Australian Capital Territory

Gene Technology Regulation 2004

SL2004-17

made under the

Gene Technology Act 2003

Republication No 7

Effective: 21 September 2011 – 1 September 2013

Republication date: 21 September 2011

Last amendment made by A2011-28

Authorised by the ACT Parliamentary Counsel

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 21 September 2011. It also includes any commencement, amendment, repeal or expiry affecting this republished law to 21 September 2011.

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 does not include 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 $110 for an individual and $550 for a corporation (see *Legislation Act 2001*, s 133).

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Contents

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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.

5 Organisms that are not genetically modified organisms

For the Act, dictionary, definition of ***genetically modified organism***, paragraph (e), an organism mentioned in schedule 1 is not a genetically modified 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) Australian Quarantine and Inspection Service;

(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 and Ageing.

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 (other than a dealing also 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 notifiable low risk dealing mentioned in schedule 3, part 3.1 or part 3.2; and

(c) the dealing undertaken is the dealing described in the institutional biosafety committee's record of assessment of the proposal; and

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

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

(f) the dealing is undertaken in facilities mentioned in the institutional biosafety committee's record of assessment as being appropriate for the dealing; and

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

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

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

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

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

(a) for a kind of dealing mentioned in 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, part 3.2—

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

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

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

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

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

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

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

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

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

13A Time limits for stopping notifiable low risk dealings

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

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

(b) 31 August 2016, if the dealing is assessed by an institutional biosafety committee in the period 31 March 2008 to 31 August 2011 (inclusive); and

(c) 31 March 2015, if the dealing is assessed by an institutional biosafety committee before 31 March 2008.

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

13B Requirements for institutional biosafety committees about records of assessments of notifiable low risk dealing proposals

An institutional biosafety committee that has assessed a proposal as to whether a dealing is a notifiable low risk dealing must—

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

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

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

(iii) its assessment whether the dealing is a notifiable low risk dealing mentioned in schedule 3, part 3.1 or part 3.2;

(iv) if the committee has assessed the dealing as being a notifiable low risk dealing mentioned in schedule 3, part 3.1 or part 3.2—the kind of notifiable low risk dealing that the dealing is, in terms of those parts;

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

(vi) the 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;

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

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

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

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

13C Information to be kept or given to the regulator by people or accredited organisations

(1) A person or an accredited organisation that has been given a copy of a record of assessment by an institutional biosafety committee must, if the dealing has been assessed by the committee as a notifiable low risk dealing, give the regulator a record of the proposed dealing, in the form approved by the regulator, that includes—

(a) the particulars, prescribed under section 39 (1) in relation to the dealing, to be included in the record of GMO and GM product dealings; and

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

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

(2) The record of the proposed dealing mentioned in subsection (1) must be given to the regulator in the financial year in which the institutional biosafety committee made the assessment—

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

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

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

(4) The regulator may at any time, by written notice, require from the following 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 and GM product dealings

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

(a) the name of the organisation proposing to undertake the notified dealing;

(b) the kind of notifiable low risk dealing proposed (described using the terms in schedule 3, part 3.1 or part 3.2);

(c) the identifying name given to the proposed undertaking by the organisation;

(d) the date of assessment by an institutional biosafety committee that the dealing is a notifiable low risk dealing.

(2) For the Act, section 138 (3), the following particulars are prescribed for a GM product mentioned in a designated notification:

(a) the name of the organisation producing the GM product;

(b) a description of the GM product, with reference to—

(i) whichever of the following Acts is applicable:

(A) *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cwlth);

(B) *Food Standards Australia New Zealand Act 1991* (Cwlth);

(C) *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth);

(D) *Therapeutic Goods Act 1989* (Cwlth); and

(ii) its common name as a product, or type or class of product;

Examples

1 bread

2 insulin

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(c) information about the GM product, including—

(i) the common name and the scientific name of the parent organism involved; and

(ii) details of the introduced trait in the GMO from which the GM product is derived; and

(iii) the identity of the introduced gene responsible for conferring the introduced trait;

(d) the date when a decision under the applicable Act that enables supply of the GM product in Australia takes effect;

(e) details of any conditions attaching to that permission.

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.

Part 9 Transitional—Gene Technology Amendment Regulation 2011 (No 1)

45 Transitional

(1) Subject to subsection (2) and despite anything in this regulation—

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

(b) a dealing that was a notifiable low risk dealing immediately before 1 September 2011 continues to be a notifiable low risk dealing under the Act, part 6, division 6.2 if the dealing is undertaken by the same person.

(2) Subsection (1) ceases to apply on the earlier of—

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

(b) 1 September 2012.

(3) Subject to subsection (4) and despite anything in this regulation, a dealing that was an exempt dealing immediately before 1 September 2011 continues to be an exempt dealing under the Act if the dealing is undertaken by the same person.

(4) Subsection (3) ceases to apply on the earlier of—

(a) the day on which the institutional biosafety committee assesses the dealing; and

(b) 1 September 2012.

(5) In this section:

licence means a licence under the Act, part 5.

46 Expiry—pt 9

This part expires on 1 September 2013.

Note Transitional provisions are kept with the original provisions for a limited time to ensure people are aware of them. However, the expiry of a transitional provision does not end its effect (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. *Note* An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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
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

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 part 2.2 and producing not more than 25L of GMO culture in each vessel containing the resultant culture. (2) The donor nucleic acid—

column 1 item	column 2 description of dealing

(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.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(b) must not code for a toxin with an LD50 of less than 100μg/kg; and

(c) must not code for a toxin with an LD50 of 100μg/kg or more, if the intention is to express the toxin at high levels; and

(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and

(e) must not include a viral sequence, unless the donor nucleic acid—

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

(A) is not available in the cell into which the nucleic acid is introduced; and

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

(ii) cannot restore replication competence to the vector.

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 part 2.2, item 1, 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

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	1 non-conjugative plasmids 2 bacteriophage— (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3 none (non-vector systems)
		Bacillus—specified species—asporogenic strains with a reversion frequency of less than 10^{-7}: (a) *B. amyloliquefaciens* (b) *B. licheniformis* (c) *B. pumilus* (d) *B. subtilis* (e) *B. thuringiensis*	1 non-conjugative plasmids 2 plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus* 3 none (non-vector systems)
		Pseudomonas putida—strain KT 2440	1 non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2 none (non-vector systems)

column 1 item	column 2 class	column 3 host	column 4 vector
		Streptomyces—specified species: (a) *S. aureofaciens* (b) *S. coelicolor* (c) *S. cyaneus* (d) *S. griseus* (e) *S. lividans* (f) *S. parvulus* (g) *S. rimosus* (h) *S. venezuelae*	1 non-conjugative plasmids 2 certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3 actinophage phi C31 and erivatives 4 none (non-vector systems)
		Agrobacterium radiobacter *Agrobacterium rhizogenes*—disarmed strains *Agrobacterium tumefaciens*—disarmed strains	1 non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2 none (non-vector systems)
		Lactobacillus *Lactococcus lactis* *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicata* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Streptococcus thermophilus* *Synechococcus*—specified strains: (a) PCC 7002	1 non-conjugative plasmids 2 none (non-vector systems)

column 1 item	column 2 class	column 3 host	column 4 vector
		(b) PCC 7942 (c) WH 8102 *Synechocystis* species—strain PCC 6803 *Vibrio cholerae* CVD103-HgR	
2	fungi	*Kluyveromyces lactis* *Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei* *Yarrowia lipolytica*	1 all vectors 2 none (non-vector systems)
3	slime moulds	*Dictyostelium* species	1 *dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2 none (non-vector systems)

column 1 item	column 2 class	column 3 host	column 4 vector
4	tissue culture	any of the following if they cannot spontaneously generate a whole animal: (a) animal or human cell cultures (including packaging cell lines) (b) isolated cells, isolated tissues or isolated organs, whether animal or human (c) early non-human mammalian embryos cultured *in vitro* either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures (b) isolated plant tissues or organs	1 non-conjugative plasmids 2 non-viral vectors, or replication defective viral vectors unable to transduce human cells 3 baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 4 none (non-vector systems) 1 non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens*, *Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2 non-pathogenic viral vectors 3 none (non-vector systems)

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.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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) (b) applies, in facilities certified to at least physical containment level 1 and that are appropriate for the dealings:

(a) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit or a genetically modified laboratory rat, unless—

(i) an advantage is conferred on the animal by the genetic modification; or

(ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification;

(c) a dealing involving a replication defective vector derived from *Human adenovirus* or *Adeno associated virus* in a host mentioned in schedule 2, part 2.2, item 4, if the donor nucleic acid—

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

(ii) does not—

(A) confer an oncogenic modification in humans; or

(B) encode a protein with immunomodulatory activity in humans.

Part 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) (b) applies, in facilities certified to at least physical containment level 2 and that are appropriate for the dealings:

(a) a dealing involving whole animals (including non-vertebrates) that—

(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and

(ii) does not involve any of the following:

(A) a genetically modified laboratory guinea pig;

(B) a genetically modified laboratory mouse;

(C) a genetically modified laboratory rabbit;

(D) a genetically modified laboratory rat;

(E) a genetically modified *Caenorhabditis elegans*;

(aa) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat or a genetically modified *Caenorhabditis elegans*, if—

(i) the genetic modification confers an advantage on the animal; and

(ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;

(b) a dealing involving a genetically modified plant;

(c) a dealing involving a host/vector system not mentioned in section 3.1 (c) or schedule 2, part 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 and vector not mentioned as a host/vector system in schedule 2, part 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 donor nucleic acid is characterised; and

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

Example

Donor nucleic acid would not comply with 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.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(e) a dealing involving a host/vector system mentioned in schedule 2, part 2.2, if the donor nucleic acid—

(i) encodes a pathogenic determinant; or

(ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy—

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi;

(f) a dealing involving a host/vector system mentioned in schedule 2, part 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.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in schedule 2, part 2.2, item 1, if the donor nucleic acid is derived from either—

(i) a pathogen; or

(ii) a toxin-producing organism;

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

(j) a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells, other than a dealing mentioned in section 3.1 (c), into a host mentioned in schedule 2, part 2.2 if the donor nucleic acid cannot restore replication competence to the vector;

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

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

(ii) the donor nucleic acid does not—

(A) confer an oncogenic modification in humans; or

(B) encode a protein with immunomodulatory activity in humans;

(l) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host mentioned in schedule 2, part 2.2 if—

(i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied *in trans*; and

(ii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iii) either—

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;

(m) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host not mentioned in schedule 2, part 2.2, if—

(i) the donor nucleic acid does not—

(A) confer an oncogenic modification in humans; or

(B) encode a protein with immunomodulatory activity in humans; and

(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied *in trans*; and

(iii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci

with minimal sequence overlap with the vector to limit or prevent recombination; and

(iv) either—

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these.

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

Any kind of dealing mentioned in this part involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 must be undertaken, unless section 13 (2) (c) or 13 (3) (b) applies, in facilities that are—

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

(b) appropriate for the dealing.

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 A dealing that is not a notifiable low risk dealing, or an exempt dealing, can only be undertaken by a person who is licensed, under the Act, for the dealing (see the Act, s 32).

3.3 Kinds of dealings

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing:

(a) a dealing (other than a dealing mentioned in section 3.2 (h)) involving cloning of nucleic acid encoding a toxin having an LD_{50} of less than 100μg/kg;

(b) a dealing involving high level expression of toxin genes, even if the LD_{50} is 100μg/kg 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 the introduction of a replication defective viral vector into a host not mentioned in schedule 2, part 2.2 other than a dealing mentioned in section 3.2 (i), if the donor nucleic acid—

(i) confers an oncogenic modification in humans; or

(ii) encodes a protein with immunomodulatory activity in humans;

(e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in schedule 2, part 2.2 if the donor nucleic acid—

(i) confers an oncogenic modification in humans; or

(ii) encodes a protein with immunomodulatory activity 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, part 2.2;

(B) the donor nucleic acid is characterised and its characterisation shows that it is unlikely to increase the capacity of the host or vector to cause harm;

(C) the dealing is a dealing mentioned in section 3.2 (g);

Example

Donor nucleic acid 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.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(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, part 2.2;

(h) a dealing involving the introduction into a micro-organism, other than a host mentioned in schedule 2, part 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.

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
- 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:

- Commonwealth Act
- deal with
- ethics and community committee
- exempt dealing
- gene technology
- genetically modified organism
- GMO
- GM product
- institutional biosafety committee
- 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, in relation to nucleic acid, means nucleic acid that has been sequenced and in relation to which there is an understanding of potential gene products or potential 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.

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 μg/kg.

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.

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))

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

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

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

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

Requirements in relation to notifying regulator of notifiable low risk dealings
s 13A ins SL2008-17 s 19
sub SL2011-26 s 8

Requirements for institutional biosafety committees about records of assessments of notifiable low risk dealing proposals
s 13B ins SL2011-26 s 8

Information to be kept or given to the regulator by people or accredited organisations
s 13C ins SL2011-26 s 8

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 and GM product dealings
s 39 am SL2008-17 s 21; SL2011-26 s 9, s 10

Transitional
pt 8 hdg om SL2008-17 s 22

Existing facilities—certification
s 41 om SL2008-17 s 22

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)

Techniques that are not gene technology
sch 1A ins SL2008-17 s 23

Organisms that are not genetically modified organisms

sch 1 sub SL2008-17 s 23
am SL2011-26 s 12

Dealings exempt from licensing

sch 2 sub SL2008-17 s 23
am SL2011-26 ss 13-16

Notifiable low risk dealings in relation to a GMO

sch 3 sub SL2008-17 s 23; SL2011-26 s 17

Prescribed information—application for licence

sch 4 om SL2008-17 s 23

Dictionary

dict am SL2008-17 s 24; SL2011-26 s 18
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
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 ***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
def ***transduce*** ins SL2008-17 s 37

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