Queensland

Gene Technology Act 2001

Gene Technology Regulation 2002

Current as at 25 November 2011

Information about this reprint

This reprint shows the legislation current as at the date on the cover and is authorised by the Parliamentary Counsel.

A new reprint of the legislation will be prepared by the Office of the Queensland Parliamentary Counsel when any change to the legislation takes effect. This change may be because a provision of the original legislation, or an amendment to it, commences or because a particular provision of the legislation expires or is repealed.

When a new reprint is prepared, this reprint will become a historical reprint. Also, if it is necessary to replace this reprint before a new reprint is prepared, for example, to include amendments with a retrospective commencement, an appropriate note would be included on the cover of the replacement reprint and on the copy of this reprint at www.legislation.qld.gov.au.

The endnotes to this reprint contain detailed information about the legislation and reprint. For example—

- The table of reprints endnote lists any previous reprints and, for this reprint, gives details of any discretionary editorial powers under the *Reprints Act 1992* used by the Office of the Queensland Parliamentary Counsel in preparing it.

- The list of legislation endnote gives historical information about the original legislation and the legislation which amended it. It also gives details of uncommenced amendments to this legislation. For information about possible amendments to the legislation by Bills introduced in Parliament, see the Queensland Legislation Current Annotations at www.legislation.qld.gov.au/Leg_Info/information.htm.

- The list of annotations endnote gives historical information at section level.

All Queensland reprints are dated and authorised by the Parliamentary Counsel. The previous numbering system and distinctions between printed and electronic reprints are not continued.

Queensland

Gene Technology Regulation 2002

Contents

Gene Technology Regulation 2002

[as amended by all amendments that commenced on or before 25 November 2011]

Part 1 Preliminary

1 Short title

This regulation may be cited as the *Gene Technology Regulation 2002*.

2 Commencement

Note—

Regulation 2 of the Commonwealth regulations provides when those regulations commence.

3 Definitions

The dictionary in schedule 5 defines particular words used in this regulation.

Note—

This section differs from regulation 3 of the Commonwealth regulations.

3A Numbering

(1) In order to maintain consistent numbering between this regulation and the Commonwealth regulations—

(a) if the Commonwealth regulations contain a regulation (***Commonwealth regulation***) that is not required in this regulation, the provision number and heading to the Commonwealth regulation is included in this regulation despite the omission of the body of the regulation; and

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

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

Note 1—

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

Note 2—

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

Note 3—

This section does not appear in the Commonwealth regulations.

3B Notes

Notes do not form part of this regulation.

Note—

This section does not appear in the Commonwealth regulations.

Part 2 Interpretation and general operation

4 Techniques not constituting gene technology

For the Act, schedule 3, definition *gene technology*, paragraph (c), gene technology does not include a technique mentioned in schedule 1A.

5 Organisms that are not genetically modified organisms

For the Act, schedule 3, definition *genetically modified organism*, paragraph (e), an organism mentioned in schedule 1 is declared not to be a genetically modified organism.

Part 3 Dealings with GMOs

Division 1 Licensing system

6 Dealings exempt from licensing

(1) For the Act, schedule 3, definition *exempt dealing*, a dealing, in relation to a GMO, is an exempt dealing if—

(a) it is a dealing of a kind mentioned in schedule 2, part 1; and

(b) it does not involve a genetic modification other than a modification mentioned in schedule 2, part 1; and

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

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

Note 1—

A dealing affected by this section may be any form of dealing mentioned in the definition *deal with* in schedule 3 of the Act.

Note 2—

Exemption from provisions of the Act does not preclude the application of another law of the State or a law of the Commonwealth or another State.

7 Application for licence—prescribed fee

Note 1—

At the commencement of this section, no application fee is prescribed under section 40(6) of the Act.

Note 2—

This section differs from regulation 7 of the Commonwealth regulations.

8 Time limit for deciding an application

(1) For section 43(3) of the Act, the period within which the regulator must issue, or refuse to issue, a licence is—

(a) for an application to which part 5, division 3 of the Act applies—90 days after the day on which the regulator receives the application; or

(b) for an application to which part 5, division 4 of the Act 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 on which the regulator receives the application; and

(ii) for a limited and controlled release application for which the regulator is satisfied that at least 1 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 on which the regulator receives the application; and

(iii) otherwise—255 days after the day on which the regulator receives the application.

(2) For deciding the end of a period mentioned in subsection (1), each of the following days are not counted—

(a) a Saturday, Sunday or public holiday in the Australian Capital Territory;

(b) a day on which the regulator can not proceed with the decision-making process or a related function because the regulator is awaiting information the applicant has been requested, in writing, to give;

(c) if the regulator, under section 53 of the Act, publishes notice of a public hearing about the application, 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 on which the regulator can not proceed with the decision-making process or a related function because—

(i) the applicant has made a section 184 application; and

(ii) the regulator is either—

(A) considering the section 184 application; or

(B) waiting until any review rights under section 181 or 183 of the Act, for the section 184 application, are exhausted;

(e) if the regulator requests the ethics and community committee to provide advice on an ethical issue relating to the application, 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 when the advice is given or, if the advice is not given within a period stated under the subsection, on the last day of the period.

(3) When seeking advice under section 50(3) or 52(3) of the Act, or advice from the ethics and community committee, the regulator—

(a) may state a reasonable period within which the advice must be received; and

(b) if the advice is not received within the stated 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 section 50A of the Act applies.

section 184 application means an application, under section 184 of the Act, for a declaration that information given about the applicant's licence application is confidential commercial information.

9 Prescribed authorities

For sections 50(3)(c) and 52(3)(c) of the Act, each of 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;

(e) Australian Pesticides and Veterinary Medicines Authority;

(f) Therapeutic Goods Administration, Department of Health and Aged Care.

9A Risks posed by dealings proposed to be authorised by licence

For section 51(1)(a) of the Act, 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

(1) For section 51(1)(d) and (2)(d) of the Act, other matters to be taken into account for dealings proposed to be authorised by a licence include—

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

(b) the potential of the GMO to do any or all of the following—

(i) harm other organisms;

(ii) adversely affect any ecosystems;

(iii) transfer genetic material to another organism;

(iv) spread or persist in the environment;

(v) have an advantage in the environment;

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

(2) The regulator must also consider each of the following—

(a) in taking into account a risk mentioned in section 51(1)(a) of the Act—the risk for both the short term and the long term;

(b) in taking into account a potential capacity mentioned in subsection (1)(b)—the potential capacity for 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 section 61(b) of the Act.

11A Time limit for deciding variation application

(1) For section 71(7) of the Act, 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 in the Australian Capital Territory;

(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 2 Notifiable low risk dealings

12 Notifiable low risk dealings

(1) For section 74(1) of the Act, 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 1 or 2 (other than a dealing of a kind also mentioned in schedule 3, part 3); and

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

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

Note 1—

A dealing affected by this section may be any form of dealing mentioned in the definition *deal with* in schedule 3 of the Act.

Note 2—

See section 11 of the Act for the definition of *intentional release of the GMO into the environment*.

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 1 or 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 paragraph (e) if the person is in a class of persons 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 paragraph (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 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 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 section 27(d) of the Act; or

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

(4) For subsection (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) and (3)(a), 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 section.

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 1 or 2;

(iv) if the committee has assessed the dealing as being a notifiable low risk dealing mentioned in schedule 3, part 1 or 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 persons or classes of persons 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 persons 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 persons or organisations further 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 Certification and accreditation

14 Regulator to decide certification application within 90 days

Note—

Regulation 14 of the Commonwealth regulations states the period within which the regulator must consider and decide an application for certification of a facility.

15 Application for certification—failure to provide section 85 information

Note 1—

Regulation 15 of the Commonwealth regulations states that the regulator may refuse to certify a facility if the applicant fails, without reasonable explanation, to provide information requested under section 85 of the Commonwealth Act.

Note 2—

A refusal to certify a facility is a reviewable decision (see part 12, division 2 of the Act).

16 Regulator to decide accreditation application within 90 days

Note—

Regulation 16 of the Commonwealth regulations states the period within which the regulator must consider and decide an application for accreditation of an organisation.

17 Application for accreditation—failure to provide section 93 information

Note 1—

Regulation 17 of the Commonwealth regulations states that the regulator may refuse to accredit an organisation if the applicant fails, without reasonable explanation, to provide information requested under section 93 of the Commonwealth Act.

Note 2—

A refusal to accredit an organisation is a reviewable decision (see part 12, division 2 of the Act).

Part 4 Gene technology technical advisory committee

Division 1 Conditions of appointment

18 GTTAC members and advisers—term of appointment

Note—

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

19 GTTAC members and advisers—resignation

Note—

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

20 GTTAC members—disclosure of interests

Note—

Regulation 20 of the Commonwealth regulations states when and how members of the gene technology technical advisory committee must disclose an interest in a matter of a kind likely to be considered by the committee.

21 GTTAC members and advisers—termination of appointment

Note—

Regulation 21 of the Commonwealth regulations states the circumstances in which the appointment of members of, and expert advisers to, the gene technology technical advisory committee may be terminated.

22 GTTAC members—leave of absence

Note—

Regulation 22 of the Commonwealth regulations provides for leave of absence of the chairperson and members of the gene technology technical advisory committee.

23 Expert advisers—disclosure of interests

Note—

Regulation 23 of the Commonwealth regulations states when and how expert advisers to the gene technology technical advisory committee must disclose an interest in a matter of a kind likely to be considered by the committee.

Division 2 Committee procedures

24 Committee procedures generally

Note—

Regulation 24 of the Commonwealth regulations provides for the gene technology technical advisory committee to perform its functions

informally and quickly and states how the committee may obtain information.

25 Committee meetings

Note—

Regulation 25 of the Commonwealth regulations states when and how meetings of the gene technology technical advisory committee may be held.

26 Presiding member

Note—

Regulation 26 of the Commonwealth regulations provides for a presiding member at meetings of the gene technology technical advisory committee.

27 Quorum

Note—

Regulation 27 of the Commonwealth regulations provides for a quorum for the gene technology technical advisory committee.

28 Voting

Note—

Regulation 28 of the Commonwealth regulations provides for the making of decisions of the gene technology technical advisory committee.

29 Records and reports

Note—

Regulation 29 of the Commonwealth regulations provides for the keeping of records of the gene technology technical advisory committee's proceedings and preparation of reports about the committee's activities.

Division 3 Subcommittees

30 Operation of subcommittees

Note—

Regulation 30 of the Commonwealth regulations states that regulations 24 to 26 and 28 of the Commonwealth regulations apply to a subcommittee established under section 105(1) of the Commonwealth Act.

Part 5 Ethics and community committee

31 Ethics and community committee—conditions of appointment

Note—

Regulation 31 of the Commonwealth regulations states that part 4, division 1 of the Commonwealth regulations applies to the conditions of appointment of a member of the ethics and community committee, or an expert adviser.

32 Ethics and community committee—consultative committee procedures

Note—

Regulation 32 of the Commonwealth regulations states that part 4, division 2 of the Commonwealth regulations applies to the procedures of the ethics and community committee.

33 Ethics and community committee—operation of subcommittees

Note—

Regulation 33 of the Commonwealth regulations states that regulations 24 to 26 and 28 of the Commonwealth regulations apply to a subcommittee established under section 111(1) of the Commonwealth Act.

Part 7 Miscellaneous

37 Reviewable State decisions

Note—

At the commencement of this regulation, no decision has been declared under the Commonwealth Act to be a reviewable State decision mentioned in section 19 of the Act.

38 Review of decisions

Note—

Regulation 38 of the Commonwealth regulations deals with review of decisions about the termination of appointment of members of the gene technology technical advisory committee, or an expert adviser.

39 Record of GMO and GM product dealings

(1) For section 138(2)(b) of the Act, 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 dealing;

(b) with reference to the kinds of dealing mentioned in schedule 3, parts 1 and 2, the kind of notifiable low risk dealing proposed;

(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 section 138(3) of the Act, the following information is 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) the applicable Act; and

(ii) the GM product's common name as a product, or type or class of product;

Examples for subparagraph (ii)—

1 bread

2 insulin

(c) the following information about the GM product—

(i) the common and scientific names of any organism from which the GM product is derived or produced;

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

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

(d) the date on which a decision under the applicable Act, that permits supply of the GM product in Australia, takes effect;

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

(3) In this section—

applicable Act means the applicable Act under regulation 39 of the Commonwealth regulations.

designated notification has the meaning given by section 138(6) of the Act.

Note—

This section differs from regulation 39 of the Commonwealth regulations.

40 Inspector identity card

Note—

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

Part 8 Transitional provision for Gene Technology Amendment Regulation (No. 1) 2007

41 Transitional provision for notifiable low risk dealings carried on by same person

(1) The purpose of this section is to enable a person (the ***affected person***) who conducted a relevant dealing before 31 March 2007 to apply for a GMO licence for the relevant dealing.

(2) Subject to subsection (3), the relevant dealing continues to be a notifiable low risk dealing under the Act, part 6, division 2 if the dealing is carried on by the affected person.

(3) Subsection (2) stops applying to the affected person on the earlier of the following—

(a) the day on which a GMO licence is issued to the affected person for the relevant dealing;

(b) 31 March 2008.

(4) In this section—

relevant dealing means a dealing that—

(a) was a notifiable low risk dealing before 31 March 2007; and

(b) is now a dealing requiring a GMO licence.

Note 1—

This section differs from regulation 4 of the *Gene Technology Amendment Regulations 2006 (No. 1)* (Cwlth).

Note 2—

This part does not appear in the Commonwealth regulations.

Part 9 Transitional provision for Gene Technology Amendment Regulation (No. 1) 2011

42 Transitional provision for particular dealings

(1) The first purpose of this section is to provide the opportunity to apply for a licence to a person who was undertaking 1 of the following kinds of dealings before the commencement that now requires a licence—

(a) an exempt dealing;

(b) a notifiable low risk dealing.

(2) Subject to subsection (3), despite the amendments made to schedules 2 and 3 by the *Gene Technology Amendment Regulation (No. 1) 2011*—

(a) a dealing that was an exempt dealing immediately before the commencement 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 the commencement continues to be a notifiable low risk dealing under part 6, division 2 of the Act if the dealing is undertaken by the same person.

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

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

(b) 1 September 2012.

(4) The second purpose of this section is to provide the opportunity to a person who was undertaking a dealing before the commencement, that was then an exempt dealing but that is now likely to be a notifiable low risk dealing, to have a proposal assessed by an institutional biosafety committee as to whether the dealing is a notifiable low risk dealing.

(5) Subject to subsection (6), despite the amendments made to schedules 2 and 3 by the *Gene Technology Amendment Regulation (No. 1) 2011*, a dealing mentioned in subsection (4) that was an exempt dealing immediately before the commencement continues to be an exempt dealing under the Act if the dealing is undertaken by the same person.

(6) Subsection (5) ceases to apply on the earlier of—

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

(b) 1 September 2012.

Note—

This section does not appear in the Commonwealth regulations, but see the *Gene Technology Amendment Regulations 2011 (No. 1) (Cwlth),* section 4.

(7) In this section—

commencement means the commencement of this section.

Schedule 1A Techniques that are not gene technology

section 4

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 of a natural process for item 10—

- conjugation
- transduction
- transformation
- transposon mutagenesis

Schedule 1 Organisms that are not genetically modified organisms

section 5

1 A mutant organism in which the mutational event did not involve the introduction of foreign nucleic acid (that is, non-homologous DNA, usually from another species).

2 A whole animal, or human being, modified by the introduction of naked recombinant nucleic acid (for example, 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 resulting 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 resulting from an exchange of DNA between the donor species and the host species if—

(a) the exchange can happen 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; 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 an organism other than an organism involved in the exchange.

Schedule 2 Dealings exempt from licensing

section 6(1)(a) and (b)

Note—

Section 6(1) states other requirements for exempt dealings.

Part 1 Exempt dealings

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 (2), a dealing involving a host/vector system mentioned in part 2 of this schedule and producing no more than 25L of GMO culture in each vessel containing the resultant culture.

4(2) The donor nucleic acid—

(a) must meet either of the following requirements—

(i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy—

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi;

(ii) it must be characterised and the information derived from its characterisation must show that it is unlikely to increase the capacity of the host or vector to cause harm; and

Example—

Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it—

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility.

(b) must not code for a toxin with an LD_{50} of less than 100µg/kg; and

(c) must not code for a toxin with an LD_{50} 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.

5 A dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in part 2, item 1 of this schedule if the donor nucleic acid is not derived from—

(a) a pathogen; or

(b) a toxin-producing organism.

Part 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 or *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 (for example, 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 another pathogenic strain of *Bacillus* 3 none (non-vector systems)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector	
		Pseudomonas putida—strain KT 2440	1	non-conjugative plasmids including certified plasmids—pKT 262, pKT 263, pKT 264
			2	none (non-vector systems)
		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 derivatives
			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)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
		Lactobacillus Lactococcus lactis	1 non-conjugative plasmids
		Oenoccus oeni syn. *Leuconostoc oeni*	2 none (non-vector systems)
		Pediococcus	
		Photobacterium angustum	
		Pseudoalteromonas tunicata	
		Rhizobium (including the genus *Allorhizobium)*	
		Sphingopyxis alaskensis syn.	
		Sphingomonas alaskensis	
		Streptococcus thermophilus	
		Synechococcus—specified strains: (a) PCC 7002; (b) PCC 7942; (c) WH 8102	
		Synechocystis species—strain PCC 6803	
		Vibrio cholerae CVD103-HgR	

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector	
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*	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)
		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-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)

Schedule 3 Notifiable low risk dealings in relation to a GMO

sections 12 and 13

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

Note—

Under section 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.

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

The following kinds of notifiable low risk dealings may be conducted, unless section 13(2)(c) or (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, 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 2 Notifiable low risk dealings suitable for at least physical containment level 2 or 3

Note—

Under section 12(1), a dealing mentioned in this part is not a notifiable low risk dealing if it is also mentioned in part 3.

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

The following kinds of notifiable low risk dealings may be conducted, unless section 13(2)(c) or (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 1.1(c) or schedule 2, part 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, 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 subparagraph (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, part 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 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 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 paragraph (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, part 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, 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 1.1(c) or into a host mentioned in schedule 2, part 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, 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, 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, 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.

2.2 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 conducted, unless section 13(2)(c) or (3)(b) applies, in facilities that are—

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

(b) appropriate for the dealing.

Part 3 Dealings that are not notifiable low risk dealings

Notes—

1 The following list qualifies the list in parts 1 and 2 and is not an exhaustive list of dealings that are not notifiable low risk dealings.

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

3.1 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 2.1(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 2.1(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, other than a dealing mentioned in section 2.1(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, 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 subsubparagraphs apply—

(A) the host/vector system is a system mentioned in schedule 2, part 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 2.1(g);

Example—

Donor nucleic acid would not comply with sub subparagraph (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 2.1(g); or

(ii) the micro organism is a host mentioned in schedule 2, part 2;

(h) a dealing involving the introduction into a micro organism, other than a host mentioned in schedule 2, part 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 paragraph (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 2.1(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 2.1(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 subsubparagraph (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.

Schedule 5 Dictionary

section 3

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

animal means an animal other than a human.

AS/NZS means a joint Standards Australia and Standards New Zealand standard.

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.

characterised, for nucleic acid, means—

(a) the nucleic acid has been sequenced; and

(b) there is an understanding of potential gene products of the nucleic acid.

code, for a toxin or other product, means specify the amino acid sequence of the toxin or other product.

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

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.

IBC means an institutional biosafety committee.

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

known means known within the scientific community.

licence means a GMO licence.

non-conjugative plasmid, for schedule 2, part 2, means a plasmid that is not self-transmissible, and includes, but is not limited to, a non-conjugative form of a following plasmid—

(a) a bacterial artificial chromosome (BAC);

(b) a cosmid;

(c) a P1 artificial chromosome (PAC);

(d) a yeast artificial chromosome (YAC).

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

Example—

the use of electroporation or particle bombardment

(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.

Example—

cells that were transduced with a replication defective retroviral vector in which no vector particles remain

nucleic acid means DNA or RNA, or both DNA and 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 containing 1 or more 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, for an organism, means having the capacity to cause disease or abnormality.

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

physical containment level, followed by a numeral, means a containment level stated in guidelines for the certification of facilities issued under section 90 of the Act.

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

recombinant, for matter that is a sequence or an organism, means matter of a kind containing recombinant DNA.

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 a vertebrate.

toxin-producing organism means an organism producing toxin with an LD_{50} of less than 100μg/kg.

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

1 Index to endnotes

2 Key

Key to abbreviations in list of legislation and annotations

Key		Explanation	Key		Explanation
AIA	=	**Acts Interpretation Act 1954**	**(prev)**	=	**previously**
amd	=	**amended**	**proc**	=	**proclamation**
amdt	=	**amendment**	**prov**	=	**provision**
ch	=	**chapter**	**pt**	=	**part**
def	=	**definition**	**pubd**	=	**published**
div	=	**division**	**R[X]**	=	**Reprint No. [X]**
exp	=	**expires/expired**	**RA**	=	**Reprints Act 1992**
gaz	=	**gazette**	**reloc**	=	**relocated**
hdg	=	**heading**	**renum**	=	**renumbered**
ins	=	**inserted**	**rep**	=	**repealed**
lap	=	**lapsed**	**(retro)**	=	**retrospectively**
notfd	=	**notified**	**rv**	=	**revised version**
num	=	**numbered**	**s**	=	**section**
o in c	=	**order in council**	**sch**	=	**schedule**
om	=	**omitted**	**sdiv**	=	**subdivision**
orig	=	**original**	**SIA**	=	**Statutory Instruments Act 1992**
p	=	**page**	**SIR**	=	**Statutory Instruments Regulation 2012**
para	=	**paragraph**	**SL**	=	**subordinate legislation**
prec	=	**preceding**	**sub**	=	**substituted**
pres	=	**present**	**unnum**	=	**unnumbered**
prev	=	**previous**			

3 Table of reprints

A new reprint of the legislation is prepared by the Office of the Queensland Parliamentary Counsel each time a change to the legislation takes effect.

The notes column for this reprint gives details of any discretionary editorial powers under the

Reprints Act 1992

used by the Office of the Queensland Parliamentary Counsel in preparing it. Section 5(c) and (d) of the Act are not mentioned as they contain mandatory requirements that all amendments be included and all necessary consequential amendments be incorporated, whether of punctuation, numbering or another kind. Further details of the use of any discretionary editorial power noted in the table can be obtained by contacting the Office of the Queensland Parliamentary Counsel by telephone on 3003 9601 or email legislation.queries@oqpc.qld.gov.au.

From 29 January 2013, all Queensland reprints are dated and authorised by the Parliamentary Counsel. The previous numbering system and distinctions between printed and electronic reprints is not continued with the relevant details for historical reprints included in this table.

Reprint No.	Amendments included	Effective	Notes
1	none	26 July 2002	
1A	2007 SL No. 45	31 March 2007	
1B	2008 SL No. 109	2 May 2008	R1B withdrawn, see R2
2	—	2 May 2008	
2A	2011 SL No. 232	25 November 2011	

4 List of legislation

Gene Technology Regulation 2002 No. 189
made by the Governor in Council on 25 July 2002
notfd gaz 26 July 2002 pp 1212–13
commenced on date of notification
exp 31 August 2017 (see SIA s 56(1) and SIR s 4 sch 2 pt 1)
Note—The expiry date may have changed since this reprint was published. See the latest reprint of the SIR for any change.
amending legislation—

Gene Technology Amendment Regulation (No. 1) 2007 SL No. 45
notfd gaz 30 March 2007 pp 1483–4

ss 1–2 commenced on date of notification
remaining provisions commenced 31 March 2007 (see s 2)

Gene Technology Amendment Regulation (No. 1) 2008 SL No. 109
notfd gaz 2 May 2008 pp 164–5
commenced on date of notification

Gene Technology Amendment Regulation (No. 1) 2011 SL No. 232
notfd gaz 25 November 2011 pp 603–6
commenced on date of notification

5 List of annotations

Techniques not constituting gene technology
s 4 amd 2007 SL No. 45 s 4

Organisms that are not genetically modified organisms
s 5 amd 2007 SL No. 45 s 5

Dealings exempt from licensing
s 6 amd 2007 SL No. 45 s 6; 2008 SL No. 109 s 3; 2011 SL No. 232 s 3

Application for licence—prescribed fee
s 7 sub 2007 SL No. 45 s 7

Time limit for deciding an application
s 8 amd 2008 SL No. 109 s 4

Prescribed authorities
s 9 amd 2007 SL No. 45 s 8; 2008 SL No. 109 s 5

Risks posed by dealings proposed to be authorised by licence
s 9A ins 2008 SL No. 109 s 6

Risk assessment—matters to be taken into account
s 10 amd 2007 SL No. 45 s 9

Time limit for deciding variation application
s 11A ins 2008 SL No. 109 s 7
sub 2011 SL No. 232 s 4

Notifiable low risk dealings
s 12 amd 2008 SL No. 109 s 8

Requirements for undertaking notifiable low risk dealings
s 13 sub 2007 SL No. 45 s 10; 2008 SL No. 109 s 9; 2011 SL No. 232 s 5

Time limits for stopping notifiable low risk dealings
s 13A ins 2008 SL No. 109 s 9
sub 2011 SL No. 232 s 5

Requirements for institutional biosafety committees about records of assessments of notifiable low risk dealing proposals
s 13B ins 2011 SL No. 232 s 5

Information to be kept or given to the regulator by persons or accredited organisations
s 13C ins 2011 SL No. 232 s 5

PART 5—ETHICS AND COMMUNITY COMMITTEE
pt 5 (ss 31–33) sub 2008 SL No. 109 s 10

PART 6—GENE TECHNOLOGY ETHICS COMMITTEE
pt 6 (ss 34–36) om 2008 SL No. 109 s 11

Review of decisions
s 38 amd 2008 SL No. 109 s 12

Record of GMO and GM product dealings
s 39 amd 2007 SL No. 45 s 11; 2008 SL No. 109 s 13; 2011 SL No. 232 s 6

PART 8—TRANSITIONAL PROVISION FOR GENE TECHNOLOGY AMENDMENT REGULATION (NO. 1) 2007
pt hdg sub 2007 SL No. 45 s 12

Transitional provision for notifiable low risk dealings carried on by same person
s 41 sub 2007 SL No. 45 s 12

PART 9—TRANSITIONAL PROVISION FOR GENE TECHNOLOGY AMENDMENT REGULATION (No. 1) 2011
pt 9 (s 42) ins 2011 SL No. 232 s 7

Existing organisations—accreditation
s 42 om 2007 SL No. 45 s 12

SCHEDULE 1A—TECHNIQUES THAT ARE NOT GENE TECHNOLOGY
ins 2007 SL No. 45 s 13

SCHEDULE 1—ORGANISMS THAT ARE NOT GENETICALLY MODIFIED ORGANISMS
sub 2007 SL No. 45 s 13
amd 2011 SL No. 232 s 8

SCHEDULE 2—DEALINGS EXEMPT FROM LICENSING
sub 2007 SL No. 45 s 13

PART 1—EXEMPT DEALINGS
pt 1 amd 2008 SL No. 109 s 14(1)–(4); 2011 SL No. 232 s 9

PART 2—HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS
pt 2 amd 2008 SL No. 109 s 14(5)
sub 2011 SL No. 232 s 10

SCHEDULE 3—NOTIFIABLE LOW RISK DEALINGS IN RELATION TO A GMO

sch hdg sub 2007 SL No. 45 s 13; 2011 SL No. 232 s 11

PART 1—NOTIFIABLE LOW RISK DEALINGS SUITABLE FOR AT LEAST PHYSICAL CONTAINMENT LEVEL 1

pt hdg ins 2008 SL No. 109 s 15(2)
sub 2011 SL No. 232 s 11
pt 1 note sub 2011 SL No. 232 s 11

Kinds of dealings suitable for at least physical containment level 1

s 1.1 ins 2008 SL No. 109 s 15(2)
sub 2011 SL No. 232 s 11

PART 2—NOTIFIABLE LOW RISK DEALINGS SUITABLE FOR AT LEAST PHYSICAL CONTAINMENT LEVEL 2 OR 3

pt hdg sub 2007 SL No. 45 s 13
renum 2008 SL No. 109 s 15(1)
sub 2008 SL No. 109 s 15(3)
sub 2011 SL No. 232 s 11
pt 2 note amd 2008 SL No. 109 s 15(4)
sub 2011 SL No. 232 s 11

Kinds of dealings suitable for at least physical containment level 2

s 2.1 (prev s 1.1) sub 2007 SL No. 45 s 13
renum 2008 SL No. 109 s 15(5)
amd 2008 SL No. 109 s 15(6)–(8)
sub 2011 SL No. 232 s 11

Kinds of dealings suitable for at least physical containment level 3

s 2.2 sub 2011 SL No. 232 s 11

PART 3—DEALINGS THAT ARE NOT NOTIFIABLE LOW RISK DEALINGS

pt hdg prev pt 3 hdg om 2007 SL No. 45 s 13
pres pt 3 hdg (prev pt 2 hdg) renum 2008 SL No. 109 s 15(1)
sub 2011 SL No. 232 s 11
pt 3 note amd 2008 SL No. 109 s 15(9)
sub 2011 SL No. 232 s 11

Kinds of dealings

s 3.1 prev s 3.1 om 2007 SL No. 45 s 13
pres s 3.1 (prev s 2.1) renum 2008 SL No. 109 s 15(10)
amd 2008 SL No. 109 s 15(11)–(16)
sub 2011 SL No. 232 s 11

Additional information if GMO is a whole plant or is to be used in conjunction with a whole plant

s 3.2 om 2007 SL No. 45 s 13

Supporting information from IBC for a proponent

s 3.3 om 2007 SL No. 45 s 13

SCHEDULE 4—PRESCRIBED INFORMATION FOR APPLICATION FOR A LICENCE
om 2007 SL No. 45 s 13

SCHEDULE 5—DICTIONARY
def ***advantage*** amd 2007 SL No. 45 s 14(3)
def ***advice to proceed*** om 2007 SL No. 45 s 14(1)
def ***AS/NZS*** ins 2007 SL No. 45 s 14(2)
def ***AS/NZS 2243.3:2010*** ins 2011 SL No. 232 s 12(2)
def ***characterised*** amd 2007 SL No. 45 s 14(4)
def ***code*** sub 2007 SL No. 45 s 14(1)–(2)
def ***competitive advantage*** om 2008 SL No. 109 s 16
def ***division 3 application*** om 2007 SL No. 45 s 14(1)
def ***division 4 application*** om 2007 SL No. 45 s 14(1)
def ***gene-knockout mice*** om 2008 SL No. 109 s 16
def ***genetically modified laboratory guinea pig*** ins 2011 SL No. 232 s 12(2)
def ***genetically modified laboratory mouse*** ins 2007 SL No. 45 s 14(2)
def ***genetically modified laboratory rabbit*** ins 2011 SL No. 232 s 12(2)
def ***genetically modified laboratory rat*** ins 2007 SL No. 45 s 14(2)
def ***genetic manipulation advisory committee*** om 2007 SL No. 45 s 14(1)
def ***inclusion-negative*** om 2008 SL No. 109 s 16
def ***infectious agent*** ins 2007 SL No. 45 s 14(2)
def ***known*** ins 2007 SL No. 45 s 14(2)
def ***non-conjugative plasmid*** ins 2007 SL No. 45 s 14(2)
def ***non-vector system*** ins 2007 SL No. 45 s 14(2)
sub 2011 SL No. 232 s 12(1)–(2)
def ***nucleic acid*** ins 2007 SL No. 45 s 14(2)
def ***oncogenic modification*** ins 2007 SL No. 45 s 14(2)
sub 2011 SL No. 232 s 12(1)–(2)
def ***packaging cell line*** ins 2007 SL No. 45 s 14(2)
def ***pathogenic*** ins 2007 SL No. 45 s 14(2)
def ***pathogenic determinant*** ins 2007 SL No. 45 s 14(2)
def ***plasmid*** ins 2007 SL No. 45 s 14(2)
def ***selective advantage*** om 2008 SL No. 109 s 16
def ***shotgun cloning*** amd 2007 SL No. 45 s 14(5)–(6)
def ***toxin*** ins 2007 SL No. 45 s 14(2)
def ***toxin-producing organism*** ins 2007 SL No. 45 s 14(2)
def ***transduce*** ins 2007 SL No. 45 s 14(2)