Queensland

Gene Technology Act 2001

Gene Technology Regulation 2002

Reprinted as in force on 31 March 2007

Reprint No. 1A

This reprint is prepared by
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Information about this reprint

This regulation is reprinted as at 31 March 2007. The reprint shows the law as amended by all amendments that commenced on or before that day (Reprints Act 1992 s 5(c)).

The reprint includes a reference to the law by which each amendment was made—see list of legislation and list of annotations in endnotes. Also see list of legislation for any uncommenced amendments.

This page is specific to this reprint. See previous reprint for information about earlier changes made under the Reprints Act 1992. A table of reprints is included in the endnotes.

Also see endnotes for information about—

- **when provisions commenced**
- **editorial changes made in earlier reprint.**

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Queensland

Gene Technology Regulation 2002

Contents

Gene Technology Regulation 2002

[as amended by all amendments that commenced on or before 31 March 2007]

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

(c) it is conducted in accordance with applicable technical and procedural guidelines, as in force from time to time under section 27(d) of the Act, about—

(i) containment of the GMO; and

(ii) if the dealing involves transporting the GMO—transport; 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 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)[1] 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—170 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[2] 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;

1 Section 43 (Regulator must consider applications except in certain circumstances) of the Act

2 Section 53 (Regulator may take other actions) of the Act

(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[3] of the Act, for the section 184 application, are exhausted;

(e) if the regulator requests the ethics 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)[4] of the Act, or advice from the ethics 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—

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.

3 Section 181 (Internal review) or 183 (Review of decisions by Administrative Appeals Tribunal) of the Act

4 Section 50 (Regulator must prepare risk assessment and risk management plan) or 52 (Public notification of risk assessment and risk management plan) of the Act

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;

(c) National Health and Medical Research Council;

(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.

10 Risk assessment—matters to be taken into account

(1) For section 51(1)(d) and (2)(d)[5] 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.

5 Section 51 (Matters regulator must take into account in preparing risk assessment and risk management plan) of the Act

(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.

Division 2 Notifiable low risk dealings

12 Notifiable low risk dealings

(1) For section 74(1)[6] 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 (other than a dealing of a kind also mentioned in schedule 3, part 2); 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*.

6 Section 74 (Notifiable low risk dealings) of the Act

13 Requirements for notifiable low risk dealings

(1) A person must not undertake a notifiable low risk dealing unless an institutional biosafety committee has—

(a) notified the regulator, in the form approved by the regulator, of the proposed dealing; and

(b) given the person and the project supervisor for the proposed dealing written notice that—

(i) the proposed dealing is a dealing of a kind mentioned in schedule 3, part 1; and

(ii) the institutional biosafety committee considers the personnel to be involved in the proposed dealing have appropriate training and experience; and

(iii) paragraph (a) has been complied with.

(2) When undertaken, a notifiable low risk dealing must comply with each of the following requirements—

(a) the dealing must be conducted in a facility that is—

(i) certified by the regulator to at least physical containment level 2, or another containment level the regulator considers suitable for conducting the dealing; and

(ii) of a design the regulator considers suitable for the kind of dealing being undertaken;

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

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

(a) the institutional biosafety committee that has notified the regulator of a proposed notifiable low risk dealing; or

(b) an entity involved with the conduct of a notifiable low risk dealing of which the regulator has been notified;

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

(4) A committee or entity receiving notice under subsection (3) must, by the end of the period stated 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 Gene technology community consultative committee

31 GTCCC—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 the consultative committee's members.

32 GTCCC—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 consultative committee.

33 GTCCC—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 110A(1) of the Commonwealth Act.

Part 6 Gene technology ethics committee

34 GTEC—conditions of appointment

Note—

Regulation 34 of the Commonwealth regulations states that part 4, division 1 of the Commonwealth regulations applies to the conditions of appointment of members of, and advisers to, the ethics committee.

35 GTEC—committee procedures

Note—

Regulation 35 of the Commonwealth regulations states that part 4, division 2 of the Commonwealth regulations applies to the procedures of the ethics committee.

36 GTEC—operation of subcommittees

Note—

Regulation 36 of the Commonwealth regulations states that regulations 24 to 26 and 28 of the Commonwealth regulations apply to a subcommittee established under section 116(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, the consultative committee and the ethics committee.

39 Record of GMO and GM product dealings

(1) For section 138(2)(b)[7] of the Act, the following particulars are prescribed for a notifiable low risk dealing notified to the regulator—

7 Section 138 (Record of GMO and GM product dealings) of the Act

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

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

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

(d) the date of the notification.

(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.

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 2243.3:2002—Safety in laboratories—Microbiological aspects and containment facilities 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 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

1 A dealing with a genetically modified laboratory mouse or genetically modified laboratory rat, 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.

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(1) Subject to subsections (2) and (3), a dealing involving a host/vector system mentioned in part 2 of this schedule and

Schedule 2 (continued)

producing no more than 10L of GMO culture in each vessel containing the resultant culture.

(2) The donor nucleic acid—

(a) must satisfy 1 of the following requirements—

(i) it must not be derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi;

(ii) it must be characterised and not known to alter the host range or mode of transmission, or to increase the virulence, pathogenicity or transmissibility of the host or vector; and

(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) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions.

(3) If the vector is able to transduce human cells, the donor nucleic acid must 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,

Schedule 2 (continued)

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—a 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)
		Pseudomonas putida—strain KT 2440	1 non-conjugative plasmids including certified plasmids—pKT 262, pKT 263, pKT 264 2 none (non-vector systems)

Schedule 2 (continued)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
		Streptomyces—specified species— (a) *S. aureofaciens*; (b) *S. coelicolor;* (c) *S. cyaneus*; (d) *S. griseus;* (e) *S. lividans;* (f) *S. parvulus;* (g) *S. rimosus;* (h) *S. venezuelae*	1 non-conjugative plasmids 2 certified plasmids—SCP2, SLP1, SLP2, PIJ101 and derivatives 3 actinophage phi C31 and 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)
		Lactobacillus *Oenoccus 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)

Schedule 2 (continued)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
2	fungi	*Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Kluyveromyces lactis* *Trichoderma reesei*	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)
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)

Schedule 2 (continued)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
		plant cell cultures	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

section 12(1)(a)

Part 1 Dealings that are notifiable low risk dealings

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 2 of this schedule.

1.1 Kinds of dealings

The following kinds of dealings are notifiable low risk 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 mouse;

(B) a genetically modified laboratory rat;

(C) a genetically modified *Caenorhabditis elegans*;

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

Schedule 3 (continued)

(ab) a dealing involving 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, including a genetically modified flowering plant, if the dealing occurs in a facility 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 capable of carrying the material mentioned in subparagraph (i);

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

(c) a dealing involving a host and vector not mentioned as a host/vector system in schedule 2, part 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 not mentioned as a host/vector system in schedule 2, part 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

Schedule 3 (continued)

(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 to 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, if the donor nucleic acid—

(i) codes for 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; or

(iii) in a case in which the vector is able to transduce human cells—confers an oncogenic modification;

(f) a dealing involving a host/vector system mentioned in schedule 2, part 2 and producing more than 10L of GMO culture in each vessel containing the resultant culture, if—

(i) the dealing is undertaken in a facility 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 stated in schedule 2, part 1, section 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

Schedule 3 (continued)

schedule 2, part 2, item 1, if the donor nucleic acid is derived from—

(i) a pathogen; or

(ii) a toxin-producing organism;

(i) a dealing involving introducing a replication defective retroviral vector able to transduce human cells into a host mentioned in schedule 2, part 2 if the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions.

Part 2 Dealings that are not notifiable low risk dealings

Note 1—

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

Note 2—

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

2.1 Kinds of dealings

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

(a) a dealing (other than a dealing mentioned in this schedule, part 1, section 1.1(h)) involving cloning of nucleic acid coding for a toxin with 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;

Schedule 3 (continued)

(c) a dealing (other than a dealing mentioned in this schedule, part 1, section 1.1(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 or this schedule, part 1, section 1.1(i)—a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid—

(i) confers an oncogenic modification; or

(ii) codes for—

(A) immunomodulatory molecules; or

(B) cytokines; or

(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; or

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

(iii) the dealing is a dealing mentioned this schedule, part 1, section 1.1(g);

(f) a dealing involving the introduction, into a micro-organism, of nucleic acid coding for a pathogenic determinant, unless—

(i) the dealing is a dealing mentioned in this schedule, part 1, section 1.1(g); or

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

Schedule 3 (continued)

(g) a dealing involving the introduction into a micro-organism, other than a host mentioned in schedule 2, part 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 able to transduce human cells unless—

(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 coding for an envelope protein;

(j) a dealing involving a genetically modified animal, plant or fungus capable of secreting or producing infectious agents as a result of the genetic modification;

(k) a dealing producing more than 10L of GMO culture in each vessel containing the resultant culture, other than a dealing mentioned in this schedule, part 1, section 1.1(f);

(l) a dealing inconsistent with a policy principle issued by the Ministerial council;

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

Schedule 3 (continued)

(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.

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.

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).

competitive advantage means—

(a) for a GMO—a superior ability of the GMO, relative to the unmodified parental organism, to survive in an environment in competition with other organisms; and

(b) for the host of a GMO that is a micro-organism living in or on an animal—a superior ability of the host, relative to a host in or on which the GMO does not live, to survive in an environment in competition with other organisms.

gene-knockout mice means mice whose genetic modification involves deleting or inactivating a specific gene.

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

Schedule 5 (continued)

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.

inclusion-negative, for a recombinant of insect cell cultures, means the vector baculovirus used is in a mutant form that is unable to make polyhedrin (that is, a material surrounding a virus and protecting it from adverse environmental effects, including, for example, UV radiation).

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, for schedule 2, part 2, means a system by which donor nucleic acid is introduced (including, for example, by electroporation or particle bombardment) into a host in the absence of a nucleic acid-based vector.

Examples of a nucleic acid-based vector—

- a plasmid
- a viral vector
- a transposon

nucleic acid means DNA or RNA, or both DNA and RNA, of any length.

Schedule 5 (continued)

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

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.

selective advantage, for a GMO, means a superior ability of the GMO, relative to another organism, to survive in a particular environment.

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.

Endnotes

1 Index to endnotes

2 Date to which amendments incorporated

This is the reprint date mentioned in the Reprints Act 1992, section 5(c). Accordingly, this reprint includes all amendments that commenced operation on or before 31 March 2007. Future amendments of the Gene Technology Regulation 2002 may be made in accordance with this reprint under the Reprints Act 1992, section 49.

3 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 edition**
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 2002**
para	**=**	**paragraph**	**SL**	**=**	**subordinate legislation**
prec	**=**	**preceding**	**sub**	**=**	**substituted**
pres	**=**	**present**	**unnum**	**=**	**unnumbered**
prev	**=**	**previous**			

4 Table of reprints

Reprints are issued for both future and past effective dates. For the most up-to-date table of reprints, see the reprint with the latest effective date.

If a reprint number includes a letter of the alphabet, the reprint was released in unauthorised, electronic form only.

Reprint No.	Amendments included	Effective	Notes
1	none	26 July 2002	
1A	2007 SL No. 45	31 March 2007	

5 Tables in earlier reprints

Name of table	Reprint No.
Corrected minor errors	1

6 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 1 September 2012 (see SIA s 54)
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)

7 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

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

Prescribed authorities
s 9 amd 2007 SL No. 45 s 8

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

Requirements for notifiable low risk dealings
s 13 sub 2007 SL No. 45 s 10

Record of GMO and GM product dealings
s 39 amd 2007 SL No. 45 s 11

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

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

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

SCHEDULE 3—NOTIFIABLE LOW RISK DEALINGS IN RELATION TO A GMO
sch hdg sub 2007 SL No. 45 s 13

PART 1—DEALINGS THAT ARE NOTIFIABLE LOW RISK DEALINGS
pt hdg sub 2007 SL No. 45 s 13

Kinds of dealings
s 1.1 sub 2007 SL No. 45 s 13

PART 2—DEALINGS THAT ARE NOT NOTIFIABLE LOW RISK DEALINGS
pt hdg sub 2007 SL No. 45 s 13

Kinds of dealings
s 2.1 sub 2007 SL No. 45 s 13

PART 3—PRESCRIBED INFORMATION FOR NOTICE OF PROPOSED NOTIFIABLE LOW RISK DEALING
pt hdg om 2007 SL No. 45 s 13

Information about proponent and proposed dealing
s 3.1 om 2007 SL No. 45 s 13

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 **"characterised"** amd 2007 SL No. 45 s 14(4)
def **"code"** sub 2007 SL No. 45 s 14(1)–(2)
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 **"genetically modified laboratory mouse"** ins 2007 SL No. 45 s 14(2)
def **"genetically modified laboratory rat"** ins 2007 SL No. 45 s 14(2)
def **"genetic manipulation advisory comittee"** om 2007 SL No. 45 s 14(1)
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)
def **"nucleic acid"** ins 2007 SL No. 45 s 14(2)
def **"oncogenic modification"** ins 2007 SL No. 45 s 14(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 **"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)