Australian Capital Territory

Gene Technology Amendment Regulation 2020 (No 1)

Subordinate Law SL2020-38

The Australian Capital Territory Executive makes the following regulation under the *Gene Technology Act 2003*.

Dated 8 September 2020.

RACHEL STEPHEN-SMITH
Minister

GORDON RAMSAY
Minister

J2019-1154

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Australian Capital Territory

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Contents

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1 Name of regulation

This regulation is the *Gene Technology Amendment Regulation 2020 (No 1)*.

2 Commencement

(1) This regulation (other than schedule 1) commences on the day after its notification day.

Note The naming and commencement provisions automatically commence on the notification day (see Legislation Act, s 75 (1)).

(2) Schedule 1 commences on 8 October 2020.

3 Legislation amended

This regulation amends the *Gene Technology Regulation 2004*.

4 New section 4A

insert

4A Organisms that are genetically modified organisms

For the Act, dictionary, definition of ***genetically modified organism***, paragraph (c), an organism mentioned in schedule 1B is a genetically modified organism.

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5 Section 5

substitute

5 Organisms that are not genetically modified organisms

For the Act, dictionary, definition of ***genetically modified organism***, paragraph (e), an organism is not a genetically modified organism if—

(a) 1 or more items mentioned in schedule 1 applies to the organism; and

(b) the organism has not been modified by gene technology, other than any modification mentioned in schedule 1; and

(c) the organism has not inherited any traits from an organism (the ***initial organism***) that occurred in the initial organism because of gene technology, other than as mentioned in schedule 1, item 9; and

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

6 Section 9 (b)

substitute

(b) the Commonwealth department administered by the Minister administering the *Biosecurity Act 2015* (Cwlth), chapter 8, part 1 (Biosecurity emergencies);

7 Section 12 (1) (a)

substitute

(a) it is a dealing of a kind mentioned in schedule 3, part 3.1 or part 3.2; and

(aa) it is not a dealing of a kind mentioned in schedule 3, part 3.3; and

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8 Section 13 (1) (b)

substitute

(b) the institutional biosafety committee has assessed the dealing to be a kind of dealing—

(i) mentioned in schedule 3, part 3.1 or part 3.2; and

(ii) not mentioned in schedule 3, part 3.3; and

9 Section 13 (1) (d)

substitute

(d) the dealing is only undertaken not later than the day 5 years after the date of the assessment; and

10 Section 13 (1) (e)

after

the person is mentioned in

insert

, or is in a class of people mentioned in,

11 Section 13 (1) (f)

substitute

(f) subject to subsection (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 the dealing may be undertaken under subsection (2); and

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12 Section 13 (1) (i) and note

omit

13 Section 13 (2) (b)

substitute

(b) for a kind of dealing mentioned in schedule 3, section 3.2, but not in section 3.2A—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 schedule 3, section 3.2A—in a facility certified by the regulator to at least physical containment level 3 and that is appropriate for the dealing; or

14 Section 13 (3)

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 subsections (1) (f) and (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, issued by the regulator under the Commonwealth Act, section 27 (d); or

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

15 Section 13A

omit

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16 Section 13B (a) (i)

omit

proposing to undertake the dealing

substitute

that submitted the proposal

17 Section 13B (a) (iii) and (iv)

substitute

(iii) its assessment whether the dealing is a kind of dealing mentioned in schedule 3, part 3.1 or part 3.2, and not mentioned in schedule 3, part 3.3;

(iv) if the committee has assessed the dealing to be a kind of dealing mentioned in schedule 3, part 3.1 or part 3.2 (and not mentioned in schedule 3, part 3.3)—which kind of dealing in those parts that the dealing is;

18 Section 13B (a) (vii)

after

the dealing

insert

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

19 Section 13B (a) (x)

omit

or accredited organisation

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20 Section 13C (1) and (2)

substitute

(1) A person or accredited organisation that has been given a copy of a record of assessment by an institutional biosafety committee under section 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) For subsection (1), a record of a dealing must include—

(a) the particulars, prescribed under section 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) not later than 30 September in the financial year following the financial year in which the institutional biosafety committee made the assessment.

(2B) An accredited organisation that is required to, as a condition of accreditation, 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.

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21 Section 13C (3)

after

an institutional biosafety committee

insert

under section 13B (b)

22 Section 39

substitute

39 Record of GMO dealings

For the Act, section 138 (2) (b), the following particulars are prescribed for a notifiable low risk dealing notified to the regulator:

(a) the person 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 (described using the terms in schedule 3, part 3.1 or part 3.2);

(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.

23 New section 41

insert

41 Disapplication of Legislation Act, s 47 (5)

The Legislation Act, section 47 (5) does not apply to AS/NZS 2243.3:2010 under this regulation.

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24 New part 10

insert

Part 10 Transitional—Gene Technology Amendment Regulation 2020 (No 1)

50 Meaning of *commencement day*—pt 10

In this part:

commencement day means the day the *Gene Technology Amendment Regulation 2020 (No 1)*, section 3 commences.

51 Changed requirements—former exempt dealings

(1) This section applies if—

(a) immediately before the commencement day—

(i) a person was undertaking a dealing; and

(ii) the dealing was an exempt dealing; and

(b) on or after the commencement day—the dealing is not an exempt dealing.

(2) The dealing is taken to be an exempt dealing if the dealing is undertaken by the person on or after the commencement day.

(3) This section applies until the earliest of—

(a) the day the dealing is assessed to be a notifiable low risk dealing by an institutional biosafety committee; and

(b) the day a GMO licence for the dealing is issued to the person; and

(c) 12 months after the commencement day.

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52 Changed requirements—former notifiable low risk dealings

(1) This section applies if—

(a) immediately before the commencement day—

(i) a person was undertaking a dealing; and

(ii) the dealing was a notifiable low risk dealing; and

(b) on or after the commencement day—the dealing is not—

(i) a notifiable low risk dealing; or

(ii) an exempt dealing.

(2) The dealing is taken to be a notifiable low risk dealing if the dealing is undertaken by the person on or after the commencement day.

(3) This section applies until the earlier of—

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

(b) 12 months after the commencement day.

53 Changed requirements—notifiable low risk dealings

(1) This section applies if a person was undertaking a notifiable low risk dealing immediately before the commencement day.

(2) For the Act, section 37, the dealing is taken to be undertaken in accordance with this regulation if the dealing is undertaken in accordance with this regulation as in force—

(a) immediately before the commencement day; or

(b) on or after the commencement day.

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54 Previous assessment by institutional biosafety committee

(1) This section applies if—

(a) before the commencement day, an institutional biosafety committee assessed a dealing to be a notifiable low risk dealing mentioned in schedule 3, part 3.1 or part 3.2; 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 schedule 3, part 3.3.

(2) The committee is taken to have assessed the dealing to be a kind of dealing that is not mentioned in schedule 3, part 3.3.

55 Giving records to regulator for notifiable low risk dealings assessed in previous financial year

(1) This section applies to a dealing that has been assessed by an institutional biosafety committee to be a notifiable low risk dealing—

(a) on or after 1 July 2019; but

(b) before the commencement day.

(2) Section 13C as in force on the commencement day applies in relation to the dealing.

56 Expiry—pt 10

This part expires 12 months after the commencement day.

Note Transitional provisions are kept in the regulation for a limited time. A transitional provision is repealed on its expiry but continues to have effect after its repeal (see Legislation Act, s 88).

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25 Schedule 1A, new item 11

insert

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

26 New schedule 1B

after schedule 1A, insert

Schedule 1B Organisms that are genetically modified organisms

(see s 4A)

column 1 item	column 2 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

27 Schedule 1, new item 4

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

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28 Schedule 1, new items 8 to 12

insert

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***) 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 section 5); or (b) all such inherited traits are traits that occurred in the initial organism as a result of a modification mentioned 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

29 Schedule 2, part 2.1, item 4, column 2, subsection (2) (b) and (c)

omit

100 μg/kg

substitute

100 micrograms per kilogram

30 Schedule 2, part 2.1, item 4, column 2, subsection (2) (e)

substitute

(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

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(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.

31 Schedule 2, part 2.1, item 5, column 2

omit

part 2.2, item 1

substitute

table 2.2, items 1 to 6

32 Schedule 2, part 2.2

substitute

Part 2.2 Host/vector systems for exempt dealings

2.2 Hosts and vectors

In this part:

host means a host mentioned in column 3 of an item in table 2.2.

host/vector system means any of the following:

(a) a system involving a host mentioned in column 3 of an item in table 2.2 and a vector mentioned in column 4 of the item;

(b) a non-vector system involving a host mentioned in column 3 of an item in table 2.2;

(c) a system involving a GMO mentioned as a vector in column 4 of an item in table 2.2 (other than item 7), without a host.

vector means a vector mentioned in column 4 of an item in table 2.2.

Note Column 2 of table 2.2 is included for information only.

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Table 2.2

column 1 item	column 2 class	column 3 host	column 4 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	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*
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

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column 1 item	column 2 class	column 3 host	column 4 vector
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*; (k) *Streptococcus thermophilus*; (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102; (m) *Synechocystis* species strain PCC 6803; (n) *Vibrio cholerae* CVD 103-HgR; (o) *Zymomonas mobilis*	non-conjugative plasmids

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column 1 item	column 2 class	column 3 host	column 4 vector
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) polyhedron-minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV)

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column 1 item	column 2 class	column 3 host	column 4 vector
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

33 Schedule 3, section 3.1

omit

or 13 (3) (b)

substitute

or 13 (3)

34 Schedule 3, section 3.1 (c)

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 column 3 of item 9 in schedule 2, table 2.2 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.

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35 Schedule 3, section 3.2

omit

or 13 (3) (b)

substitute

or 13 (3)

36 Schedule 3, section 3.2 (d)

omit everything before subparagraph (i), substitute

(d) a dealing involving a host/vector system not mentioned in schedule 2, table 2.2 if—

37 Schedule 3, section 3.2 (d) (ii) and (iii)

omit

donor nucleic acid

substitute

genetic modification

38 Schedule 3, section 3.2 (d), example

omit

Donor nucleic acid

substitute

A genetic modification

39 Schedule 3, section 3.2 (e) (i)

substitute

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

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40 Schedule 3, section 3.2 (h)

omit

part 2.2, item 1

substitute

table 2.2, items 1 to 6

41 Schedule 3, section 3.2 (i)

substitute

(i) a dealing involving virions of a replication defective viral vector unable to transduce human cells and a host not mentioned in schedule 2, table 2.2 if the donor nucleic acid cannot restore replication competence to the vector;

42 Schedule 3, section 3.2 (j)

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 schedule 2, table 2.2, if—

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

(ii) the dealing is not a dealing mentioned in section 3.1 (c);

43 Schedule 3, section 3.2 (k)

omit everything before subparagraph (i), substitute

(k) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells and a host not mentioned in schedule 2, table 2.2 if—

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44 Schedule 3, section 3.2 (k) (ii)

substitute

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

45 Schedule 3, section 3.2 (l)

omit everything 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 schedule 2, table 2.2, if—

46 Schedule 3, section 3.2 (l) (i)

omit

into a virion

substitute

new virions

47 Schedule 3, section 3.2 (m)

omit everything before subparagraph (i), substitute

(m) a dealing involving virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in schedule 2, table 2.2 if—

48 Schedule 3, section 3.2 (m) (i)

substitute

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

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49 Schedule 3, section 3.2 (m) (ii)

omit

into a virion

substitute

new virions

50 Schedule 3, section 3.2A

substitute

3.2A Kinds of dealing suitable for at least physical containment level 3

(1) This section applies to a kind of dealing that—

(a) is mentioned in section 3.2; and

(b) involves a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3.

(2) Unless section 13 (2) (c) or 13 (3) applies, the dealing must be undertaken in facilities that are—

(a) certified to at least physical containment level 3; and

(b) appropriate for the dealings.

(3) For subsection (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.

(4) However, subsection (3) does not apply in relation to a replication defective retroviral vector that meets the criteria in section 3.2 (l) or (m).

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51 Schedule 3, part 3.3 heading, note 2

substitute

Note 2 If a dealing is not a notifiable low risk dealing or an exempt dealing under this regulation, 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 Act, s 32).

52 Schedule 3, section 3.3 (a) and (b)

omit

100 µg/kg

substitute

100 micrograms per kilogram

53 Schedule 3, section 3.3 (d) and (e)

substitute

(d) a dealing involving virions of a replication defective viral vector and a host not mentioned in schedule 2, table 2.2 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 section 3.2 (i);

(e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in schedule 2, table 2.2, column 4, if the genetic modification confers an oncogenic modification or immunomodulatory effect in humans;

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54 Schedule 3, section 3.3 (f) (ii) (B)

omit

donor nucleic acid

substitute

genetic modification

55 Schedule 3, section 3.3 (f) (ii), example

omit

Donor nucleic acid

substitute

A genetic modification

56 Schedule 3, new section 3.3 (q) to (s)

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 in a facility—

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

(ii) 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);

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(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.

57 Schedule 3, new section 3.3 (2) to (4)

insert

(2) For subsection (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 subsection (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, subsection (3) does not apply in relation to a replication defective retroviral vector that meets the criteria in section 3.2 (l) or (m).

58 Dictionary, note 3

insert

- accredited organisation
- environment
- facility
- gene technology technical advisory committee
- intentional release of a GMO into the environment (see s 11)

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59 Dictionary, note 3

omit

- GM product

60 Dictionary, definition of *characterised*

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.

61 Dictionary, new definitions

insert

host, for part 2.2 (Host/vector systems for exempt dealings)—see schedule 2, section 2.2.

host/vector system, for part 2.2 (Host/vector systems for exempt dealings)—see schedule 2, section 2.2.

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62 Dictionary, definition of *toxin-producing organism*

omit

100 μg/kg

substitute

100 micrograms per kilogram

63 Dictionary, new definition of *vector*

insert

vector, for part 2.2 (Host/vector systems for exempt dealings)—see schedule 2, section 2.2.

64 Further amendments, mentions of *part 2.2*

omit

part 2.2

substitute

table 2.2

in

- schedule 2, part 2.1, item 4 (1)
- schedule 3, section 3.2 (c), (e) and (f)
- schedule 3, section 3.3 (f) (ii) (A), (g) (ii) and (h)

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Schedule 1 Delayed amendment

(see s 3)

[1.1] Schedule 1, item 1

omit

Endnotes

1 Notification

Notified under the Legislation Act on 8 September 2020.

2 Republications of amended laws

For the latest republication of amended laws, see www.legislation.act.gov.au.

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