept or given to the Regulator by persons or accredited organisations

(1) Regulation 13C(1) and (2)—delete subregulations (1) and (2) and 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, give the Regulator a record of the dealing.

(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 proposal relating to the dealing; and

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

(2A) The record must be given to the Regulator—

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

(b) no later than 30 September in the financial year following the one in which the Institutional Biosafety Committee made the assessment.

(2B) An accredited organisation that is required, as a condition of accreditation, to give an annual report to the Regulator, must—

(a) include the record in the annual report for the year in which the Institutional Biosafety Committee made the assessment; or

(b) certify in the annual report that the record has previously been given to the Regulator.

(2) Regulation 13C(3)—after "Committee" insert:

under paragraph 13B(b)

23—Substitution of regulation 39

Regulation 39—delete the regulation and 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.

24—Insertion of regulations 42 and 43

After regulation 41 insert:

42—Previous assessment by an Institutional Biosafety Committee

(1) This regulation applies if—

(a) before 1 July 2020, an Institutional Biosafety Committee assessed a dealing as being a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3; and

(b) the record of the Committee's assessment does not indicate that the Committee assessed whether the dealing is of a kind mentioned in Part 3 of Schedule 3.

(2) The Committee is taken to have assessed the dealing as being a kind of dealing that is not mentioned in Part 3 of Schedule 3.

43—New requirements for giving records to Regulator apply to notifiable low risk dealing assessed in previous financial year

Regulation 13C as amended by the *Gene Technology Variation Regulations 2019* applies in relation to a dealing that has been assessed by an Institutional Biosafety Committee as a notifiable low risk dealing on or after 1 July 2019.

Part 4—Variation of *Gene Technology Regulations 2017* (commencing on 8 October 2020)

25—Variation of Schedule 1—Organisms that are not genetically modified organisms

Schedule 1, Table of Particulars, item 1—delete item 1

Note—

As required by section 10AA(2) of the *Subordinate Legislation Act 1978*, the Minister has certified that, in the Minister's opinion, it is necessary or appropriate that these regulations come into operation as set out in these regulations.

Made by the Governor

with the advice and consent of the Executive Council
on 3 October 2019

No 216 of 2019