Australian Capital Territory

Gene Technology Regulation 2004

SL2004-17

made under the

Gene Technology Act 2003

Republication No 5
Effective: 1 May 2008 – 31 August 2011

Republication date: 1 May 2008

Last amendment made by SL2008-17

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 1 May 2008. It also includes any amendment, repeal or expiry affecting the republished law to 1 May 2008.

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 or is affected by an uncommenced amendment, the symbol **U** appears immediately before the provision heading. The text of the uncommenced provision or amendment appears only in the last endnote.

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 *Legislation Act 2001*, section 95.

Penalties

The value of a penalty unit for an offence against this republished law at the republication date is—

(a) if the person charged is an individual—$100; or

(b) if the person charged is a corporation—$500.

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Contents

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

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Australian Capital Territory

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Gene Technology Act 2003

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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.

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(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***).

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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.

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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.

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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; and

(e) it does not involve a retroviral vector that is able to transduce human cells.

(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—

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(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 in the ACT;

(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;

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(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.

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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.

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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)

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.

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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 (other than a dealing also mentioned in schedule 3, part 3.2); 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 in relation to 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 requested an institutional biosafety committee to assess whether the proposed dealing is a notifiable low risk dealing; and

(b) the committee has assessed the proposed dealing to be a notifiable low risk dealing; and

(c) the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the committee—

(i) has assessed the proposed dealing to be a notifiable low risk dealing; and

(ii) considers that the personnel to be involved in the proposed dealing have appropriate training and experience.

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(2) A notifiable low risk dealing must comply with the following requirements:

(a) the dealing must be conducted—

(i) for a kind of dealing mentioned in schedule 3, part 3.1—in a facility that is certified by the regulator to at least physical containment level 1 and is of appropriate design for the kind of dealing being undertaken; or

(ii) for a kind of dealing mentioned in schedule 3, part 3.2—in a facility that is certified by the regulator to at least physical containment level 2 and is of appropriate design for the kind of dealing being undertaken; or

(iii) in another facility in accordance with any technical and procedural guidelines relating to containment of GMOs, as in force from time to time under the Act, section 27 (d) that the regulator has determined in writing are appropriate for conducting the dealing;

(b) to the extent that the dealing involves transporting a GMO, the transporting must be conducted in accordance with applicable technical and procedural guidelines, as in force from time to time under the Act, section 27 (d).

13A Requirements in relation to notifying regulator of notifiable low risk dealings

(1) An institutional biosafety committee that has assessed a proposed dealing to be a notifiable low risk dealing must—

(a) make a record of the proposed dealing in a form approved by the regulator; and

(b) if the regulator, by written notice given to the committee, requests a copy of the record—give a copy of the record to the regulator by the end of the period mentioned in the notice; and

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(c) give a copy of the record to—

(i) the person or accredited organisation that requested the committee to assess the proposed dealing; and

(ii) the project supervisor for the proposed dealing.

(2) The person or accredited organisation must—

(a) for the financial year in which the committee assessed the proposed dealing, include a copy of the committee's record—

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

(ii) in any other case—in a report given to the regulator, in the form approved by the regulator, by the person for the financial year; and

(b) retain a copy of the committee's record for 3 years after the date that the person or accredited organisation ceased to be involved with the conduct of the dealing.

(3) The regulator may, by written notice, require—

(a) the committee; or

(b) the person or accredited organisation; or

(c) any other person involved with the conduct of the proposed dealing;

to give the regulator any further information about the dealing that the regulator requires in order to be satisfied that the dealing is a notifiable low risk dealing.

(4) A committee, person or accredited organisation receiving a notice under subsection (3) must, by the end of the period mentioned in the notice, give the regulator the information required by the notice.

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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).

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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.

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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.

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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).

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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).

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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);

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

(d) the date of the notification.

(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;

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(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.

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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.

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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).

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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 2243.3:2002 (Safety in laboratories, Part 3: Microbiological aspects and containment facilities) jointly published by Standards Australia and Standards New Zealand, 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

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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
4	a dealing involving a host/vector system mentioned in part 2.2 and producing not more than 10 litres of GMO culture in each vessel containing the resultant culture if the donor nucleic acid— (a) is— (i) not derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi; or (ii) characterised and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; and (b) does not code for a toxin with an LD50 of less than 100μg/kg; and

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column 1 item	column 2 description of dealing
	(c) does 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) is not an 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) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and
	(f) does not confer an oncogenic modification
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

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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 or *E. coli* C—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)

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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)

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column 1 item	column 2 class	column 3 host	column 4 vector
		Lactobacillus *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Vibrio cholerae* CVD103-HgR	1 non-conjugative plasmids 2 none (non-vector systems)
2	fungi	*Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Kluyveromyces lactis* *Trichoderma reesei*	1 all vectors 2 none (non-vector systems)

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column 1 item	column 2 class	column 3 host	column 4 vector
3	slime moulds	*Dictyostelium* species	1 *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
			2 none (non-vector systems)
4	tissue culture	animal or human cell cultures (including packaging cell lines)	1 non-conjugative plasmids
			2 non-viral vectors, or defective viral vectors (other than a retroviral vector that is able to transduce human cells)
			3 avipox vectors (attenuated vaccine strains)
			4 baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus
			5 none (non-vector systems)
		plant cell cultures	1 non-tumorigenic disarmed Ti plasmid vectors, or

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column 1 item	column 2 class	column 3 host	column 4 vector
			Ri plasmid vectors, in *Agrobacterium tumefaciens*, *Agrobacterium radiobacter* or *Agrobacterium rhizogenes*
			2 non-pathogenic viral vectors
			3 none (non-vector systems)

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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 by which donor nucleic acid is introduced (for example, by electroporation or particle bombardment) into a host in the absence of a nucleic acid-based vector (for example, a plasmid, viral vector or transposon).

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).

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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 physical containment level 1

Note For this part, because of s 12 (1), a dealing mentioned in this part is not a notifiable risk dealing if it is also a dealing of a kind mentioned in this schedule, pt 3.3.

3.1 Kinds of dealings

The following kinds of notifiable low risk dealings may be conducted in physical containment level 1 facilities:

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

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

(ii) because of the genetic modification, the animal is capable of secreting or producing an infectious agent;

(b) a dealing involving a host/vector system mentioned in schedule 2, part 2.2, if the donor nucleic acid confers an oncogenic modification;

(c) a dealing involving a defective viral vector able to transduce human cells in a host mentioned in schedule 2, part 2.2, item 4 (animal or human cell culture), unless—

(i) the vector is a retroviral vector; or

(ii) the donor nucleic acid confers an oncogenic modification.

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Part 3.2 Notifiable low risk dealings suitable for physical containment level 2

Note For this part, because of s 12 (1), a dealing mentioned in this part is not a notifiable risk dealing if it is also a dealing of a kind mentioned in this schedule, pt 3.3.

3.2 Kinds of dealings

The following kinds of notifiable low risk dealings may be conducted in physical containment level 2 facilities:

(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 mouse;

(B) a genetically modified laboratory rat;

(C) a genetically modified *Caenorhabditis elegans*;

(aa) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, 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;

(ab) a dealing involving a genetically modified *Caenorhabditis elegans*, if—

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(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 (including a genetically modified flowering plant), if the dealing occurs in a facility that is designed to prevent the escape from the facility of—

(i) pollen, seed, spores or other propagules which may be produced in the course of the dealing; and

(ii) invertebrates that are capable of carrying the material mentioned in subparagraph (i);

(ba) a dealing involving a genetically modified flowering plant, if, before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed;

(c) a dealing involving a host and vector that are not mentioned as a host/vector system in schedule 2, part 2.2, if—

(i) the host has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi; and

(ii) the vector has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi;

(d) a dealing involving a host and vector that are not mentioned as a host/vector system in schedule 2, part 2.2, if—

(i) either—

(A) the host has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or

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(B) the vector has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; and

(ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector;

(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 human beings, animals, plants or fungi;

(f) a dealing involving a host/vector system mentioned in schedule 2, part 2.2, and producing more than 10 litres 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—

(A) as a large scale facility; and

(B) to at least physical containment level 2; and

(ii) the donor nucleic acid satisfies the conditions set out in schedule 2, part 2.1, item 4;

(g) a dealing involving complementation of knocked-out genes, if the complementation does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of the parent organism before the genes were knocked-out;

(h) a dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in

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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 able to transduce human cells into a host mentioned in schedule 2, part 2.2, if—

(i) the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions; and

(ii) either—

(A) the vector is a retroviral vector; or

(B) the donor nucleic acid confers an oncogenic modification.

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Part 3.3 Dealings that are not notifiable low risk dealings

Note 1 For this part, 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 For this part, a dealing that is not a notifiable low risk dealing, or an exempt dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see 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 this schedule, part 3.2, section 3.2 (h)) involving cloning of nucleic acid encoding a toxin having an LD_{50} of less than 100 μg/kg;

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

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

(d) unless the viral vector is part of a host/vector system mentioned in schedule 2, part 2.2 or in this schedule, part 3.1, section 3.1 (c) or part 3.2, section 3.2 (i)—a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid—

(i) confers an oncogenic modification; or

(ii) encodes—

(A) immunomodulatory molecules; or

(B) cytokines; or

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(C) growth factors, or components of a signal transduction pathway, that, when expressed, may lead to cell proliferation;

(e) a dealing involving, as host or vector, a micro-organism that has been implicated in, or has a history of causing, disease in humans, animals, plants or fungi, unless—

(i) the host/vector system is a system mentioned in schedule 2, part 2.2; or

(ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; or

(iii) the dealing is a dealing mentioned in this schedule, part 3.2, section 3.2 (g);

(f) 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 this schedule, part 3.2, section 3.2 (g); or

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

(g) 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 have a heightened risk of inducing an auto-immune response;

(h) 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 altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility in relation to any parent or donor organism;

(i) a dealing involving a lentiviral vector unless—

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(i) all structural and accessory genes have been removed from the vector to render it incapable of replication or assembly into a virion without these functions being supplied *in trans*; and

(ii) the vector includes a deletion that results in a transcriptionally inactive vector which, even when packaging functions are supplied *in trans*, cannot be converted into full length viral RNA; and

(iii) the packaging cell line and packaging plasmids used contain only viral genes *gag*, *pol*, *rev* and a gene encoding an envelope protein;

(j) 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;

(k) a dealing producing, in each vessel containing the resultant GMO culture, more than 10 litres of that culture, other than a dealing mentioned in this schedule, part 3.2, section 3.2 (f);

(l) a dealing that is inconsistent with a policy principle issued by the ministerial council;

(m) a dealing involving the intentional introduction of a GMO into a human being;

(n) 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.

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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
- 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.

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

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 mouse means a laboratory strain of mouse of the species *Mus musculus* 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.

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.

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oncogenic modification means a genetic modification that is capable of inducing unregulated cell proliferation in a vertebrate cell.

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.

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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 and expiries are listed in the legislation history and the amendment history. These details are underlined. Uncommenced provisions and amendments are not included in the republished law but are set out in the last endnote.

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

am = amended
amdt = amendment
ch = chapter
def = definition
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
o = order
om = omitted/repealed
ord = ordinance
orig = original
par = paragraph/subparagraph
pres = present
prev = previous
(prev...) = previously
pt = part
r = rule/subrule
renum = renumbered
reloc = relocated
R[X] = Republication No
RI = reissue
s = section/subsection
sch = schedule
sdiv = subdivision
sub = substituted
SL = Subordinate Law
underlining = whole or part not commenced or to be expired

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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)

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

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

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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

Requirements in relation to 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

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

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

Transitional
pt 8 hdg om SL2008-17 s 22

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

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Existing organisations—accreditation
s 42 exp 5 June 2006 (s 42 (4) (LA s 88 declaration applies))

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

Dealings exempt from licensing
sch 2 sub SL2008-17 s 23

Notifiable low risk dealings in relation to a GMO
sch 3 sub SL2008-17 s 23

Prescribed information—application for licence
sch 4 om SL2008-17 s 23

Dictionary
dict am SL2008-17 s 24
def ***advantage*** sub SL2008-17 s 25
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 mouse*** ins SL2008-17 s 31
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 ***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
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

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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

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