Gene Technology Regulations 2001

Statutory Rules 2001 No. 106 as amended

made under the

Gene Technology Act 2000

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Part 1 Preliminary

1 Name of Regulations [*see* Note 1]

These Regulations are the *Gene Technology Regulations 2001*.

2 Commencement [*see* Note 1]

These Regulations commence on the date of commencement of provisions of the Act to which subsection 2 (3) of the Act apply.

3 Definitions

In these Regulations:

Act means the *Gene Technology Act 2000*.

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.

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

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

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

expert adviser means:

(a) in Part 4 — an expert adviser appointed under subsection 102 (1) of the Act; and

(b) in Part 5 — an expert adviser appointed under subsection 112 (1) of the Act.

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

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genetically modified laboratory rat means a laboratory strain of rat of either the species *Rattus rattus* or *Rattus norvegicus* that has been modified by gene technology.

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

known means known within the scientific community.

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

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

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

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

out of session, for regulation 25, has the meaning given in subregulation 25 (4).

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

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

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

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

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

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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.

toxin means a substance that is toxic to any vertebrate.

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

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

Note Several other words and expressions used in these Regulations have the meaning given by section 10, or another provision, of the Act. For example:

- accredited organisation
- deal with
- environment
- Ethics and Community Committee
- facility
- Gene Technology Technical Advisory Committee
- GMO
- GM product
- Institutional Biosafety Committee
- intentional release of the GMO into the environment (see section 11)
- notifiable low risk dealing
- Regulator.

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Part 2 Interpretation and general operation

4 Techniques not constituting gene technology

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

5 Organisms that are not genetically modified organisms

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

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Part 3 Dealings with GMOs

Division 1 Licensing system

6 Dealings exempt from licensing

(1) For subsection 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 mentioned 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

(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) 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.

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

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

7 Application for licence — prescribed fee

Note At the commencement of the Regulations, no application fee is prescribed under subsection 40 (6) of the Act.

8 Time limit for deciding an application

(1) For subsection 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

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(b) for an application to which Division 4 of Part 5 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 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

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(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:

(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 subsection 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.

(4) In subregulation (1):

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

9 Prescribed authorities

For paragraphs 50 (3) (c) and 52 (3) (c) of the Act, the following Commonwealth authorities and agencies are prescribed:

(a) Food Standards Australia New Zealand;

(b) Australian Quarantine and Inspection Service;

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

(e) Australian Pesticides and Veterinary Medicines Authority;

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

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

For paragraph 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 paragraphs 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

(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

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

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(2) In taking into account a risk mentioned in subsection 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 the Regulations, no conditions are prescribed under paragraph 61 (b) of the Act.

11A Time limit for deciding variation application

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

Division 2 Notifiable low risk dealings

12 Notifiable low risk dealings

(1) For subsection 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.

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

13 Requirements in relation to undertaking notifiable low risk dealings

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

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(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 paragraph 27 (d) of the Act, that the Regulator has determined in writing are appropriate for conducting the dealing; and

(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 paragraph 27 (d) of the Act.

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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 by the organisation for the financial year; or

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

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

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

(a) the Committee; or

(b) the person or accredited organisation; or

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

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

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(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

(1) For section 84 of the Act, the period within which the Regulator must consider, and decide, an application for certification of a facility is:

(a) 90 days after the day the application is received by the Regulator; or

(b) if the Regulator has given the applicant a notice under subsection 85 (1) of the Act, 90 days plus the period beginning on the day the notice is given and ending when the required information is given to the Regulator.

(2) For the purpose of determining the end of a period mentioned in subregulation (1), Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted.

15 Application for certification — failure to provide section 85 information

If an applicant for certification fails to provide information required under subsection 85 (1) of the Act within the period specified in a notice given under subsection 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).

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16 Regulator to decide accreditation application within 90 days

(1) For subsection 92 (1) of the Act, the period within which the Regulator must consider, and decide, an application for accreditation of an organisation is:

(a) 90 days after the day the application is received by the Regulator; or

(b) if the Regulator has given the applicant a notice under subsection 93 (1) of the Act, 90 days plus the period beginning on the day the notice is given and ending when the required information is given to the Regulator.

(2) For the purpose of determining the end of a period mentioned in subregulation (1), Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted.

17 Application for accreditation — failure to provide section 93 information

If an applicant for accreditation fails to provide information required under subsection 93 (1) of the Act within the period specified in a notice given under subsection 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).

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Part 4 Gene Technology Technical Advisory Committee

Division 1 Conditions of appointment

18 GTTAC members and advisers — term of appointment

(1) The term of appointment of a member of the Gene Technology Technical Advisory Committee, or an expert adviser, is 3 years, or a lesser period specified in the instrument of appointment of the member or adviser.

(2) A member or adviser may be reappointed for a further term or terms.

19 GTTAC members and advisers — resignation

A member of the Gene Technology Technical Advisory Committee, or an expert adviser, may resign by giving the Minister written notice of resignation.

20 GTTAC members — disclosure of interests

(1) Before the Minister appoints a person as a member of the Gene Technology Technical Advisory Committee, the Minister must obtain from the person a declaration setting out all direct or indirect interests, pecuniary or otherwise, that the person is aware of having in a matter of a kind likely to be considered at a meeting of the Committee.

(2) A member of the Gene Technology Technical Advisory Committee who is aware of having a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.

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(3) Disclosure must include interests that could be perceived to represent a possible conflict of interest in relation to:

(a) for subregulation (1) — a matter likely to be considered at a meeting of the Committee; or

(b) for subregulation (2) — the matter being considered or about to be considered.

(4) A disclosure under this regulation must be recorded in the minutes of the meeting and the member must not:

(a) be present during any deliberation of the Committee about the matter, except to give information requested by the Committee; or

(b) take part in any decision of the Committee about that matter.

21 GTTAC members and advisers — termination of appointment

(1) The Minister may terminate the appointment of a member of the Gene Technology Technical Advisory Committee, or an expert adviser, for misbehaviour (including failure to disclose an interest) or physical or mental incapacity:

(a) in the case of the chairperson of the Committee — with the agreement of a majority of jurisdictions; or

(b) in any other case — on the initiative of the Minister.

(2) The Minister must terminate a member's appointment if the member:

(a) becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his or her creditors or makes an assignment of his or her remuneration for their benefit; or

(b) fails to fulfil his or her obligations, as a member, in enabling the Committee to comply with section 101 of the Act; or

(c) fails to attend for 3 consecutive attendance days of the Committee, except with leave of absence granted under regulation 22.

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Note Under section 27A of the *Administrative Appeals Tribunal Act 1975*, a decision-maker must give to persons whose interests are affected by the making of the decision, notice of the decision and of their right to have the decision reviewed. In notifying such a person, the decision-maker must have regard to the Code of Practice determined under section 27B of that Act (see *Gazette* No. S 432, 7 December 1994), which is accessible on the Internet at:

http://scaleplus.law.gov.au/html/instruments/0/14/0/IN000020.htm.

22 GTTAC members — leave of absence

(1) The Minister may grant the Chairperson of the Gene Technology Technical Advisory Committee leave of absence.

(2) The Chairperson may grant a member of the Gene Technology Technical Advisory Committee leave of absence.

23 Expert advisers — disclosure of interests

(1) Before the Minister appoints a person as an expert adviser to the Gene Technology Technical Advisory Committee, the Minister must obtain from the person a declaration setting out all direct or indirect interests, pecuniary or otherwise, that the person is aware of having in a matter of a kind likely to be considered at a meeting of the Committee.

(2) An expert adviser who is aware of having a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the Committee for which he or she is providing advice must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.

(3) Disclosure must include interests that could be perceived to represent a possible conflict of interest in relation to:

(a) for subregulation (1) — a matter likely to be considered at a meeting of the Committee; or

(b) for subregulation (2) — the matter being considered or about to be considered.

(4) A disclosure under this regulation must be recorded in the minutes of the meeting.

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Division 2 Committee procedures

24 Committee procedures generally

In performing its functions, the Gene Technology Technical Advisory Committee:

(a) must act according to these Regulations; and

(b) must act with as little formality and as quickly as the requirements of these Regulations, and a proper consideration of the issues before the Committee, allow; and

(c) may obtain information about an issue in any way it considers appropriate, subject to any direction in a request from the Regulator or Ministerial Council about the extent to which, or manner in which, information is to be obtained.

25 Committee meetings

(1) The Chairperson of the Gene Technology Technical Advisory Committee may, by written notice to the Committee, direct the Committee to hold a meeting:

(a) at the time and place stated in the notice; and

(b) to deal with specified matters in the manner stated in the notice.

(2) In each year, the Committee may have as many meetings (other than meetings by videoconference or teleconference) as:

(a) before the beginning of the year — the Regulator and the Chairperson have agreed may be held; and

(b) the Regulator and the Chairperson agree should be additionally held.

(3) If the Chairperson of the Committee considers it appropriate and efficient in the circumstances, the Committee may be directed:

(a) to meet, and resolve decisions, by videoconference or teleconference; and

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(b) to meet out of session.

(4) For this regulation:

out of session, in relation to a meeting, means a meeting in which the members take part by correspondence, electronic mail, telephone or in any other way that does not involve formal simultaneous meeting and voting.

(5) Subject to these Regulations, the procedure of a meeting is as decided by the Committee.

26 Presiding member

(1) At a meeting of the Gene Technology Technical Advisory Committee, the Chairperson of the Committee must:

(a) preside; or

(b) nominate, in writing, a member of the Committee (other than a member to whom paragraph 100 (7A) (a) or (b) of the Act applies) to preside.

(2) If the Chairperson is temporarily absent from a meeting, the members present must choose a member to preside in the Chairperson's absence.

27 Quorum

At a meeting of the Gene Technology Technical Advisory Committee, a quorum exists if half of the members appointed under subsection 100 (2) of the Act are present.

28 Voting

(1) A decision of the Gene Technology Technical Advisory Committee is made by a majority of the members present, and voting for the decision, at a Committee meeting.

(2) The member presiding at a Committee meeting has a deliberative vote and also has a casting vote in the event of an equality of votes by members present.

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29 Records and Reports

(1) The Gene Technology Technical Advisory Committee must keep a record of its proceedings, and must give to the Regulator a copy of each resolution passed by the Committee.

(2) Copies of resolutions are to be maintained by the Regulator in a form accessible to the public, except to the extent that information in a resolution is considered by the Regulator to be confidential commercial information.

(3) The Committee must prepare any other report about its activities that is requested by the Ministerial Council or the Regulator.

Division 3 Subcommittees

30 Operation of subcommittees

(1) Regulations 24, 25, 26 and 28 apply to a subcommittee established under subsection 105 (1) of the Act as if a reference in those regulations to the Gene Technology Technical Advisory Committee were a reference to the subcommittee.

(2) At a meeting of a subcommittee, a quorum exists if half of the members of the subcommittee are present.

(3) A subcommittee must keep a record of its proceedings, and must give to the Gene Technology Technical Advisory Committee a copy of each resolution passed by the subcommittee.

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Part 5 Ethics and Community Committee

31 Ethics and Community Committee — conditions of appointment

Division 1 of Part 4 applies to the conditions of appointment of a member of the Ethics and Community Committee, or an expert adviser, as if:

(a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Ethics and Community Committee; and

(b) a reference to a member of the Gene Technology Technical Advisory Committee were a reference to a member of the Ethics and Community Committee; and

(c) the reference, in paragraph 21 (2) (b), to section 101 of the Act were a reference to section 107 of the Act.

32 Ethics and Community Committee — Committee procedures

Division 2 of Part 4 applies to the procedures of the Ethics and Community Committee as if:

(a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Ethics and Community Committee; and

(b) a reference to a member or Chairperson of the Gene Technology Technical Advisory Committee were a reference to a member or Chairperson of the Ethics and Community Committee; and

(c) the reference, in paragraph 26 (1) (b), to paragraph 100 (7A) (a) or (b) of the Act were a reference to paragraph 108 (4) (a) or (b) of the Act; and

(d) the reference, in regulation 27, to subsection 100 (2) of the Act were a reference to subsection 108 (1) of the Act.

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33 Ethics and Community Committee — operation of subcommittees

(1) Regulations 24, 25, 26 and 28 apply to a subcommittee established under subsection 111 (1) of the Act as if a reference in those regulations to the Gene Technology Technical Advisory Committee were a reference to the subcommittee.

(2) At a meeting of a subcommittee, a quorum exists if half of the members of the subcommittee are present.

(3) A subcommittee must keep a record of its proceedings, and must give to the Ethics and Community Committee a copy of each resolution passed by the subcommittee.

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Part 7 Miscellaneous

37 Reviewable State decisions

Note At the commencement of these Regulations, no decisions of the Regulator are reviewable State decisions under section 19 of the Act.

38 Review of decisions

Subject to the *Administrative Appeals Tribunal Act 1975*, a person whose interests are affected by a decision of the Minister under regulation 21, or that regulation as applied to Part 5 of these Regulations, may apply to the Administrative Appeals Tribunal for review of the decision.

39 Record of GMO and GM Product Dealings

(1) For subsection 138 (4) 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 subsection 138 (5) 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 (Administration) Act 1992*;

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(B) *Australia New Zealand Food Authority Act 1991*;

(C) *Industrial Chemicals (Notification and Assessment) Act 1989*;

(D) *Therapeutic Goods Act 1989*; 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

(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.

40 Inspector identity card

For paragraph 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.

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Schedule 1A Techniques that are not gene technology

(regulation 4)

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.

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Schedule 1 Organisms that are not genetically modified organisms

(regulation 5)

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.
6	An organism that results from an exchange of DNA if: (a) the donor species is also the host species; and (b) the vector DNA does not contain any heterologous DNA.
7	An organism that results from an exchange of DNA between the donor species and the host species if: (a) such exchange can occur by naturally occurring processes; and (b) the donor species and the host species are micro-organisms that: (i) satisfy the criteria in AS/NZS 2243.3:2002 (Safety in laboratories, Part 3: Microbiological aspects and containment facilities) jointly published by Standards Australia and Standards New Zealand, for classification as Risk Group 1; and (ii) are known to exchange nucleic acid by a natural physiological process; and (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

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Schedule 2 Dealings exempt from licensing

(regulation 6)

Note Subregulation 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 (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

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Item	Description of dealing
	(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)

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Item	Class	Host	Vector
		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)
		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*	1. Non-conjugative plasmids 2. None (non-vector

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Item	Class	Host	Vector
		Pediococcus *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Vibrio cholerae* CVD103-HgR	systems)
2	Fungi	*Neurospora crassa* – laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Kluyveromyces lactis* *Trichoderma reesei*	1. All vectors 2. None (non-vector systems)
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)

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Item	Class	Host	Vector
			4. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus
			5. None (non-vector systems)
		Plant cell cultures	1. Non-tumorigenic disarmed Ti plasmid vectors, or 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).

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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).

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Schedule 3 Notifiable low risk dealings in relation to a GMO

(regulations 12 and 13)

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

Note Because of subregulation 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.

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

Note Because of subregulation 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

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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

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(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.

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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, can be undertaken only by a person who is licensed, under the Act, for the dealing (see Act, section 32).

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 paragraph 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 paragraph 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 paragraph 1.1 (c) of Part 1 or 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;

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(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 paragraph 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 paragraph 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

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(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 paragraph 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.

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Notes to the *Gene Technology Regulations 2001*

Note 1

The *Gene Technology Regulations 2001* (in force under the *Gene Technology Act 2000*) as shown in this compilation comprise Statutory Rules 2001 No. 106 amended as indicated in the Tables below.

For all relevant information pertaining to application, saving or transitional provisions *see* Table A.

Under the *Legislative Instruments Act 2003*, which came into force on 1 January 2005, it is a requirement for all non-exempt legislative instruments to be registered on the Federal Register of Legislative Instruments. From 1 January 2005 the Statutory Rules series ceased to exist and was replaced with Select Legislative Instruments (SLI series). Numbering conventions remain the same, ie Year and Number.

Table of Instruments

Year and Number	Date of notification in *Gazette* or FRLI registration	Date of commencement	Application, saving or transitional provisions
2001 No. 106	31 May 2001	22 June 2001 (*see* r. 2)	
2006 No. 314	1 Dec 2006 (*see* F2006L03558)	31 Mar 2007	R. 4
2007 No. 128	24 May 2007 (*see* F2007L01317)	Schedule 1: 1 July 2007 (*see* r. 2 (a)) Schedule 2: (*a*) Schedule 3: 1 Jan 2008 (*see* r. 2 (c))	—

(a) Regulation 2 (b) of SLI 2007 No. 128 provides as follows:

These regulations commence as follows:

(b) immediately after the commencement of Schedule 1 — Schedule 2.

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Part 1	
R. 3	rs. 2006 No. 314 am. 2007 No. 128
Note to r. 3	am. 2007 No. 128
Part 2	
R. 4	rs. 2006 No. 314
Part 3	
Division 1	
R. 6	am. 2006 No. 314; 2007 No. 128
R. 7	rs. 2006 No. 314
R. 8	am. 2007 No. 128
R. 9	am. 2006 No. 314; 2007 No. 128
R. 9A	ad. 2007 No. 128
R. 10	am. 2006 No. 314
R. 11A	ad. 2007 No. 128
Division 2	
R. 13	rs. 2006 No. 314; 2007 No. 128
R. 13A	ad. 2007 No. 128
Part 4	
Division 3	
R. 29	am. 2006 No. 314
Part 5	
Part 5	rs. 2007 No. 128
R. 31	rs. 2007 No. 128
R. 32	rs. 2007 No 128
R. 33	rs. 2007 No. 128
Part 6	rep. 2007 No. 128
Rr. 34–36	rep. 2007 No. 128
Part 7	
R. 38	am. 2007 No. 128
R. 39	am. 2006 No. 314
Part 8	rep. 2006 No. 314
Rr. 41, 42	rep. 2006 No. 314
Schedule 1A	
Schedule 1A	ad. 2006 No. 314

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Table of Amendments

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Provision affected	How affected
Schedule 1	
Schedule 1	rs. 2006 No. 314
Schedule 2	
Schedule 2	rs. 2006 No. 314 am. 2007 No. 128
Schedule 3	
Schedule 3	rs. 2006 No. 314 am. 2007 No. 128
Schedule 4	rep. 2006 No. 314

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Table A Application, saving or transitional provisions

Select Legislative Instrument 2006 No. 314

4 Transitional

(1) The purpose of this regulation is to provide the opportunity to apply for a licence to a person who conducted a dealing before 31 March 2007 that was then a notifiable low risk dealing but is now a dealing requiring a licence.

(2) Despite the substitution of Schedule 3 by these Regulations but subject to subregulation (3), a dealing (the ***relevant dealing***) that was a notifiable low risk dealing immediately before 31 March 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***).

(3) Subregulation (2) 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.

(4) In this regulation:

Act means the *Gene Technology Act 2000*.

licence means a licence under Part 5 of the Act.

notifiable low risk dealing means a dealing under Division 2 of Part 3 of the *Gene Technology Regulations 2001*.

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