Version No. 004

Gene Technology Regulations 2001

S.R. No. 153/2001

Version incorporating amendments as at 1 January 2008

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PART 1—PRELIMINARY

1 Objective

The objective of these Regulations is to prescribe those matters that are required, permitted, necessary or convenient to be prescribed for the implementation of the **Gene Technology Act 2001**.

Note

This regulation differs from regulation 1 of the Commonwealth Regulations.

1A Authorising provision

These Regulations are made under section 193 of the **Gene Technology Act 2001**.

Note

This regulation does not appear in the Commonwealth Regulations.

2 Commencement

Note

The Commonwealth Regulations provide when those Regulations come into operation.

3 Definitions

In these Regulations—

Act means the **Gene Technology Act 2001**;

Reg. 3 def. of *advantage* inserted by S.R. No. 50/2007 reg. 4(1).

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

Reg. 3 def. of *advice to proceed* revoked by S.R. No. 50/2007 reg. 4(3).

* * * * *

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

Reg. 3 def. of *characterised* inserted by S.R. No. 50/2007 reg. 4(1).

characterised, in relation to nucleic acid, means nucleic acid that has been sequenced and in respect of which there is an understanding of potential gene products or potential functions;

Reg. 3 def. of *code for* inserted by S.R. No. 50/2007 reg. 4(1).

code for, for Schedule 2, has the meaning given in Part 3 of that Schedule;

Commonwealth Regulations means the Gene Technology Regulations 2001 of the Commonwealth;

Reg. 3 def. of *expert adviser* substituted by S.R. No. 147/2007 reg. 5.

expert adviser means—

(a) in Part 4, an expert adviser appointed under section 102(1) of the Commonwealth Act; and

(b) in Part 5, an expert adviser appointed under section 112(1) of the Commonwealth Act;

* * * * *

Reg. 3 def. of *Genetic Manipulation Advisory Committee* revoked by S.R. No. 50/2007 reg. 4(3).

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

Reg. 3 def. of *genetically modified laboratory mouse* inserted by S.R. No. 50/2007 reg. 4(1).

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;

Reg. 3 def. of *genetically modified laboratory rat* inserted by S.R. No. 50/2007 reg. 4(1).

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

Reg. 3 def. of *infectious agent* inserted by S.R. No. 50/2007 reg. 4(1).

known means known within the scientific community;

Reg. 3 def. of *known* inserted by S.R. No. 50/2007 reg. 4(1).

non-conjugative plasmid, for Schedule 2, has the meaning given in Part 3 of that Schedule;

Reg. 3 def. of *non-conjugative plasmid* inserted by S.R. No. 50/2007 reg. 4(1).

Reg. 3 def. of *non-vector system* inserted by S.R. No. 50/2007 reg. 4(1).

non-vector system, for Schedule 2, has the meaning given in Part 3 of that Schedule;

Reg. 3 def. of *nucleic acid* inserted by S.R. No. 50/2007 reg. 4(1).

nucleic acid means either, or both, deoxyribonucleic acid (DNA), or ribonucleic acid (RNA), of any length;

Reg. 3 def. of *oncogenic modification* inserted by S.R. No. 50/2007 reg. 4(1).

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

Reg. 3 def. of *packaging cell line* inserted by S.R. No. 50/2007 reg. 4(1).

packaging cell line means an animal or human cell line that contains a gene or genes that when expressed *in trans* are necessary and sufficient to complement packaging defects of a replication defective viral vector in order to produce packaged replication defective virions;

Reg. 3 def. of *pathogenic* inserted by S.R. No. 50/2007 reg. 4(1).

pathogenic, in relation to an organism, means having the capacity to cause disease or abnormality;

Reg. 3 def. of *pathogenic determinant* inserted by S.R. No. 50/2007 reg. 4(1).

pathogenic determinant means a characteristic that has the potential to increase the capacity of a host or vector to cause disease or abnormality;

Reg. 3 def. of *plasmid* inserted by S.R. No. 50/2007 reg. 4(1).

plasmid means a DNA molecule capable of autonomous replication and stable extra-chromosomal maintenance in a host cell;

physical containment level, followed by a numeral, is a specified containment level under guidelines made by the Regulator, under section 90 of the Act, for the certification of facilities

Reg. 3 def. of *physical containment level* substituted by S.R. No. 50/2007 reg. 4(2).

shot-gun cloning means the production of a large random collection of cloned fragments of nucleic acid from which genes of interest can later be selected;

Reg. 3 def. of *shot-gun cloning* inserted by S.R. No. 50/2007 reg. 4(1).

toxin means a substance that is toxic to any vertebrate;

Reg. 3 def. of *toxin* inserted by S.R. No. 50/2007 reg. 4(1).

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

Reg. 3 def. of *toxin-producing organism* inserted by S.R. No. 50/2007 reg. 4(1).

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

Reg. 3 def. of *transduce* inserted by S.R. No. 50/2007 reg. 4(1).

3A Numbering

(1) In order to maintain consistent numbering between these Regulations and the Commonwealth Regulations—

(a) if the Commonwealth Regulations contain a regulation that is not required in these Regulations, the provision number and heading to the regulation appearing in the Commonwealth Regulations are included in

these Regulations despite the omission of the body of the regulation; and

(b) if these Regulations contain a regulation that is not included in the Commonwealth Regulations, the regulation is numbered so as to maintain consistency in numbering between regulations common to both Regulations.

(2) A provision number and heading referred to in subregulation (1)(a) form part of these Regulations.

Notes

1 A note appears under each heading of a kind referred to in subregulation (1)(a) describing the omitted regulation of the Commonwealth Regulations.

2 A note appears under each regulation of a kind referred to in subregulation (1)(b) highlighting the non-appearance of an equivalent regulation in the Commonwealth Regulations.

3 This regulation does not appear in the Commonwealth Regulations.

3B Notes

Notes do not form part of these Regulations.

Note

This regulation does not appear in the Commonwealth Regulations.

PART 2—INTERPRETATION AND GENERAL OPERATION

4 Techniques not constituting gene technology

Reg. 4 amended by S.R. No. 50/2007 reg. 5.

For the purposes of paragraph (c) in the definition of ***gene technology*** in section 10 of the Act, gene technology does not include a technique listed in Schedule 1.

5 Organisms that are not genetically modified organisms

Reg. 5 amended by S.R. No. 50/2007 reg. 6.

For the purposes of paragraph (e) in the definition of ***genetically modified organism*** in section 10 of the Act, an organism listed in Schedule 1A is not a genetically modified organism.

PART 3—DEALINGS WITH GMOs

Division 1—Licensing system

6 Dealings exempt from licensing

(1) For the purposes of section 32(3) of the Act, a dealing, in relation to a GMO, is an exempt dealing if—

(a) it is a dealing of a kind referred to in Part 1 of Schedule 2; and

(b) it does not involve a genetic modification other than a modification described in Part 1 of Schedule 2; and

Reg. 6(1)(c) substituted by S.R. No. 50/2007 reg. 7, revoked by S.R. No. 147/2007 reg. 6.

* * * * *

Reg. 6(1)(d) substituted by S.R. No. 50/2007 reg. 7.

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

Reg. 6(1)(e) inserted by S.R. No. 50/2007 reg. 7.

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

(2) For the avoidance of doubt, exemption under subregulation (1) does not apply to a dealing that does not comply with subregulation (1), whether or not that dealing is related to a dealing that does so comply.

Notes

1 A dealing affected by this regulation could be any of the forms of dealing mentioned in the definition of ***deal with*** in section 10(1) of the Act.

2 Exemption from provisions of the Act does not preclude the application of other Commonwealth and State laws.

7 Application for licence—prescribed fee

Reg. 7 substituted by S.R. No. 50/2007 reg. 8.

Note

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

8 Time limit for deciding an application

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

(a) in relation to an application to which Division 3 of Part 5 of the Act applies, 90 days after the day the application is received by the Regulator; or

(b) in relation to an application to which Division 4 of Part 5 of the Act applies—

Reg. 8(1)(b) substituted by S.R. No. 147/2007 reg. 7(1).

(i) for a limited and controlled release application for which the Regulator is satisfied that the dealings proposed to be authorised by the licence do not pose significant risks to the health and safety of people or to the environment—150 days after the day the application is received by the Regulator; and

(ii) for a limited and controlled release application for which the Regulator is satisfied that at least one of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment—170 days after the day the application is received by the Regulator; and

(iii) in any other case—255 days after the day the application is received by the Regulator.

(2) For the purpose of determining the end of a period mentioned in subregulation (1), the following days are not counted—

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

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

(c) if, in relation to the application, the Regulator publishes notice of a public hearing under section 53 of the Act, 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 cannot proceed with the decision-making process, or a related function, because—

(i) the applicant has requested, under section 184 of the Act, that information given in relation to the application be declared confidential commercial information for the purposes of the Act; and

(ii) the Regulator is—

(A) considering the application; or

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

(e) if, in relation to the application, the Regulator requests the Ethics and Community Committee to provide advice on an ethical issue, a day in the period that—

Reg. 8(2)(e) amended by S.R. No. 147/2007 reg. 7(2).

(i) begins on the day the request is made; and

(ii) subject to subregulation (3), ends on the day when the advice is given or, if the advice is not given within the period, if any, specified under subregulation (3), on the last day of that period.

(3) The Regulator, when seeking advice under section 50(3) or 52(3) of the Act, or from the Ethics and Community Committee, may specify a reasonable period within which the advice must be received, and, if the advice is not received within that period, must proceed without regard to that advice.

Reg. 8(3) amended by S.R. No. 147/2007 reg. 7(2).

(4) In subregulation (1)—

Reg. 8(4) inserted by S.R. No. 147/2007 reg. 7(3).

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

9 Prescribed authorities

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

(a) Food Standards Australia New Zealand;

Reg. 9(a) substituted by S.R. No. 50/2007 reg. 9(1).

(b) Australian Quarantine and Inspection Service;

Reg. 9(c) revoked by S.R. No. 147/2007 reg. 8.

* * * * *

Reg. 9(d) substituted by S.R. No. 50/2007 reg. 9(2).

(d) the Director, National Industrial Chemical Notification and Assessment Scheme under the Industrial Chemicals (Notification and Assessment) Act 1989 of the Commonwealth;

Reg. 9(e) substituted by S.R. No. 50/2007 reg. 9(2).

(e) Australian Pesticides and Veterinary Medicines Authority;

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

Reg. 9A inserted by S.R. No. 147/2007 reg. 9.

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

For the purpose of 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 the purposes of sections 51(1)(g) and 51(2)(g) of the Act, other matters to be taken into account in relation to 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 overseas, in relation to allowing or approving dealings with the GMO; and

Reg. 10(1)(a) substituted by S.R. No. 50/2007 reg. 10(1).

(b) the potential of the GMO concerned to—

(i) be harmful to other organisms; and

(ii) adversely affect any ecosystems; and

(iii) transfer genetic material to another organism; and

(iv) spread, or persist, in the environment; and

(v) have, in comparison to related organisms, an advantage in the environment; and

Reg. 10 (1)(b)(v) amended by S.R. No. 50/2007 reg. 10(2).

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

(2) In taking into account a risk mentioned in section 51(1) of the Act, or a potential capacity mentioned in subregulation (1), the Regulator must consider both the short term and the long term.

11 Prescribed conditions of licence

Note

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

Reg. 11A inserted by S.R. No. 147/2007 reg. 10.

11A Time limit for deciding variation application

For the purposes of section 71(7) of the Act, the Regulator must vary the licence, or refuse to vary the licence, within 90 days after the day an application for variation of the licence is received by the Regulator.

Division 2—Notifiable low risk dealings

12 Notifiable low risk dealings

(1) For the purposes of 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 Part 1 of Schedule 3 (other than a dealing also mentioned in Part 2 of Schedule 3); and

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

(2) For the avoidance of doubt, subregulation (1) does not apply to a dealing that does not comply with subregulation (1), whether or not that dealing is related to a dealing that does so comply.

Notes

1 A dealing affected by this regulation could be any of the forms of dealing mentioned in the definition of ***deal with*** in section 10(1) of the Act.

2 ***Intentional release of the GMO into the environment*** is defined in section 11 of the Act.

13 Requirements in relation to undertaking notifiable low risk dealings

Reg. 13 substituted by S.R. Nos 50/2007 reg. 11, 147/2007 reg. 11.

(1) A person may undertake a notifiable low risk dealing only if—

(a) a person or an accredited organisation has requested an Institutional Biosafety Committee to assess whether the proposed dealing is a notifiable low risk dealing; and

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

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

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

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

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

(a) the dealing must be conducted—

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

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

(iii) in another facility in accordance with any technical and procedural guidelines relating to containment of GMOs, as in force from time to time under 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.

Reg. 13A inserted by S.R. No. 147/2007 reg. 12.

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

(1) An Institutional Biosafety Committee that has assessed a proposed dealing to be a notifiable low risk dealing must—

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

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

(c) give a copy of the record to—

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

(ii) the project supervisor for the proposed dealing.

(2) The person or accredited organisation must—

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

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

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

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

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

(a) the Committee; or

(b) the person or accredited organisation; or

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

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

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

Division 3—Certification and accreditation

14 Regulator to decide certification application within 90 days

Note

The Commonwealth Regulations provide 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

If an applicant for certification fails to provide information required under section 85(1) of the Act within the period specified in a notice given under section 85(2) of the Act, and gives no reasonable explanation for the failure, the Regulator may refuse to certify the facility that is the subject of the application.

Note

A refusal to certify a facility is a reviewable decision (see Division 2 of Part 12 of the Act).

16 Regulator to decide accreditation application within 90 days

Note

The Commonwealth Regulations provide 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

If an applicant for accreditation fails to provide information required under section 93(1) of the Act within the period specified in a notice given under section 93(2) of the Act, and gives no reasonable explanation for the failure, the Regulator may refuse to accredit the organisation that is the subject of the application.

Note

A refusal to accredit an organisation is a reviewable decision (see Division 2 of Part 12 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 the Gene Technology Technical Advisory Committee and expert advisers to the GTTAC.

19 GTTAC members and advisers—resignation

Note

Regulation 19 of the Commonwealth Regulations provides for the resignation of members of the Gene Technology Technical Advisory Committee and expert advisers to the GTTAC.

20 GTTAC members—disclosure of interests

Note

Regulation 20 of the Commonwealth Regulations sets out when and how members of the Gene Technology Technical Advisory Committee must disclose any interests of a kind likely to be considered at a meeting of the GTTAC.

21 GTTAC members and advisers—termination of appointment

Note

Regulation 21 of the Commonwealth Regulations sets out the circumstances of terminating the appointment of members of the Gene Technology Technical Advisory Committee and expert advisers to the GTTAC.

22 GTTAC members—leave of absence

Note

Regulation 22 of the Commonwealth Regulations provides when the Chairperson and members of the Gene Technology Technical Advisory Committee may be granted leave.

23 Expert advisers—disclosure of interests

Note

Regulation 23 of the Commonwealth Regulations sets out when and how expert advisers to the Gene Technology Technical Advisory Committee must disclose any interests of a kind likely to be considered at a meeting of the GTTAC.

Division 2—Committee procedures

24 Committee procedures generally

Note

Regulation 24 of the Commonwealth Regulations provides that the Gene Technology Technical Advisory Committee must perform its functions as informally as the Commonwealth Regulations allow and how the GTTAC may obtain information.

25 Committee meetings

Note

Regulation 25 of the Commonwealth Regulations provides when the Gene Technology Technical Advisory Committee may have meetings and provides that in certain circumstances meetings may be by videoconference or teleconference.

26 Presiding member

Note

Regulation 26 of the Commonwealth Regulations provides that the Chairperson of the Gene Technology Technical Advisory Committee presides at its meetings and who presides in the Chairperson's absence.

27 Quorum

Note

Regulation 27 of the Commonwealth Regulations provides that half the members of the Gene Technology Technical Advisory Committee comprises the GTTAC's quorum.

28 Voting

Note

Regulation 28 of the Commonwealth Regulations provides that decisions of the Gene Technology Technical Advisory Committee must be made by a majority of members present and voting and that the Chairperson has a deliberative and casting vote.

29 Records and Reports

Note

Regulation 29 of the Commonwealth Regulations provides that records must be kept of the Gene Technology Technical Advisory Committee's proceedings and when reports must be prepared.

Division 3—Subcommittees

30 Operation of subcommittees

Note

Regulation 30 of the Commonwealth Regulations states that regulations 24, 25, 26 and 28 of those Regulations apply to a subcommittee established under section 105(1) of the Commonwealth Act.

Pt 5 (Heading and regs 31–33) substituted by S.R. No. 147/2007 reg. 13.

PART 5—ETHICS AND COMMUNITY COMMITTEE

Reg. 31 substituted by S.R. No. 147/2007 reg. 13.

31 Ethics and Community Committee—conditions of appointment

Note

Regulation 31 of the Commonwealth Regulations provides that Division 1 of Part 4 of the Commonwealth Regulations applies to the conditions of appointment of members of the Ethics and Community Committee.

Reg. 32 substituted by S.R. No. 147/2007 reg. 13.

32 Ethics and Community Committee—Committee procedures

Note

Regulation 32 of the Commonwealth Regulations provides that Division 2 of Part 4 of the Commonwealth Regulations applies to the procedures of members of the Ethics and Community Committee.

Reg. 33 substituted by S.R. No. 147/2007 reg. 13.

33 Ethics and Community Committee—operation of subcommittees

Note

Regulation 33 of the Commonwealth Regulations provides that regulations 24, 25, 26 and 28 of the Commonwealth Regulations apply to a subcommittee established under subsection 111(1) of the Commonwealth Act.

Pt 6 (Heading and regs 34–36) revoked by S.R. No. 147/2007 reg. 13.

* * * * *

PART 7—MISCELLANEOUS

37 Reviewable State decisions

Note

At the commencement of these Regulations, no decision has been declared by the Commonwealth Regulations to be a reviewable State decision for the purposes of the section 19 of the Commonwealth Act.

38 Review of decisions

Note

Regulation 38 of the Commonwealth Regulations provides that a person whose interests are affected by a decision in relation to the appointment of a member to a committee under those Regulations may apply to the Administrative Appeals Tribunal for review of the decision.

39 Record of GMO and GM Product Dealings

(1) For the purposes of section 138(2) of the Act, the following particulars are prescribed in relation to a notifiable low risk dealing that is notified to the Regulator—

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

(b) in terms of Part 1 of Schedule 3, 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 the purposes of section 138(3) of the Act, the following particulars are prescribed in relation to 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*** (that is, whichever of the following Acts is applicable)—

(A) **Agricultural and Veterinary Chemicals (Victoria) Act 1994**;

(B) **Therapeutic Goods (Victoria) Act 1994**; and

(ii) its common name as a product, or type or class of product (for example, bread or insulin);

(c) information about the GM product, including—

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

Reg. 39(2)(c)(ii) amended by S.R. No. 50/2007 reg. 12.

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

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

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

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

Note

This regulation differs from regulation 39 of the Commonwealth Regulations.

40 Inspector identity card

For the purposes of section 151(2)(a) of the Act, an inspector's identity card must—

(a) display a recent photograph of the inspector's face; and

(b) state the date of issue; and

(c) state the period of its validity.

PART 8—TRANSITIONAL

41 Existing facilities—certification

(1) If, at the commencement of Part 7 of the Act, there is in force for an existing facility a notice from the Genetic Manipulation Advisory Committee that the facility provides a specified physical containment level, the facility is taken to be certified to that physical containment level under section 84 of the Act.

(2) Subregulation (1) applies—

(a) subject to sections 86(b), 86(c), 87 and 88 of the Act; and

(b) for a facility in relation to which the notice specifies that it is a physical containment level 2 facility (other than a PC2 Large Scale facility), until the end of 2 years after the commencement of Part 7 of the Act, provided the facility maintains compliance with the Regulator's guidelines about the requirements for certification at that level; and

(c) for a facility in relation to which the notice specifies that it is a physical containment level 3 or level 4 facility, a PC2 Large Scale facility or a facility providing appropriate physical containment for a specified purpose, until the end of 1 year after the commencement of Part 7 of the Act, provided the facility maintains compliance with the Regulator's guidelines about the requirements for certification at its specified containment level.

(3) For the purposes of subregulation (2)—

PC2 Large Scale facility means a physical containment level 2 facility so described by the notice given in relation to the facility by the Genetic Manipulation Advisory Committee.

42 Existing organisations—accreditation

(1) If, at the commencement of Part 7 of the Act, there is in force for an existing organisation a notice from the Genetic Manipulation Advisory Committee that the organisation is an accredited organisation, the organisation is taken to be an accredited organisation under section 92 of the Act.

(2) Subregulation (1) applies—

(a) subject to sections 94(b), 94(c), 95 and 96 of the Act; and

(b) until the end of 2 years after the commencement of Part 7 of the Act, provided the organisation maintains compliance with the Regulator's guidelines, if any, under section 98 of the Act.

43 Notifiable low risk dealings

Reg. 43 inserted by S.R. No. 50/2007 reg. 13.

(1) Despite the amendments made to these Regulations by the Gene Technology Amendment Regulations 2007, a dealing (the ***relevant dealing***) that was a notifiable low risk dealing under Division 2 of Part 3 of these Regulations immediately before the coming into operation of the Gene Technology Amendment Regulations 2007 continues to be a notifiable low risk dealing under Division 2 of Part 6 of the Act if the dealing is carried on by the same person (the ***affected person***).

r. 43

(2) Subregulation (1) ceases to apply in relation to an affected person on the earlier of—

(a) the day on which a licence is issued to the person in respect of the relevant dealing; and

(b) 31 March 2008.

Note

The purpose of this regulation is to provide the opportunity to apply for a licence under Part 5 of the Act to a person who conducted a dealing immediately before the day the Gene Technology Amendment Regulations 2007 came into operation that was then a notifiable low risk dealing but is now a dealing requiring a licence.

SCHEDULES

SCHEDULE 1

Sch. 1 substituted by S.R. No. 50/2007 reg 14.

Regulation 4

TECHNIQUES NOT CONSTITUTING GENE TECHNOLOGY

Item	Description of technique
1	Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
2	Electromagnetic radiation-induced mutagenesis.
3	Particle radiation-induced mutagenesis.
4	Chemical-induced mutagenesis.
5	Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.
6	Protoplast fusion, including fusion of plant protoplasts.
7	Embryo rescue.
8	*In vitro* fertilisation.
9	Zygote implantation.
10	A natural process, if the process does not involve genetically modified material. **Examples** Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

Sch. 1A inserted by S.R. No. 50/2007 reg. 14.

SCHEDULE 1A

Regulation 5

ORGANISMS THAT ARE NOT GENETICALLY MODIFIED ORGANISMS

Item	Description of organism
1	A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
2	A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.
3	Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.
4	An organism that results from an exchange of DNA if— (a) the donor species is also the host species; and (b) the vector DNA does not contain any heterologous DNA.
5	An organism that results from an exchange of DNA between the donor species and the host species if— (a) such exchange can occur by naturally occurring processes; and (b) the donor species and the host species are micro-organisms that— (i) satisfy the criteria in AS/NZS 2243.3:2002 (Safety in laboratories, Part 3: Microbiological aspects and containment facilities) jointly published by Standards Australia and Standards New Zealand, for classification as Risk Group 1; and (ii) are known to exchange nucleic acid by a natural physiological process; and (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange

SCHEDULE 2

Sch. 2 substituted by S.R. No. 50/2007 reg. 15, amended by S.R. No. 147/2007 reg. 14.

Regulation 6

DEALINGS EXEMPT FROM LICENSING

Note

Regulation 6(1) sets out other requirements for exempt dealings.

PART 1—EXEMPT DEALINGS

Item	*Description of dealing*
	* * * * *
2	A dealing with a genetically modified Caenorhabditis elegans, unless— (a) an advantage is conferred on the animal by the genetic modification; or (b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.
3	A dealing with an animal into which genetically modified somatic cells have been introduced, if— (a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and (b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
4	(1) Subject to subitem (2), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture in each vessel containing the resultant culture. (2) The donor nucleic acid— (a) must satisfy either 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; or

Sch. 2

Item	Description of dealing
	(ii) it must be characterised and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; and
	(b) must not code for a toxin with an LD_{50} of less than 100 μg/kg; and
	(c) must not code for a toxin with an LD_{50} of 100 μg/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 shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either—
	(a) a pathogen; or
	(b) a toxin-producing organism.

PART 2—HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

Item	Class	Host	Vector
1	Bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C—any derivative that does not contain— (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1 Non-conjugative plasmids 2 Bacteriophage— (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3 None (non-vector systems)
		Bacillus—specified species—asporogenic strains with a reversion frequency of less than 10^{-7} (a) *B. amyloliquefaciens* (b) *B. licheniformis* (c) *B. pumilus* (d) *B. subtilis* (e) *B. thuringiensis*	1 Non-conjugative plasmids 2 Plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus* 3 None (non-vector systems)
		Pseudomonas putida—strain KT 2440	1 Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2 None (non-vector systems)

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Item	Class	Host	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 *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Vibrio cholerae* CVD103-HgR	1 Non-conjugative plasmids 2 None (non-vector systems)

Item	Class	Host	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 unable to transduce human cells 3 Avipox vectors (attenuated vaccine strains) 4 Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 5 None (non-vector systems)

Sch. 2

Item	Class	Host	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)

PART 3—DEFINITIONS

In this Schedule—

code for, in relation to a toxin, means to specify the amino acid sequence of the toxin;

non-conjugative plasmid means a plasmid that is not self-transmissible, and includes, but is not limited to, non-conjugative forms of the following plasmids—

(a) bacterial artificial chromosomes (BACs);

(b) cosmids;

(c) P1 artificial chromosomes (PACs);

(d) yeast artificial chromosomes (YACs);

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

Sch. 3 substituted by S.R. No. 50/2007 reg. 15, amended by S.R. No. 147/2007 regs 15, 16.

SCHEDULE 3

Regulations 12 and 13

NOTIFIABLE LOW RISK DEALINGS IN RELATION TO A GMO

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

Note

Because of regulation 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 Part 2 of Schedule 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 item 4 of Part 2 of Schedule 2 (animal or human cell culture), 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

Because of regulation 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.

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 a genetically modified laboratory rat, if—

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

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

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

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

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

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

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

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

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

(c) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if—

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

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

(d) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 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 increase the virulence, pathogenicity or transmissibility of the host or vector;

(e) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid—

(i) encodes a pathogenic determinant; or

(ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi;

* * * * *

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

(i) the dealing is undertaken in a facility that is certified by the Regulator—

(A) as a large scale facility; and

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

(ii) the donor nucleic acid satisfies the conditions set out in item 4 of Part 1 of Schedule 2;

(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 shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of Schedule 2, if the donor nucleic acid is derived from either—

(i) a pathogen; or

(ii) a toxin-producing organism;

(i) a dealing involving the introduction of a replication defective viral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 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

Notes

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

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

3.1 Kinds of dealings

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

(a) a dealing (other than a dealing mentioned in clause 2.1(h) of Part 2 of this Schedule) involving cloning of nucleic acid encoding a toxin having an LD_{50} of less than 100 μg/kg;

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

(c) a dealing (other than a dealing mentioned in clause 2.1(h) of Part 2 of this Schedule) 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 Part 2 of Schedule 2 or in clause 1.1(c) of Part 1 or clause 2.1(i) of Part 2 of this Schedule—a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid—

(i) confers an oncogenic modification; or

(ii) encodes—

(A) immunomodulatory molecules; or

(B) cytokines; or

(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 Part 2 of Schedule 2; or

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

(iii) the dealing is a dealing mentioned in clause 2.1(g) of Part 2 of this Schedule;

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

(i) the dealing is a dealing mentioned in clause 2.1(g) of Part 2 of this Schedule; or

(ii) the micro-organism is a host mentioned in Part 2 of Schedule 2;

(g) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products have a heightened risk of inducing an autoimmune 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 encoding an envelope protein;

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

(k) a dealing producing, in each vessel containing the resultant GMO culture, more than 10 litres of that culture, other than a dealing mentioned in clause 2.1(f) of Part 2 of this Schedule;

(l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council;

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

(n) a dealing involving a genetically modified pathogenic organism, if the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification.

* * * * *

Sch. 4 revoked by S.R. No. 50/2007 reg. 16.

ENDNOTES

1. General Information

The Gene Technology Regulations 2001, S.R. No. 153/2001 were made on 11 December 2001 by the Governor in Council under section 193 of the **Gene Technology Act 2001**, No. 67/2001 and came into operation on 11 December 2001.

The Gene Technology Regulations 2001 will sunset 10 years after the day of making on 11 December 2011 (see section 5 of the **Subordinate Legislation Act 1994**).

2. Table of Amendments

This Version incorporates amendments made to the Gene Technology Regulations 2001 by statutory rules, subordinate instruments and Acts.

Gene Technology Amendment Regulations 2007, S.R. No. 50/2007

Date of Making:	12.6.07
Date of Commencement:	12.6.07

Gene Technology (Further Amendment) Regulations 2007, S.R. No. 147/2007

Date of Making:	18.12.07
Date of Commencement:	Regs 6, 7(1)(3), 8-12, 14-16 on 18.12.07: reg. 3(1); regs 5, 7(2), 13 on 1.1.08: reg. 3(2)

Endnotes

3. Explanatory Details

No entries at date of publication.