Australian Capital Territory

Gene Technology Regulation 2004

SL2004-17

made under the

Gene Technology Act 2003

Republication No 11

Effective: 10 September 2020 – 7 October 2020

Republication date: 10 September 2020

Last amendment made by SL2020-38

About this republication

The republished law

This is a republication of the *Gene Technology Regulation 2004*, made under the *Gene Technology Act 2003* (including any amendment made under the *Legislation Act 2001*, part 11.3 (Editorial changes)) as in force on 10 September 2020. It also includes any commencement, amendment, repeal or expiry affecting this republished law to 10 September 2020.

The legislation history and amendment history of the republished law are set out in endnotes 3 and 4.

Kinds of republications

The Parliamentary Counsel's Office prepares 2 kinds of republications of ACT laws (see the ACT legislation register at www.legislation.act.gov.au):

- authorised republications to which the *Legislation Act 2001* applies
- unauthorised republications.

The status of this republication appears on the bottom of each page.

Editorial changes

The *Legislation Act 2001*, part 11.3 authorises the Parliamentary Counsel to make editorial amendments and other changes of a formal nature when preparing a law for republication. Editorial changes do not change the effect of the law, but have effect as if they had been made by an Act commencing on the republication date (see *Legislation Act 2001*, s 115 and s 117). The changes are made if the Parliamentary Counsel considers they are desirable to bring the law into line, or more closely into line, with current legislative drafting practice.

This republication includes amendments made under part 11.3 (see endnote 1).

Uncommenced provisions and amendments

If a provision of the republished law has not commenced, the symbol **U** appears immediately before the provision heading. Any uncommenced amendments that affect this republished law are accessible on the ACT legislation register (www.legislation.act.gov.au). For more information, see the home page for this law on the register.

Modifications

If a provision of the republished law is affected by a current modification, the symbol **M** appears immediately before the provision heading. The text of the modifying provision appears in the endnotes. For the legal status of modifications, see the *Legislation Act 2001*, section 95.

Penalties

At the republication date, the value of a penalty unit for an offence against this law is $160 for an individual and $810 for a corporation (see *Legislation Act 2001*, s 133).

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Part 1 Preliminary

1 Name of regulation

This regulation is the *Gene Technology Regulation 2004*.

3 Dictionary

The dictionary at the end of this regulation is part of this regulation.

Note 1 The dictionary at the end of this regulation defines certain terms used in this regulation.

Note 2 A definition in the dictionary applies to the entire regulation unless the definition, or another provision of the regulation, provides otherwise or the contrary intention otherwise appears (see Legislation Act, s 155 and s 156 (1)).

3A Numbering

(1) To maintain consistent provision numbering between this regulation and the Commonwealth regulations—

(a) if the Commonwealth regulations contain a regulation that is not needed in this regulation—the provision number and heading to the regulation appearing in the Commonwealth regulations are included in this regulation despite the omission of the body of the Commonwealth regulation; and

(b) if this regulation contains a section that is not included in the Commonwealth regulations—the section is numbered to maintain consistency in numbering between provisions common to both.

(2) A provision number and heading mentioned in subsection (1) (a) form part of this regulation.

(3) If a provision of this regulation (other than a section) is numbered differently from the equivalent provision of the Commonwealth regulations, the provision of this regulation may be referred to using the number of the equivalent provision of the Commonwealth regulations.

(4) Also, a provision of this regulation may be referred to in the way in which a corresponding provision may be referred to in Commonwealth regulations.

Note 1 A note appears under each heading of a kind mentioned in s (1) (a) describing the omitted regulation of the Commonwealth regulations.

Note 2 A note appears under each section of a kind mentioned in s (1) (b) highlighting the non-appearance of an equivalent regulation in the Commonwealth regulations.

Note 3 This section does not appear in the Commonwealth regulations.

3B Notes

A note included in this regulation is explanatory and is not part of this regulation.

Note 1 See the Legislation Act, s 127 (1), (4) and (5) for the legal status of notes.

Note 2 This section does not appear in the Commonwealth regulations.

3C Offences against regulation—application of Criminal Code etc

Other legislation applies in relation to offences against this regulation.

Note 1 *Criminal Code*

The Criminal Code, ch 2 applies to all offences against this regulation (see Code, pt 2.1).

The chapter sets out the general principles of criminal responsibility (including burdens of proof and general defences), and defines terms used for offences to which the Code applies (eg ***conduct***, ***intention***, ***recklessness*** and ***strict liability***).

Note 2 *Penalty units*

The Legislation Act, s 133 deals with the meaning of offence penalties that are expressed in penalty units.

Note 3 This section does not appear in the Commonwealth regulations.

Part 2 Interpretation and general operation

4 Techniques not constituting gene technology

For the Act, dictionary, definition of ***gene technology***, paragraph (c), gene technology does not include a technique in schedule 1A.

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.

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.

Part 3 Dealings with GMOs

Division 3.1 Licensing system

6 Dealings exempt from licensing

(1) For the Act, dictionary, definition of ***exempt dealing***, a dealing with a GMO is an exempt dealing if—

(a) it is a dealing of a kind mentioned in schedule 2, part 2.1; and

(b) it does not involve a genetic modification other than a modification described in schedule 2, part 2.1; and

(d) it does not involve an intentional release of the GMO into the environment.

(2) To remove any doubt, an exemption under subsection (1) does not apply to a dealing that does not comply with that subsection, whether or not that dealing is related to a dealing that does comply.

Note 1 A dealing affected by this section could be any of the forms of dealing mentioned in the Act, dict, def ***deal with***.

Note 2 Exemption from provisions of the Act does not preclude the application of other Commonwealth and State laws.

7 Application for licence—prescribed fee

Note At the commencement of the regulation, no application fee is prescribed under the Act, s 40 (6).

8 Time limit for deciding an application—Act, s 43 (3)

(1) The period within which the regulator must issue, or refuse to issue, a licence is—

(a) for an application to which the Act, division 5.3 applies—90 days after the day the application is received by the regulator; or

(b) for an application to which the Act, division 5.4 applies—

(i) for a limited and controlled release application for which the regulator is satisfied that the dealings proposed to be authorised by the licence do not pose significant risks to the health and safety of people or to the environment— 150 days after the day the application is received by the regulator; and

(ii) for a limited and controlled release application for which the regulator is satisfied that at least one of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment—170 days after the day the application is received by the regulator; and

(iii) in any other case—255 days after the day the application is received by the regulator.

(2) In working out the end of a period mentioned in subsection (1), the following days are not counted:

(a) a Saturday, a Sunday or a public holiday;

(b) a day when the regulator cannot proceed with the decision-making process, or a related function, because the regulator is awaiting information that the applicant has been asked, in writing, to give;

(c) if, in relation to the application, the regulator publishes notice of a public hearing under the Act, section 53—a day in the period that—

(i) begins on the day of publication; and

(ii) ends on the day when the public hearing ends;

(d) a day when the regulator cannot proceed with the decision-making process, or a related function, because—

(i) the applicant has applied under the Act, section 184 for information given in relation to the application to be declared confidential commercial information for the Act; and

(ii) the regulator is—

(A) considering the application; or

(B) waiting until any review rights under the Act, section 181 or section 183 in relation to the application are exhausted;

(e) if, in relation to the application, the regulator requests the ethics and community committee to provide advice on an ethical issue, a day in the period that—

(i) begins on the day the request is made; and

(ii) subject to subsection (3), ends on the day the advice is given or, if the advice is not given within the period (if any) specified under that subsection, on the last day of that period.

(3) The regulator, when seeking advice under the Act, section 50 (3) or section 52 (5) or from the ethics and community committee, may specify a reasonable period within which the advice must be received, and, if the advice is not received within the period, must proceed without regard to the advice.

(4) In this section:

limited and controlled release application means an application for a licence to which the Act, section 50A applies.

9 Prescribed authorities—Act, s 50 (3) (c) and s 52 (5) (c)

The following Commonwealth authorities and agencies are prescribed:

(a) Food Standards Australia New Zealand;

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

(d) the Director, National Industrial Chemical Notification and Assessment Scheme under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth);

(e) Australian Pesticides and Veterinary Medicines Authority;

(f) Therapeutic Goods Administration, Commonwealth Department of Health.

9A Risks posed by dealings proposed to be authorised by licence—Act, s 51 (1) (a)

The regulator must have regard to the following matters:

(a) the properties of the organism to which dealings proposed to be authorised by a licence relate before it became, or will become, a GMO;

(b) the effect, or the expected effect, of the genetic modification that has occurred, or will occur, on the properties of the organism;

(c) provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;

(d) the potential for spread or persistence of the GMO or its genetic material in the environment;

(e) the extent or scale of the proposed dealings;

(f) any likely impacts of the proposed dealings on the health and safety of people.

10 Risk assessment—matters to be taken into account—Act, s 51 (1) (d) and (2) (d)

(1) Other matters to be taken into account in relation to dealings proposed to be authorised by a licence include—

(a) subject to the Act, section 45, any previous assessment by a regulatory authority, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and

(b) the potential of the GMO concerned to—

(i) be harmful to other organisms; and

(ii) adversely affect any ecosystems; and

(iii) transfer genetic material to another organism; and

(iv) spread, or persist, in the environment; and

(v) have an advantage in the environment in comparison to related organisms; and

(vi) be toxic, allergenic or pathogenic to other organisms.

(2) In taking into account a risk mentioned in the Act, section 51 (1), or a potential capacity mentioned in subsection (1), the regulator must consider both the short term and the long term.

11 Prescribed conditions of licence

Note At the commencement of this regulation, no conditions are prescribed under the Act, s 61 (b).

11A Time limit for deciding variation application—Act, s 71 (7)

(1) 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 subsection (1), the following days are not counted:

(a) a Saturday, a Sunday or a public holiday;

(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.

Division 3.2 Notifiable low risk dealings

12 Notifiable low risk dealings—Act, s 74 (1)

(1) A dealing with a GMO is a notifiable low risk dealing if—

(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

(b) it does not involve an intentional release of the GMO into the environment.

(2) To remove any doubt, subsection (1) does not apply to a dealing that does not comply with that subsection, whether or not that dealing is related to a dealing that does comply.

Note A dealing affected by this section could be any of the forms of dealing mentioned in the Act, dict, def ***deal with***.

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 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

(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 not later than the day 5 years after the date of the assessment; and

(e) the person is mentioned in, or is in a class of people mentioned in, the institutional biosafety committee's record of assessment as having the appropriate training and experience to undertake the dealing; and

(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

(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.

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

(a) for a kind of dealing mentioned in schedule 3, part 3.1—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 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

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

(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.

(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.

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 that submitted the proposal;

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

(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;

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

(vi) the people or classes of people 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, having regard to the requirements of section 13 (2);

(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 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 people or accredited organisations

(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.

(3) A person or accredited organisation given a copy of a record of assessment by an institutional biosafety committee under section 13B (b) 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 people or organisations more 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 subsection (4) must, by the end of the period mentioned in the notice, give the regulator the information required by the notice.

Division 3.3 Certification and accreditation

14 Regulator to decide certification application within 90 days

Note The Commonwealth regulations, reg 14 provides the period within which the regulator must consider and decide an application for certification of a facility.

15 Application for certification—failure to provide Act, s 85 information

If an applicant for certification of a facility fails to provide information required under the Act, section 85 (1) within the period stated in a notice given under the Act, section 85 (2) and gives no reasonable explanation for the failure, the regulator may refuse to certify the facility.

Note A refusal to certify a facility is a reviewable decision (see the Act, div 12.2).

16 Regulator to decide accreditation application within 90 days

Note The Commonwealth regulations, reg 16 provides the period within which the regulator must consider and decide an application for accreditation of an organisation.

17 Application for accreditation—failure to provide Act, s 93 information

If an applicant for accreditation of an organisation fails to provide information required under the Act, section 93 (1) within the period stated in a notice given under the Act, section 93 (2) and gives no reasonable explanation for the failure, the regulator may refuse to accredit the organisation.

Note A refusal to accredit an organisation is a reviewable decision (see the Act, div 12.2).

Part 4 Gene technology technical advisory committee

Division 4.1 Conditions of appointment

18 GTTAC members and advisers—term of appointment

Note The Commonwealth regulations, reg 18 provides for the term of appointment of members of the gene technology technical advisory committee and expert advisers to the committee.

19 GTTAC members and advisers—resignation

Note The Commonwealth regulations, reg 19 provides for the resignation of members of the gene technology technical advisory committee and expert advisers to the committee.

20 GTTAC members—disclosure of interests

Note The Commonwealth regulations, reg 20 provides for disclosure of any interests members of the gene technology technical advisory committee may have in matters likely to be considered at a meeting of the committee.

21 GTTAC members and advisers—termination of appointment

Note The Commonwealth regulations, reg 21 provides for termination of the appointment of members of the gene technology technical advisory committee and expert advisers to the committee.

22 GTTAC members—leave of absence

Note The Commonwealth regulations, reg 22 provides for the granting of leave to the chairperson and members of the gene technology technical advisory committee.

23 Expert advisers—disclosure of interests

Note The Commonwealth regulations, reg 23 provides for disclosure of any interests expert advisers to the gene technology technical advisory committee may have in matters likely to be considered at a meeting of the committee.

Division 4.2 Committee procedures

24 Committee procedures generally

Note The Commonwealth regulations, reg 24—

- provides that the gene technology technical advisory committee must act without formality; and
- provides for how the committee may obtain information.

25 Committee meetings

Note The Commonwealth regulations, reg 25 provides for when and how the gene technology technical advisory committee may have meetings.

26 Presiding member

Note The Commonwealth regulations, reg 26 provides for who is to preside at a meeting of the gene technology technical advisory committee.

27 Quorum

Note The Commonwealth regulations, reg 27 provides that there is a quorum at a meeting of the gene technology technical advisory committee if half of the appointed members are present.

28 Voting

Note The Commonwealth regulations, reg 28 provides that—

- a decision of the gene technology technical advisory committee is made by half of the members present, and voting for the decision, at a meeting of the committee; and
- the presiding member has a deliberative and casting vote.

29 Records and reports

Note The Commonwealth regulations, reg 29 provides for—

- records of proceedings and resolutions of the gene technology technical advisory committee to be kept; and
- resolutions of the committee to be publicly available; and
- reports to be prepared about the committee's activities.

Division 4.3 Subcommittees

30 Operation of subcommittees

Note The Commonwealth regulations, reg 30 provides for the matters covered by the Commonwealth regulations, pt 4, div 2 for subcommittees established under the Commonwealth Act, s 105 (1).

Part 5 Ethics and community committee

31 Ethics and community committee—conditions of appointment

Note The Commonwealth regulations, reg 31 provides for the Commonwealth Act, pt 4, div 1 to apply to the conditions of appointment of a member of the ethics and community committee.

32 Ethics and community committee—committee procedures

Note The Commonwealth regulations, reg 32 provides for the Commonwealth Act, pt 4, div 2 to apply to the procedures of the ethics and community committee.

33 Ethics and community committee—operation of subcommittees

Note The Commonwealth regulations, reg 33 provides for the matters covered by the Commonwealth Act, pt 4, div 2 for subcommittees established under the Commonwealth Act, s 111 (1).

Part 7 Miscellaneous

37 Reviewable State decisions

Note At the commencement of this regulation, the Commonwealth regulations have not declared any decisions of the regulator to be reviewable State decisions for the Commonwealth Act, s 19.

38 Review of decisions

Note The Commonwealth regulations, reg 38 provides that a person whose interests are affected by a decision terminating an appointment to a committee may apply to the Commonwealth administrative appeals tribunal for review of the decision.

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.

40 Inspector identity card

Note The Commonwealth regulations, reg 40 prescribes the form of an inspector's identity card. Under the Act, s 151 the card must be in the approved form.

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.

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.

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.

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).

Schedule 1A Techniques that are not gene technology

(see s 4)

column 1 item	column 2 description of technique
1	somatic cell nuclear transfer, if the transfer does not involve genetically modified material
2	electromagnetic radiation-induced mutagenesis
3	particle radiation-induced mutagenesis
4	chemical-induced mutagenesis
5	fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human
6	protoplast fusion, including fusion of plant protoplasts
7	embryo rescue
8	*in-vitro* fertilisation
9	zygote implantation
10	a natural process, if the process does not involve genetically modified material **Examples—natural processes** 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

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

Schedule 1 Organisms that are not genetically modified organisms

(see s 5)

column 1 item	column 2 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

column 1 item	column 2 description of organism
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

Schedule 2 Dealings exempt from licensing

(see s 6)

Note For this schedule, s 6 (1) sets out other requirements for exempt dealings.

Part 2.1 Exempt dealings

column 1 item	column 2 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 subsection (1), a dealing involving a host/vector system mentioned in table 2.2 and producing not more than 25L of GMO culture in each vessel containing the resultant culture.

column 1 item	column 2 description of dealing
	(2) The donor nucleic acid—
	(a) must meet either of the following requirements:
	(i) the acid 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) the acid 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 par (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 LD50 of less than 100 micrograms per kilogram; and
	(c) must not code for a toxin with an LD50 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.

column 1 item	column 2 description of dealing
5	a dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in table 2.2, items 1 to 6, if the donor nucleic acid is not derived from either— (a) a pathogen; or (b) a toxin-producing organism

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.

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

column 1 item	column 2 class	column 3 host	column 4 vector
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)	disarmed Ri or Ti plasmids

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

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)

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

Part 2.3 Definitions—sch 2

In this schedule:

code for, in relation to a toxin, means to specify the amino acid sequence of the toxin.

non-conjugative plasmid means a plasmid that is not self-transmissible, and includes, but is not limited to, non-conjugative forms of the following plasmids:

(a) bacterial artificial chromosomes (BACs);

(b) cosmids;

(c) P1 artificial chromosomes (PACs);

(d) yeast artificial chromosomes (YACs).

non-vector system means a system in which donor nucleic acid is or was introduced into a host cell—

(a) in the absence of a nucleic acid-based vector; or

(b) using a nucleic acid-based vector in the course of a previous dealing and the vector is—

(i) no longer present; or

(ii) present but cannot be remobilised from a host cell.

Examples

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

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

Schedule 3 Notifiable low risk dealings in relation to a GMO

(see s 12 and s 13)

Part 3.1 Notifiable low risk dealings suitable for at least physical containment level 1

Note Because of s 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 pt 3.3.

3.1 Kinds of dealings suitable for at least physical containment level 1

The following kinds of notifiable low risk dealings must be undertaken, unless section 13 (2) (c) or 13 (3) 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 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.

Part 3.2 Notifiable low risk dealings suitable for at least physical containment level 2 or 3

Note Because of s 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 3.3.

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

The following kinds of notifiable low risk dealings must be undertaken, unless section 13 (2) (c) or 13 (3) 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 section 3.1 (c) or schedule 2, table 2.2 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/vector system not mentioned in schedule 2, table 2.2 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 genetic modification is characterised; and

(iii) the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;

Example

A genetic modification would not comply with par (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 schedule 2, table 2.2, if the donor nucleic acid—

(i) is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; 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 schedule 2, table 2.2 and producing more than 25L 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 schedule 2, part 2.1, item 4 (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 par (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 schedule 2, table 2.2, items 1 to 6, if the donor nucleic acid is derived from either—

(i) a pathogen; or

(ii) a toxin-producing organism;

(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;

(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);

(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—

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

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

(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—

(i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions 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 virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in schedule 2, table 2.2 if—

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

(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions 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.

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).

Part 3.3 Dealings that are not notifiable low risk dealings

Note 1 The following list qualifies the list in pt 3.1 and pt 3.2 and is not an exhaustive list of dealings that are not notifiable low risk dealings.

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 the Act, s 32).

3.3 Kinds of dealings

(1) 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 section 3.2 (h)) involving cloning of nucleic acid encoding a toxin having an LD_{50} of less than 100 micrograms per kilogram;

(b) a dealing involving high level expression of toxin genes, even if the LD_{50} is 100 micrograms per kilogram or more;

(c) a dealing (other than a dealing mentioned in section 3.2 (h)) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;

(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;

(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 apply:

(A) the host/vector system is a system mentioned in schedule 2, table 2.2;

(B) the genetic modification 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 section 3.2 (g);

Example

A genetic modification would not comply with par (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 section 3.2 (g); or

(ii) the micro-organism is a host mentioned in schedule 2, table 2.2;

(h) a dealing involving the introduction into a micro-organism, other than a host mentioned in schedule 2, table 2.2 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 par (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 section 3.2 (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 25L of that culture, other than a dealing mentioned in section 3.2 (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;

(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);

(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 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).

Dictionary

(see s 3)

Note 1 The Legislation Act contains definitions and other provisions relevant to this regulation.

Note 2 For example, the Legislation Act, dict, pt 1, defines the following terms:

- for
- function
- in relation to
- person (see s 160)
- public holiday
- under.

Note 3 Terms used in this regulation have the same meaning that they have in the *Gene Technology Act 2003* (see Legislation Act, s 148). For example, the following terms are defined in the *Gene Technology Act 2003*, dict:

- accredited organisation
- Commonwealth Act
- deal with
- environment
- ethics and community committee
- exempt dealing
- facility
- gene technology
- gene technology technical advisory committee
- genetically modified organism
- GMO
- institutional biosafety committee
- intentional release of a GMO into the environment (see s 11)
- ministerial council
- notifiable low risk dealing
- regulator.

advantage, in relation to an organism that is genetically modified, means a superior ability in its modified form, relative to the unmodified parent organism, to survive, reproduce or otherwise contribute to the gene pool.

animal includes every kind of organism in the animal kingdom, including non-vertebrates but not including human beings.

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.

Note AS/NZS 2243.3:2010 may be purchased at www.standards.org.au.

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.

code for, in relation to a toxin, for schedule 2 (Dealings exempt from licensing)—see schedule 2, part 2.3.

Commonwealth regulations means the *Gene Technology Regulations 2001* (Cwlth).

expert adviser means—

(a) for part 4 (Gene technology technical advisory committee)—an expert adviser appointed under the Act, section 102 (1); and

(b) for part 5 (Ethics and community committee)—an expert adviser appointed under the Act, section 112 (1).

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

genetically modified laboratory mouse means a laboratory strain of mouse of the species *Mus musculus* that has been modified by gene technology.

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

genetically modified laboratory rat means a laboratory strain of rat of either the species *Rattus rattus* or *Rattus norvegicus* that has been modified by gene technology.

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.

infectious agent means an agent that is capable of entering, surviving in, multiplying, and potentially causing disease in, a susceptible host.

inspector means a person appointed by the regulator under the Act, section 150 as an inspector.

known means known within the scientific community.

non-conjugative plasmid, for schedule 2—see schedule 2, part 2.3.

non-vector system, for schedule 2—see schedule 2, part 2.3.

nucleic acid means either, or both, deoxyribonucleic acid (DNA), or ribonucleic acid (RNA), of any length.

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.

packaging cell line means an animal or human cell line that contains a gene or genes that when expressed *in trans* are necessary and sufficient to complement packaging defects of a replication defective viral vector in order to produce packaged replication defective virions.

pathogenic, in relation to an organism, means having the capacity to cause disease or abnormality.

pathogenic determinant means a characteristic that has the potential to increase the capacity of a host or vector to cause disease or abnormality.

physical containment level, followed by a numeral, is a specified containment level under guidelines made by the regulator under the Act, section 90 for the certification of facilities.

plasmid means a DNA molecule capable of autonomous replication and stable extra-chromosomal maintenance in a host cell.

shotgun cloning means the production of a large random collection of cloned fragments of nucleic acid from which genes of interest can later be selected.

toxin means a substance that is toxic to any vertebrate.

toxin-producing organism means an organism producing toxin with an LD_{50} of less than 100 micrograms per kilogram.

transduce, in relation to a viral vector or viral particle, means enter an intact cell by interaction of the viral particle with the cell membrane.

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

Endnotes

1 About the endnotes

Amending and modifying laws are annotated in the legislation history and the amendment history. Current modifications are not included in the republished law but are set out in the endnotes.

Not all editorial amendments made under the *Legislation Act 2001*, part 11.3 are annotated in the amendment history. Full details of any amendments can be obtained from the Parliamentary Counsel's Office.

Uncommenced amending laws are not included in the republished law. The details of these laws are underlined in the legislation history. Uncommenced expiries are underlined in the legislation history and amendment history.

If all the provisions of the law have been renumbered, a table of renumbered provisions gives details of previous and current numbering.

The endnotes also include a table of earlier republications.

2 Abbreviation key

A = Act
AF = Approved form
am = amended
amdt = amendment
AR = Assembly resolution
ch = chapter
CN = Commencement notice
def = definition
DI = Disallowable instrument
dict = dictionary
disallowed = disallowed by the Legislative Assembly
div = division
exp = expires/expired
Gaz = gazette
hdg = heading
IA = Interpretation Act 1967
ins = inserted/added
LA = Legislation Act 2001
LR = legislation register
LRA = Legislation (Republication) Act 1996
mod = modified/modification
NI = Notifiable instrument
o = order
om = omitted/repealed
ord = ordinance
orig = original
par = paragraph/subparagraph
pres = present
prev = previous
(prev...) = previously
pt = part
r = rule/subrule
reloc = relocated
renum = renumbered
R[X] = Republication No
RI = reissue
s = section/subsection
sch = schedule
sdiv = subdivision
SL = Subordinate law
sub = substituted
underlining = whole or part not commenced or to be expired

3 Legislation history

This regulation was originally the *Gene Technology Regulations 2004*. It was renamed under the *Legislation Act 2001*.

Gene Technology Regulation 2004 SL2004-17
notified LR 4 June 2004
s 1, s 2 commenced 4 June 2004 (LA s 75 (1))
remainder commenced 5 June 2004 (s 2)

as amended by

Statute Law Amendment Act 2005 A2005-20 sch 3 pt 3.25
notified LR 12 May 2005
s 1, s 2 taken to have commenced 8 March 2005 (LA s 75 (2))
sch 3 pt 3.25 commenced 2 June 2005 (s 2 (1))

Gene Technology Amendment Regulation 2008 (No 1) SL2008-17
notified LR 17 April 2008
s 1, s 2 commenced 17 April 2008 (LA s 75 (1))
remainder commenced 1 May 2008 (s 2 and see Gene Technology Amendment Act 2008 A2008-10, s 2 and CN2008-5)

Gene Technology Amendment Regulation 2011 (No 1) SL2011-26
notified LR 31 August 2011
s 1, s 2 commenced 31 August 2011 (LA s 75 (1))
remainder commenced 1 September 2011 (s 2)

Statute Law Amendment Act 2011 (No 2) A2011-28 sch 3 pt 3.16
notified LR 31 August 2011
s 1, s 2 commenced 31 August 2011 (LA s 75 (1))
sch 3 pt 3.16 commenced 21 September 2011 (s 2 (1))

Gene Technology Amendment Act 2017 A2017-15 pt 3
notified LR 14 June 2017
s 1, s 2 commenced 14 June 2017 (LA s 75 (1))
pt 3 commenced 15 June 2017 (s 2)

Statute Law Amendment Act 2019 A2019-42 sch 3 pt 3.12
notified LR 31 October 2019
s 1, s 2 commenced 31 October 2019 (LA s 75 (1))
sch 3 pt 3.12 commenced 14 November 2019 (s 2 (1))

Gene Technology Amendment Regulation 2020 (No 1) SL2020-38

notified LR 9 September 2020

s 1, s 2 commenced 9 September 2020 (LA s 75 (1))

sch 1 awaiting commencement

remainder commenced 10 September 2020 (s 2 (1))

4 Amendment history

Name of regulation
s 1 am R2 LA

Commencement
s 2 om LA s 89 (4)

Numbering
s 3A am A2005-20 amdt 3.162

Techniques not constituting gene technology
s 4 am SL2008-17 s 4

Organisms that are genetically modified organisms
s 4A ins SL2020-38 s 4

Organisms that are not genetically modified organisms
s 5 sub SL2020-38 s 5

Dealings exempt from licensing
s 6 am SL2008-17 ss 5-7; SL2011-26 s 4

Application for licence—prescribed fee
s 7 sub SL2008-17 s 8

Time limit for deciding an application—Act, s 43 (3)
s 8 am SL2008-17 ss 9-12; A2011-28 amdt 3.122

Prescribed authorities—Act, s 50 (3) (c) and s 52 (5) (c)
s 9 am SL2008-17 s 13, s 14; A2019-42 amdt 3.17; SL2020-38 s 6

Risks posed by dealings proposed to be authorised by licence—Act, s 51 (1) (a)
s 9A ins SL2008-17 s 15

Risk assessment—matters to be taken into account—Act, s 51 (1) (d) and (2) (d)
s 10 am SL2008-17 s 16, s 17

Time limit for deciding variation application—Act, s 71 (7)
s 11A ins SL2008-17 s 18
sub SL2011-26 s 5

Notifiable low risk dealings—Act, s 74 (1)
s 12 am SL2011-26 s 6; SL2020-38 s 7

Requirements for undertaking notifiable low risk dealings
s 13 (5)-(7) exp 5 June 2006 (s 13 (7) (LA s 88 declaration applies))
sub SL2008-17 s 19; SL2011-26 s 7
am SL2020-38 ss 8-14

Requirements in relation to notifying regulator of notifiable low risk dealings

s 13A ins SL2008-17 s 19
sub SL2011-26 s 8
om SL2020-38 s 15

Requirements for institutional biosafety committees about records of assessments of notifiable low risk dealing proposals

s 13B ins SL2011-26 s 8
am SL2020-38 ss 16-19

Information to be kept or given to the regulator by people or accredited organisations

s 13C ins SL2011-26 s 8
am SL2020-38 s 20, s 21

Ethics and community committee

pt 5 hdg sub SL2008-17 s 20

Ethics and community committee—conditions of appointment

s 31 sub SL2008-17 s 20

Ethics and community committee—committee procedures

s 32 sub SL2008-17 s 20

Ethics and community committee—operation of subcommittees

s 33 sub SL2008-17 s 20

Gene technology ethics committee

pt 6 hdg om SL2008-17 s 20

GTEC—conditions of appointment

s 34 om SL2008-17 s 20

GTEC—committee procedures

s 35 om SL2008-17 s 20

GTEC—operation of subcommittees

s 36 om SL2008-17 s 20

Record of GMO dealings

s 39 hdg sub A2017-15 s 19
s 39 am SL2008-17 s 21; SL2011-26 s 9, s 10; A2017-15 s 20
sub SL2020-38 s 22

Transitional

pt 8 hdg om SL2008-17 s 22

Disapplication of Legislation Act, s 47 (5)

s 41 om SL2008-17 s 22
ins SL2020-38 s 23

Existing organisations—accreditation

s 42 exp 5 June 2006 (s 42 (4) (LA s 88 declaration applies))

Transitional—Gene Technology Amendment Regulation 2011 (No 1)

pt 9 hdg ins SL2011-26 s 11
exp 1 September 2013 (s 46)

Transitional

s 45 ins SL2011-26 s 11
exp 1 September 2013 (s 46)

Expiry—pt 9

s 46 ins SL2011-26 s 11
exp 1 September 2013 (s 46)

Transitional—Gene Technology Amendment Regulation 2020 (No 1)

pt 10 hdg ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Meaning of *commencement day*—pt 10

s 50 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Changed requirements—former exempt dealings

s 51 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Changed requirements—former notifiable low risk dealings

s 52 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Changed requirements—notifiable low risk dealings

s 53 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Previous assessment by institutional biosafety committee

s 54 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

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

s 55 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Expiry—pt 10

s 56 ins SL2020-38 s 24
exp 10 September 2021 (s 56)

Techniques that are not gene technology

sch 1A ins SL2008-17 s 23
am SL2020-38 s 25

Organisms that are genetically modified organisms

sch 1B ins SL2020-38 s 26

Organisms that are not genetically modified organisms

sch 1 sub SL2008-17 s 23
am SL2011-26 s 12; SL2020-38 s 27, s 28

Dealings exempt from licensing

sch 2 sub SL2008-17 s 23
am SL2011-26 ss 13-16; SL2020-38 ss 29-32, s 64

Notifiable low risk dealings in relation to a GMO

sch 3 sub SL2008-17 s 23; SL2011-26 s 17
am SL2020-38 ss 33-57, s 64

Prescribed information—application for licence

sch 4 om SL2008-17 s 23

Dictionary

dict am SL2008-17 s 24; SL2011-26 s 18; SL2020-38 s 58, s 59
def ***advantage*** sub SL2008-17 s 25
def ***AS/NZS 2243.3:2010*** ins SL2011-26 s 19
def ***characterised*** sub SL2008-17 s 26; SL2020-38 s 60
def ***division 5.3 application*** om SL2008-17 s 27
def ***division 5.4 application*** om SL2008-17 s 27
def ***expert advisor*** sub SL2008-17 s 28
def ***gene-knockout mice*** om SL2008-17 s 29
def ***genetic manipulation advisory committee*** om SL2008-17 s 30
def ***genetically modified laboratory guinea pig*** ins SL2011-26 s 20
def ***genetically modified laboratory mouse*** ins SL2008-17 s 31
def ***genetically modified laboratory rabbit*** ins SL2011-26 s 20
def ***genetically modified laboratory rat*** ins SL2008-17 s 31
def ***host*** ins SL2020-38 s 61
def ***host/vector system*** ins SL2020-38 s 61
def ***inclusion-negative*** om SL2008-17 s 32
def ***infectious agent*** ins SL2008-17 s 33
def ***inspector*** ins SL2011-26 s 20
def ***known*** ins SL2008-17 s 33
def ***non-conjugative plasmid*** ins SL2008-17 s 33
def ***non-vector system*** ins SL2008-17 s 33
def ***nucleic acid*** ins SL2008-17 s 33
def ***oncogenic modification*** ins SL2008-17 s 33
sub SL2011-26 s 21
def ***packaging cell line*** ins SL2008-17 s 33
def ***pathogenic*** ins SL2008-17 s 33
def ***pathogenic determinant*** ins SL2008-17 s 33
def ***plasmid*** ins SL2008-17 s 34
def ***recombinant*** om SL2008-17 s 35

def ***shotgun cloning*** sub SL2008-17 s 36
def ***toxin*** ins SL2008-17 s 37
def ***toxin-producing organism*** ins SL2008-17 s 37
am SL2020-38 s 62
def ***transduce*** ins SL2008-17 s 37
def ***vector*** ins SL2020-38 s 63

5 Earlier republications

Some earlier republications were not numbered. The number in column 1 refers to the publication order.

Since 12 September 2001 every authorised republication has been published in electronic pdf format on the ACT legislation register. A selection of authorised republications have also been published in printed format. These republications are marked with an asterisk (*) in column 1. Electronic and printed versions of an authorised republication are identical.

Republication No and date	Effective	Last amendment made by	Republication for
R1 5 June 2004	5 June 2004– 3 Nov 2004	not amended	new regulation
R2 4 Nov 2004	4 Nov 2004– 1 June 2005	not amended	editorial amendments under Legislation Act
R3 2 June 2005	2 June 2005– 5 June 2006	A2005-20	amendments by A2005-20
R4 6 June 2006	6 June 2006– 30 Apr 2008	A2005-20	commenced expiry
R5 1 May 2008	1 May 2008– 31 Aug 2011	SL2008-17	amendments by SL2008-17
R6 1 Sept 2011	1 Sept 2011– 20 Sept 2011	SL2011-26	amendments by SL2011-26
R7 21 Sept 2011	21 Sept 2011– 1 Sept 2013	A2011-28	amendments by A2011-28
R8 2 Sept 2013	2 Sept 2013– 14 June 2017	A2011-28	expiry of transitional provisions (pt 9)
R9 15 June 2017	15 June 2017– 13 Nov 2019	A2017-15	amendments by A2017-15
R10 14 Nov 2019	14 Nov 2019– 9 Sept 2020	A2019-42	amendments by A2019-42

6 Expired transitional or validating provisions

This Act may be affected by transitional or validating provisions that have expired. The expiry does not affect any continuing operation of the provisions (see *Legislation Act 2001*, s 88 (1)).

Expired provisions are removed from the republished law when the expiry takes effect and are listed in the amendment history using the abbreviation 'exp' followed by the date of the expiry.

To find the expired provisions see the version of this Act before the expiry took effect. The ACT legislation register has point-in-time versions of this Act.