



Gene Technology Act 2001

Gene Technology Regulation 2002

Reprinted as in force on 2 May 2008

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- **when provisions commenced**
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Queensland

Gene Technology Regulation 2002

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Gene Technology Regulation 2002

[as amended by all amendments that commenced on or before 2 May 2008]

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

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- (b) if this regulation contains a section that is not included in the Commonwealth regulations, the section is numbered so as to maintain consistency in numbering between provisions common to both regulations.
- (2) A provision number and heading mentioned in subsection (1)(a) form part of this regulation.

Note 1—

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

Note 2—

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

Note 3—

This section does not appear in the Commonwealth regulations.

3B Notes

Notes do not form part of this regulation.

Note—

This section does not appear in the Commonwealth regulations.

Part 2 Interpretation and general operation

4 Techniques not constituting gene technology

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

5 Organisms that are not genetically modified organisms

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

Part 3 Dealings with GMOs

Division 1 Licensing system

6 Dealings exempt from licensing

- (1) For the Act, schedule 3, definition *exempt dealing*, a dealing, in relation to a GMO, is an exempt dealing if—
 - (a) it is a dealing of a kind mentioned in schedule 2, part 1; and
 - (b) it does not involve a genetic modification other than a modification mentioned in schedule 2, part 1; and
 - (d) it does not involve an intentional release of the GMO into the environment; 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.

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7 Application for licence—prescribed fee

Note 1—

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

Note 2—

This section differs from regulation 7 of the Commonwealth regulations.

8 Time limit for deciding an application

- (1) For section 43(3) of the Act, the period within which the regulator must issue, or refuse to issue, a licence is—
 - (a) for an application to which part 5, division 3 of the Act applies—90 days after the day on which the regulator receives the application; or
 - (b) for an application to which part 5, division 4 of the Act applies—
 - (i) for a limited and controlled release application for which the regulator is satisfied that the dealings proposed to be authorised by the licence do not pose significant risks to the health and safety of people or to the environment—150 days after the day on which the regulator receives the application; and
 - (ii) for a limited and controlled release application for which the regulator is satisfied that at least 1 of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment—170 days after the day on which the regulator receives the application; and
 - (iii) otherwise—255 days after the day on which the regulator receives the application.
- (2) For deciding the end of a period mentioned in subsection (1), each of the following days are not counted—

- (a) a Saturday, Sunday or public holiday in the Australian Capital Territory;
 - (b) a day on which the regulator can not proceed with the decision-making process or a related function because the regulator is awaiting information the applicant has been requested, in writing, to give;
 - (c) if the regulator, under section 53 of the Act, publishes notice of a public hearing about the application, a day in the period that—
 - (i) begins on the day of publication; and
 - (ii) ends on the day when the public hearing ends;
 - (d) a day on which the regulator can not proceed with the decision-making process or a related function because—
 - (i) the applicant has made a section 184 application; and
 - (ii) the regulator is either—
 - (A) considering the section 184 application; or
 - (B) waiting until any review rights under section 181 or 183 of the Act, for the section 184 application, are exhausted;
 - (e) if the regulator requests the ethics and community committee to provide advice on an ethical issue relating to the application, a day in the period that—
 - (i) begins on the day the request is made; and
 - (ii) subject to subsection (3), ends on the day when the advice is given or, if the advice is not given within a period stated under the subsection, on the last day of the period.
- (3) When seeking advice under section 50(3) or 52(3) of the Act, or advice from the ethics and community committee, the regulator—
- (a) may state a reasonable period within which the advice must be received; and

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- (b) if the advice is not received within the stated period, must proceed without regard to the advice.

- (4) In this section—

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

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

9 Prescribed authorities

For sections 50(3)(c) and 52(3)(c) of the Act, each of the following Commonwealth authorities and agencies are prescribed—

- (a) Food Standards Australia New Zealand;
- (b) Australian Quarantine and Inspection Service;
- (d) the director, National Industrial Chemical Notification and Assessment Scheme;
- (e) Australian Pesticides and Veterinary Medicines Authority;
- (f) Therapeutic Goods Administration, Department of Health and Aged Care.

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

For section 51(1)(a) of the Act, the regulator must have regard to the following matters—

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

- (b) the effect, or the expected effect, of the genetic modification that has occurred, or will occur, on the properties of the organism;
- (c) provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;
- (d) the potential for spread or persistence of the GMO or its genetic material in the environment;
- (e) the extent or scale of the proposed dealings;
- (f) any likely impacts of the proposed dealings on the health and safety of people.

10 Risk assessment—matters to be taken into account

- (1) For section 51(1)(d) and (2)(d) of the Act, other matters to be taken into account for dealings proposed to be authorised by a licence include—
 - (a) subject to section 45 of the Act, any previous assessment by a regulatory authority, in Australia or outside Australia, in relation to allowing or approving dealings with the GMO; and
 - (b) the potential of the GMO to do any or all of the following—
 - (i) harm other organisms;
 - (ii) adversely affect any ecosystems;
 - (iii) transfer genetic material to another organism;
 - (iv) spread or persist in the environment;
 - (v) have an advantage in the environment;
 - (vi) be toxic, allergenic or pathogenic to other organisms.
- (2) The regulator must also consider each of the following—
 - (a) in taking into account a risk mentioned in section 51(1)(a) of the Act—the risk for both the short term and the long term;

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- (b) in taking into account a potential capacity mentioned in subsection (1)(b)—the potential capacity for both the short term and the long term.

11 Prescribed conditions of licence

Note—

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

11A Time limit for deciding variation application

For section 71(7) of the Act, the prescribed period for the regulator to vary, or refuse to vary, the licence is 90 days after the day on which the regulator receives the application for the variation.

Note—

This section differs from regulation 11A of the Commonwealth regulations.

Division 2 Notifiable low risk dealings

12 Notifiable low risk dealings

- (1) For section 74(1) of the Act, a dealing with a GMO is a notifiable low risk dealing if—
 - (a) it is a dealing of a kind mentioned in schedule 3, part 1 or 2 (other than a dealing of a kind also mentioned in schedule 3, part 3); and
 - (b) it does not involve an intentional release of the GMO into the environment.
- (2) To remove any doubt, it is declared that subsection (1) does not apply to a dealing that does not comply with the subsection, whether or not the dealing is related to a dealing that does comply with the subsection.

Note 1—

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

Note 2—

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

13 Requirements for undertaking notifiable low risk dealings

- (1) A person may undertake a notifiable low risk dealing only if—
 - (a) a person or an accredited organisation has 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 the personnel to be involved in the proposed dealing have appropriate training and experience.
- (2) A notifiable low risk dealing must comply with each of the following requirements—
 - (a) the dealing must be conducted—
 - (i) for a dealing of a kind mentioned in schedule 3, part 1—in a facility that is certified by the regulator to at least physical containment level 1 and is of appropriate design for a dealing of the kind being undertaken; or
 - (ii) for a dealing of a kind mentioned in schedule 3, part 2—in a facility that is certified by the regulator to at least physical containment level 2 and is of

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appropriate design for a dealing of the kind being undertaken; or

- (iii) in another facility in accordance with any technical and procedural guidelines about containment of GMOs, as in force from time to time under section 27(d) of the Act, 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 section 27(d) of the Act.

13A Requirements for 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 stated in the notice; and
 - (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 institutional biosafety 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) otherwise—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 on which 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) another person involved with the conduct of the proposed dealing;to give the regulator any 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, person or accredited organisation receiving a 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.

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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.

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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.

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Part 5

Ethics and community committee

31 Ethics and community committee—conditions of appointment

Note—

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

32 Ethics and community committee—consultative committee procedures

Note—

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

33 Ethics and community committee—operation of subcommittees

Note—

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

Part 7

Miscellaneous

37 Reviewable State decisions

Note—

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

38 Review of decisions

Note—

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

39 Record of GMO and GM product dealings

- (1) For section 138(2)(b) of the Act, the following particulars are prescribed for a notifiable low risk dealing notified to the regulator—
 - (a) the name of the organisation proposing to undertake the dealing;
 - (b) with reference to the kinds of dealing mentioned in schedule 3, parts 1 and 2, the kind of notifiable low risk dealing proposed;
 - (c) the identifying name given to the proposed undertaking by the organisation;
 - (d) the date of 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—

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- (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

- 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 subsection (2), a dealing involving a host/vector system mentioned in part 2 of this schedule and 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 LD₅₀ of less than 100µg/kg; and
 - (c) must not code for a toxin with an LD₅₀ of 100µg/kg or more, if the intention is to express the toxin at high levels; and
 - (d) must not be uncharacterised nucleic acid from a toxin-producing organism; and
 - (e) must not include a viral sequence, unless the donor nucleic acid—
 - (i) is missing at least 1 gene essential for viral multiplication that—
 - (A) is not available in the cell into which the nucleic acid is introduced; and
 - (B) will not become available during the dealing; and
 - (ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and
 - (f) 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, 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 | <p><i>Escherichia coli</i> K12, <i>E. coli</i> B or <i>E. coli</i> C—a derivative that does not contain—</p> <p>(a) generalised transducing phages; or</p> <p>(b) genes able to complement the conjugation defect in a non-conjugative plasmid</p> | <p>1 non-conjugative plasmids</p> <p>2 bacteriophage—</p> <p>(a) lambda;</p> <p>(b) lambdoid;</p> <p>(c) Fd or F1 (for example, M13)</p> <p>3 none (non-vector systems)</p> |
| | | <p><i>Bacillus</i>—specified species—sporogenic strains with a reversion frequency of less than 10^{-7}—</p> <p>(a) <i>B. amyloliquefaciens</i>;</p> <p>(b) <i>B. licheniformis</i>;</p> <p>(c) <i>B. pumilus</i>;</p> <p>(d) <i>B. subtilis</i>;</p> <p>(e) <i>B. thuringiensis</i></p> | <p>1 non-conjugative plasmids</p> <p>2 plasmids and phages whose host range does not include <i>B. cereus</i>, <i>B. anthracis</i> or another pathogenic strain of <i>Bacillus</i></p> <p>3 none (non-vector systems)</p> |
| | | <p><i>Pseudomonas putida</i>—strain KT 2440</p> | <p>1 non-conjugative plasmids including certified plasmids—pKT 262, pKT 263, pKT 264</p> <p>2 none (non-vector systems)</p> |
| | | <p><i>Streptomyces</i>—specified species—</p> <p>(a) <i>S. aureofaciens</i>;</p> <p>(b) <i>S. coelicolor</i>;</p> <p>(c) <i>S. cyaneus</i>;</p> <p>(d) <i>S. griseus</i>;</p> <p>(e) <i>S. lividans</i>;</p> <p>(f) <i>S. parvulus</i>;</p> <p>(g) <i>S. rimosus</i>;</p> <p>(h) <i>S. venezuelae</i></p> | <p>1 non-conjugative plasmids</p> <p>2 certified plasmids—SCP2, SLP1, SLP2, PIJ101 and derivatives</p> <p>3 actinophage phi C31 and derivatives</p> <p>4 none (non-vector systems)</p> |

| Column 1 Item | Column 2 Class | Column 3 Host | Column 4 Vector |
|------------------|-------------------|---|---|
| | | <i>Agrobacterium radiobacter</i> | 1 non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors |
| | | <i>Agrobacterium rhizogenes</i> —disarmed strains | 2 none (non-vector systems) |
| | | <i>Agrobacterium tumefaciens</i> —disarmed strains | |
| | | <i>Lactobacillus</i> | 1 non-conjugative plasmids |
| | | <i>Oenococcus oeni</i> syn. <i>Leuconostoc oeni</i> | 2 none (non-vector systems) |
| | | <i>Pediococcus</i> | |
| | | <i>Photobacterium angustum</i> | |
| | | <i>Pseudoalteromonas tunicate</i> | |
| | | <i>Rhizobium</i> (including the genus <i>Allorhizobium</i>) | |
| | | <i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas</i> <i>alaskensis</i> | |
| | | <i>Vibrio cholerae</i> CVD103-HgR | |
| 2 | fungi | <i>Neurospora crassa</i> —laboratory strains | 1 all vectors 2 none (non-vector systems) |
| | | <i>Pichia pastoris</i> | |
| | | <i>Saccharomyces cerevisiae</i> | |
| | | <i>Schizosaccharomyces pombe</i> | |
| | | <i>Kluyveromyces lactis</i> | |
| | | <i>Trichoderma reesei</i> | |

Schedule 2

| Column 1 Item | Column 2 Class | Column 3 Host | Column 4 Vector |
|------------------|-------------------|--|---|
| 3 | slime moulds | <i>Dictyostelium</i> species | <ol style="list-style-type: none"> 1 <i>Dictyostelium</i> 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) <hr/> plant cell cultures | <ol style="list-style-type: none"> 1 non-conjugative plasmids 2 non-viral vectors, or defective viral vectors unable to transduce human cells 3 avipox vectors (attenuated vaccine strains) 4 baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus 5 none (non-vector systems) <hr/> <ol style="list-style-type: none"> 1 non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in <i>Agrobacterium tumefaciens</i>, <i>Agrobacterium radiobacter</i> or <i>Agrobacterium rhizogenes</i> 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 Notifiable low risk dealings suitable for physical containment level 1

Note—

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

1.1 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, 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, item 4 (animal or human cell cultures), unless—
 - (i) the vector is a retroviral vector; or

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

Part 2

Notifiable low risk dealings suitable for physical containment level 2

Note—

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

2.1 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 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—
 - (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

- (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;
- (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 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 the introduction of a replication defective viral vector able to transduce human cells into a host mentioned in schedule 2, part 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.

Part 3 Dealings that are not notifiable low risk dealings

Note 1—

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

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).

3.1 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 2, section 2.1(h)) involving cloning of nucleic acid coding for a toxin with an LD₅₀ of less than 100µg/kg;

Schedule 3

- (b) a dealing involving high level expression of toxin genes, even if the LD₅₀ is 100µg/kg or more;
- (c) a dealing (other than a dealing mentioned in this schedule, part 2, section 2.1(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(c) or part 2, section 2.1(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 in this schedule, part 2, section 2.1(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 2, section 2.1(g); or
 - (ii) the micro-organism is a host mentioned in schedule 2, part 2;
- (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 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 2, section 2.1(f);
- (l) a dealing inconsistent with a policy principle issued by the Ministerial council;

Schedule 3

- (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.

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).

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.

IBC means an institutional biosafety committee.

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

known means known within the scientific community.

licence means a GMO licence.

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

- (a) a bacterial artificial chromosome (BAC);
- (b) a cosmid;
- (c) a P1 artificial chromosome (PAC);
- (d) a yeast artificial chromosome (YAC).

non-vector system, 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.

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.

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 LD₅₀ 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

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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 2 May 2008. 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 | |
| 1B | 2008 SL No. 109 | 2 May 2008 | R1B withdrawn, see R2 |
| 2 | — | 2 May 2008 | |

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)

Gene Technology Amendment Regulation (No. 1) 2008 SL No. 109

notfd gaz 2 May 2008 pp 164–5

commenced on date of notification

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; 2008 SL No. 109 s 3

Application for licence—prescribed fee

s 7 sub 2007 SL No. 45 s 7

Time limit for deciding an application

s 8 amd 2008 SL No. 109 s 4

Prescribed authorities

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

Risks posed by dealings proposed to be authorised by licence

s 9A ins 2008 SL No. 109 s 6

Risk assessment—matters to be taken into account

s 10 amd 2007 SL No. 45 s 9

Time limit for deciding variation application

s 11A ins 2008 SL No. 109 s 7

Notifiable low risk dealings

s 12 amd 2008 SL No. 109 s 8

Requirements for undertaking notifiable low risk dealings

s 13 sub 2007 SL No. 45 s 10; 2008 SL No. 109 s 9

Requirements for notifying regulator of notifiable low risk dealings

s 13A ins 2008 SL No. 109 s 9

PART 5—ETHICS AND COMMUNITY COMMITTEE

pt 5 (ss 31–33) sub 2008 SL No. 109 s 10

PART 6—GENE TECHNOLOGY ETHICS COMMITTEE

pt 6 (ss 34–36) om 2008 SL No. 109 s 11

Review of decisions

s 38 amd 2008 SL No. 109 s 12

Record of GMO and GM product dealings

s 39 amd 2007 SL No. 45 s 11; 2008 SL No. 109 s 13

**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

PART 1—EXEMPT DEALINGS

pt 1 amd 2008 SL No. 109 s 14(1)–(4)

PART 2—HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

pt 2 amd 2008 SL No. 109 s 14(5)

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

sch hdg sub 2007 SL No. 45 s 13

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

pt hdg ins 2008 SL No. 109 s 15(2)

Kinds of dealings

s 1.1 ins 2008 SL No. 109 s 15(2)

PART 2—NOTIFIABLE LOW RISK DEALINGS SUITABLE FOR PHYSICAL CONTAINMENT LEVEL 2

pt hdg (prev pt 1 hdg) sub 2007 SL No. 45 s 13
renum 2008 SL No. 109 s 15(1)
sub 2008 SL No. 109 s 15(3)

pt 2 note amd 2008 SL No. 109 s 15(4)

Kinds of dealings

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

PART 3—DEALINGS THAT ARE NOT NOTIFIABLE LOW RISK DEALINGS

pt hdg prev pt 3 hdg om 2007 SL No. 45 s 13
pres pt 3 hdg (prev pt 2 hdg) renum 2008 SL No. 109 s 15(1)

pt 3 note amd 2008 SL No. 109 s 15(9)

Kinds of dealings

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

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 “**competitive advantage**” om 2008 SL No. 109 s 16
def “**division 3 application**” om 2007 SL No. 45 s 14(1)
def “**division 4 application**” om 2007 SL No. 45 s 14(1)
def “**gene-knockout mice**” om 2008 SL No. 109 s 16
def “**genetically modified laboratory 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 committee**” om 2007 SL No. 45 s 14(1)
def “**inclusion-negative**” om 2008 SL No. 109 s 16
def “**infectious agent**” ins 2007 SL No. 45 s 14(2)
def “**known**” ins 2007 SL No. 45 s 14(2)
def “**non-conjugative plasmid**” ins 2007 SL No. 45 s 14(2)

def **“non-vector system”** ins 2007 SL No. 45 s 14(2)
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 **“selective advantage”** om 2008 SL No. 109 s 16
def **“shotgun cloning”** amd 2007 SL No. 45 s 14(5)–(6)
def **“toxin”** ins 2007 SL No. 45 s 14(2)
def **“toxin-producing organism”** ins 2007 SL No. 45 s 14(2)
def **“transduce”** ins 2007 SL No. 45 s 14(2)

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