

Draft compilation of the
Gene Technology Regulations 2001
to show proposed amendments
2010

This compilation was prepared by the Office of the Gene Technology Regulator and is indicative only.

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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 guinea pig means a laboratory strain of guinea pig of the species *Cavia porcellus* that has been modified by gene technology.

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

Genetically modified laboratory rabbit means a laboratory strain of rabbit of the species *Oryctolagus cuniculus* that has been modified by gene technology.

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

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

inspector means a person appointed by the Regulator under section 150 of the Act as an inspector

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.

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.

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

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

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 LD₅₀ 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.

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.

Part 2A Gene Technology Regulator

5A Functions of the Regulator

For paragraph 27 (1) of the Act, the Regulator has the function of making inspectors available to be appointed as inspectors under Division 7 of Part 3 of the *National Health Security Act 2007*.

Deleted: available inspectors appointed under section 150 of the Act

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.
- (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.

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

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

(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 **waiting for:**

~~(i) information that the applicant has been requested, in writing, to give; or~~

~~(ii) advice sought from the Gene Technology Technical Advisory Committee on the risk assessment and the risk management plan prepared for dealings involving intentional release;~~

(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

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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:
 - (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.

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.

- (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

- (1) 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.
- (2) For the 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 waiting for information that the applicant has been asked, in writing, to give.

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 or 2 of Schedule 3 (other than a dealing also mentioned in Part 3, of Schedule 3); and
 - (b) it does not involve an intentional release of the GMO into the environment.

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- (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:
- (a) a person or an accredited organisation has prepared and submitted a written proposal for an Institutional Biosafety Committee to assess whether the dealing is a notifiable low risk dealing; and
 - (b) the Institutional Biosafety Committee has assessed the dealing to be a notifiable low risk dealing mentioned in Part 1 or Part 2 of Schedule 3; and
 - (c) the dealing undertaken is the dealing described in the Institutional Biosafety Committee's record of assessment of the proposal; and
 - (d) the dealing is undertaken before the day mentioned in regulation 13A for the dealing; and
 - (e) the person is mentioned in the Institutional Biosafety Committee's record of assessment as having the appropriate training and experience to undertake the dealing; and
 - (f) the person keeps or can give, on request, a copy of the record of assessment to an inspector; and
 - (g) the person does not compromise the containment of a GMO involved in the dealing; and
 - (h) the person undertakes the dealing in accordance with subregulations (2) and (3).

Note A person complies with paragraph (e) if the person is in a class of persons that an Institutional Biosafety Committee has included in the record

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of assessment as having the appropriate training and experience to undertake the dealing.

- (2) A notifiable low risk dealing must be undertaken as follows:
- (a) 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 that is appropriate for the dealing; or
 - (b) for a kind of dealing mentioned in Part 2 of Schedule 3 — in a facility certified by the Regulator to at least physical containment level 2 that is appropriate for the dealing; or
 - (c) in a facility agreed in writing by the Regulator.
- (3) However, if a notifiable low risk dealing involves the transportation, storage or disposal of a GMO:
- (a) paragraph 13 (1) (d) does not prevent the transportation, storage or disposal of the GMO on or after the day before which the dealing is to be undertaken; and
 - (b) the transportation, storage or disposal of the GMO may happen outside a facility mentioned in subregulation (2) but must be conducted in accordance with existing technical and procedural guidelines issued by the Regulator for this purpose under paragraph 27 (d) of the Act.
- (4) For paragraph (2) (c), the Regulator must consider the capacity of a facility to contain GMOs before deciding whether to agree in writing to a facility.

13A Time limits for stopping notifiable low risk dealings

For paragraph 13 (1) (d), the day on or before which the dealing must stop being undertaken is:

- (a) the day 5 years after the date of assessment, if the dealing is assessed by an Institutional Biosafety Committee on or after the 1 March 2011; and
- (b) 29 February 2016, if the dealing is assessed by an Institutional Biosafety Committee in the period 1 March 2006 to 28 February 2011 (inclusive); and

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Deleted: (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

- (c) 1 March 2013, if the dealing is assessed by an Institutional Biosafety Committee before 1 March 2006.

Note A person will have to apply for, and obtain, a new assessment of the dealing as a notifiable low risk dealing from an Institutional Biosafety Committee to continue to undertake the dealing after the applicable day mentioned in this regulation.

13B Requirements for Institutional Biosafety Committees about records of assessments of Notifiable Low Risk Dealing proposals.

An Institutional Biosafety Committee that has assessed a proposal as to whether a dealing is a notifiable low risk dealing must:

- (a) make a record of its assessment, in a form approved by the Regulator, that includes the following:
- (i) a description of the dealing to be undertaken;
 - (ii) its assessment whether the dealing is a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3;
 - (iii) the date of its assessment of the dealing;
 - (iv) the person or classes of persons considered by the Committee to have the appropriate training and experience to undertake the dealing; and
- (b) give a copy of the record of assessment to the person or accredited organisation that submitted the proposal to the Committee.

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(c)

Deleted: requested the Committee to assess the proposed dealing; and ¶
(ii) the project supervisor for the proposed dealing

13C Information to be kept or given to the Regulator by persons or accredited organisations

(1) A person or accredited organisation that has been given a copy of a record of assessment by an Institutional Biosafety Committee must, if the dealing has been assessed as a notifiable low risk dealing:

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(a) for the financial year in which the Committee made the assessment, include a copy of the notification section of the record of assessment:

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

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

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(b) keep a copy of the Institutional Biosafety Committee's record of assessment for 8 years after the date of the assessment by the Committee.

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(2) The Regulator may at any time, by written notice, require from the following persons or organisation any further information about how a notifiable low risk dealing is being undertaken, including information about the GMOs being dealt with:

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(a) the person or accredited organisation that submitted the proposal for assessment of the dealing;

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(b) any other person involved with undertaking the dealing.

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(3) A person or organisation given a notice under subregulation (2) must, by the end of the period mentioned in the notice, give the Regulator the information required by the notice.

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Division 3 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).

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).

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.

- (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.

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.

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

- (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.

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.

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.

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.

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 or 2 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 assessment by an Institutional Biosafety Committee that the dealing is a notifiable low risk dealing.

Deleted: 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*;

- (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.

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	<i>In vitro</i> fertilisation.
9	Zygote implantation.
10	A natural process, if the process does not involve genetically modified material.
	<i>Examples</i>
	Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

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.

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 <i>Caenorhabditis elegans</i> , unless: (a) an <i>advantage</i> 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.
<u>3A</u>	<u>A dealing with an animal whose somatic cells have been genetically modified <i>in vivo</i> by a replication defective viral vector, if:</u> <u>(a) the <i>in vivo</i> modification occurred as part of a previous dealing;</u> <u>and</u> <u>(b) the replication defective viral vector is no longer in the animal;</u> <u>and</u> <u>(c) no germ line cells have been genetically modified; and</u> <u>(d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and</u> <u>(e) the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.</u>

Item Description of dealing

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 25 litres of GMO culture in each vessel containing the resultant culture.

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(2) The donor nucleic acid must:

(a) meet either of the following requirements:

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(i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi;

Deleted: or

(ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm; and

Deleted: not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector

(b) not code for a toxin with an LD₅₀ of less than 100 µg/kg; and

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(c) not code for a toxin with an LD₅₀ of 100 µg/kg or more, if the intention is to express the toxin at high levels; and

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(d) not be uncharacterised nucleic acid from a toxin-producing organism; and

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(e) not include a viral sequence unless the donor nucleic acid:

Deleted: must

(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) cannot restore replication competence to the vector;

Deleted: is incapable of correcting a defect in the host/vector system leading to production of replication competent virions

Example for subparagraph (2) (a) (ii)

Donor nucleic acid would not comply with subparagraph (2) (a) (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it:

Deleted: ; and

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases the virulence, pathogenicity or transmissibility.

Deleted: (f) must not confer an oncogenic modification.

Item	Description of dealing
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: <ul style="list-style-type: none"> (a) a pathogen; or (b) a toxin-producing organism.

Part 2 Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	<p><i>Escherichia coli</i> K12, <i>E. coli</i> B, <i>E. coli</i> C or <i>E. coli</i> Nissle 1917 – any derivative that does not contain:</p> <ul style="list-style-type: none"> (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid <p><i>Bacillus</i> – specified species – asporogenic strains with a reversion frequency of less than 10^{-7}:</p> <ul style="list-style-type: none"> (a) <i>B. amyloliquefaciens</i> (b) <i>B. licheniformis</i> (c) <i>B. pumilus</i> (d) <i>B. subtilis</i> (e) <i>B. thuringiensis</i> <p><i>Pseudomonas putida</i> – strain KT 2440</p>	<ul style="list-style-type: none"> 1. Non-conjugative plasmids 2. Bacteriophage <ul style="list-style-type: none"> (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3. None (non-vector systems) <ul style="list-style-type: none"> 1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include <i>B. cereus</i>, <i>B. anthracis</i> or any other pathogenic strain of <i>Bacillus</i> 3. None (non-vector systems) <ul style="list-style-type: none"> 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:	1. Non-conjugative plasmids
		(a) <i>S. aureofaciens</i>	2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives
		(b) <i>S. coelicolor</i>	
		(c) <i>S. cyaneus</i>	3. Actinophage phi C31 and derivatives
		(d) <i>S. griseus</i>	
		(e) <i>S. lividans</i>	4. None (non-vector systems)
		(f) <i>S. parvulus</i>	
		(g) <i>S. rimosus</i>	
		(h) <i>S. venezuelae</i>	
		<i>Agrobacterium radiobacter</i>	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors
		<i>Agrobacterium rhizogenes</i> — disarmed strains	
		<i>Agrobacterium tumefaciens</i> — disarmed strains	2. None (non-vector systems)
		<i>Lactobacillus</i>	1. Non-conjugative plasmids
		<u><i>Lactococcus lactis</i></u>	2. None (non-vector systems)
		<i>Oenococcus oeni</i> syn. <i>Leuconostoc oeni</i>	
		<i>Pediococcus</i>	
		<i>Photobacterium angustum</i>	
		<i>Pseudoalteromonas tunicata</i>	
		<i>Rhizobium</i> (including the genus <i>Allorhizobium</i>)	
		<i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas alaskensis</i>	
		<u><i>Streptococcus thermophilus</i></u>	

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Item	Class	Host	Vector
		<u><i>Synechococcus</i> – specified strains</u> (a) <u>PCC 7942</u> (b) <u>PCC 7002</u> <u>(c) WH 8102</u> <u><i>Synechocystis</i> species – strain PCC 6803</u> <i>Vibrio cholerae</i> CVD103-HgR	
2	Fungi	<i>Neurospora crassa</i> – laboratory strains <i>Pichia pastoris</i> <i>Saccharomyces cerevisiae</i> <i>Schizosaccharomyces pombe</i> <i>Kluyveromyces lactis</i> <i>Trichoderma reesei</i> <u><i>Yarrowia lipolytica</i></u>	1. All vectors 2. None (non-vector systems)
3	Slime moulds	<i>Dictyostelium</i> species	1. <i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. None (non-vector systems)

Item	Class	Host	Vector
4	Tissue culture	<p><u>Any of the following that cannot spontaneously generate a whole animal:</u></p> <p>(a) <u>animal or human cell cultures (including packaging cell lines);</u></p> <p>(b) <u>isolated cells, isolated tissues or isolated organs, whether animal or human;</u></p> <p>(c) <u>early non-human mammalian embryos cultured <i>in vitro</i></u></p> <p><u>Plant cell cultures, and isolated plant tissues, that are incapable of spontaneous vegetative or sexual propagation to generate a whole plant</u></p>	<ol style="list-style-type: none"> 1. Non-conjugative plasmids 2. Non-viral vectors, or <u>replication</u> defective viral vectors unable to transduce human cells 3. Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems)
			<ol style="list-style-type: none"> 1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in <i>Agrobacterium tumefaciens</i>, <i>Agrobacterium radiobacter</i> or <i>Agrobacterium rhizogenes</i> 2. Non-pathogenic viral vectors 3. None (non-vector systems)

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Deleted: 3. Avipox vectors (attenuated vaccine strains)

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 in which donor nucleic acid is or was introduced into a host cell:

- (a) in the absence of a nucleic acid-based vector; or
- (b) using a nucleic acid-based vector in the course of a previous dealing and the vector is:
 - (i) no longer present; or
 - (ii) present but cannot be remobilised from a host cell.

Example 1

A system mentioned in paragraph (a) might involve the use of electroporation or particle bombardment.

Example 2

A system mentioned in paragraph (b) might involve cells that have been transduced with a replication defective retroviral vector and no vector particles remain.

Deleted: *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).¶

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 undertaken in physical containment level 1 facilities that are appropriate for the dealings:

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(a) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit or a genetically modified laboratory rat, unless:

- (i) an advantage is conferred on the animal by the genetic modification; or
- (ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification;

Deleted: because of the genetic modification,

(c) a dealing involving a replication defective vector derived from Human adenovirus or Adeno associated virus in a host mentioned in item 4 of Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector.

Deleted: (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 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 undertaken in certified physical containment level 2 facilities that are appropriate for the dealings:

- (a) a dealing involving whole animals (including non-vertebrates) that:
 - (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
 - (ii) does not involve any of the following:
 - (A) a genetically modified laboratory guinea pig;
 - (B) a genetically modified laboratory mouse;
 - (C) a genetically modified laboratory rabbit;
 - (D) a genetically modified laboratory rat
 - (E) a genetically modified *Caenorhabditis elegans*;
- (aa) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat or 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;

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Deleted: or

Deleted: (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;

Deleted: (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/vector system not mentioned in paragraph 1.1 (c) or Part 2 of Schedule 2, if neither the host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:

 (i) human beings; or

 (ii) animals; or

 (iii) plants; or

 (iv) fungi;

(d) a dealing involving a host and vector not mentioned as a host/vector system in Part 2 of Schedule 2, if:

 (i) the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy:

 (A) human beings; or

 (B) animals; or

 (C) plants; or

 (D) fungi; and

(ii) the donor nucleic acid is characterised; and

 (iii) the characterisation of the donor nucleic acid shows that it is unlikely to increase the capacity of the host or vector to cause harm.

Example

Donor nucleic acid would not comply with subparagraph (iii) if, in relation to the capacity of the host or vector to cause harm, it:

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility.

(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 otherwise healthy:

 (A) human beings; or

 (B) animals; or

 (C) plants; or

 (D) fungi;

Deleted: and

Deleted: that are

Deleted: as a host/vector system

Deleted: ¶
(i)

Deleted: not

Deleted: ; and¶

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

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(A)

Deleted: or

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

Deleted: 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;

(f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 25 litres of GMO culture in each vessel containing the resultant culture, if:

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(i) the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility; and

Deleted: (A)

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

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

(g) a dealing involving complementation of knocked-out genes, if the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out;

Deleted: does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of

Example

A dealing would not comply with paragraph (g) if it involved complementation that, in relation to the parent organism:

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility.

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(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 unable to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;

(j) a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells, other than a vector mentioned in paragraph 1.1 (c), into a host mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;

(k) a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid cannot restore replication competence to the vector; and

(ii) the donor nucleic acid does not encode:

(A) a protein with immunomodulatory activity in humans; or

(B) a growth factor, or a component of a signal transduction pathway, that, if expressed, may lead to cell proliferation in humans;

(l) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2, if:

(i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied *in trans*; and

(ii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iii) either:

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;

(m) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid does not encode:

(A) a protein with immunomodulatory activity in humans; or

(B) a growth factor, or a component of a signal transduction pathway, that, if expressed, may lead to cell proliferation in humans; and

(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied *in trans*; and

(iii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iv) either:

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these.

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).

Deleted: (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.¶

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)) involving cloning of nucleic acid encoding a toxin having an LD₅₀ of less than 100 µg/kg;

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(b) a dealing involving high level expression of toxin genes, even if the LD₅₀ is 100 µg/kg or more;

(c) a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;

(d) a dealing involving the introduction of a replication defective viral vector into a host not mentioned in Part 2 of Schedule 2, other than a dealing mentioned in paragraph 2.1 (i), if the donor nucleic acid encodes:

(i) a protein with immunomodulatory activity in humans; or

(ii) a growth factor, or a component of a signal transduction pathway, that, if expressed, may lead to cell proliferation in humans; and

(e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the donor nucleic acid encodes:

(i) a protein with immunomodulatory activity in humans; or

(ii) a growth factor, or a component of a signal transduction pathway, that, if expressed, may lead to cell proliferation in humans;

(f) a dealing involving, as host or vector, a micro-organism, if:

(i) the micro-organism, has been implicated in, or has a history of causing, disease in otherwise healthy:

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi; and

(ii) none of the following sub-subparagraphs apply:

(A) the host/vector system is a system mentioned in Part 2 of Schedule 2; or

(B) the donor nucleic acid is characterised and its characterisation shows that it is unlikely to increase the capacity of the host or vector to cause harm; or

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Deleted: 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 —

Deleted: donor nucleic acid in a viral vector

Deleted: (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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Deleted: 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

(C) the dealing is a dealing mentioned in paragraph 2.1 (g);

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Example

Donor nucleic acid would not comply with sub-subparagraph (B) if, in relation to the capacity of the host or vector to cause harm, it:

- (a) provides an advantage; or
- (b) adds a potential host species of mode of transmissibility; or
- (c) increases the virulence, pathogenicity or transmissibility.

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

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(h) 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 are likely to increase the capacity of the micro-organisms to induce an autoimmune response;

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(i) 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 an increased capacity to cause harm compared to the capacity of the parent or donor organism;

Deleted: altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility in relation to any

Example:

A dealing would not comply with paragraph (i) if it produces a novel replication competent virus that has a higher capacity to cause harm to any potential host species than the parent organism because the new virus has:

- (a) an advantage; or
- (b) a new potential host species or mode of transmissibility; or
- (c) increased virulence, pathogenicity or transmissibility.

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- (i) all structural and accessory genes have been removed from the vector to render it incapable of replication or assembly into a virion without these functions being supplied in trans; and¶
- (ii) the vector includes a deletion that results in a transcriptionally inactive vector which, even when packaging functions are supplied in trans, cannot be converted into full length viral RNA; and¶
- (iii) the packaging cell line and packaging plasmids used contain only viral genes gag, pol, rev and a gene encoding an envelope protein

(j) a dealing, other than a dealing mentioned in paragraph 2.1 (l) or (m), with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells;

- (k) 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;
- (l) a dealing producing, in each vessel containing the resultant GMO culture, more than 25 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f);
- (m) a dealing that is inconsistent with a policy principle issued by the Ministerial Council;
- (n) a dealing involving the intentional introduction of a GMO into a human being, unless the GMO:
 - (i) is a human somatic cell; and
 - (ii) cannot secrete or produce infectious agents as a result of the genetic modification; and
 - (iii) if it was generated using viral vectors:
 - (A) has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells; and
 - (B) the testing did not detect a virus mentioned in sub-subparagraph (A); and
 - (C) the viral vector used to generate the GMO as part of the previous dealing is no longer present in the somatic cells;
- (o) 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;
- (p) A dealing involving a micro-organism that satisfies 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 a Risk Group 3 or Risk Group 4 pathogen.

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Table A **Application, saving or transitional provisions**

4 **Transitional**

- (1) The first purpose of this regulation is to provide the opportunity to apply for a licence to a person who was undertaking 1 of the following kinds of dealings before 1 March 2011 that now requires a licence:
- (a) an exempt dealing;
 - (b) a notifiable low risk dealing.
- (2) Subject to subregulation (3), despite the amendments made to Schedules 2 and 3 by these Regulations:
- (a) a dealing that was an exempt dealing immediately before 1 March 2011 continues to be an exempt dealing under the Act if the dealing is undertaken by the same person; and
 - (b) a dealing that was a notifiable low risk dealing immediately before 1 March 2011 continues to be a notifiable low risk dealing under Division 2 of Part 6 of the Act if the dealing is undertaken by the same person.
- (3) Subregulation (2) ceases to apply on the earlier of:
- (a) the day on which a licence is issued to the person for the dealing; and
 - (b) 1 March 2012.
- (4) The second purpose of this regulation is to provide the opportunity to a person who was undertaking a dealing before 1 March 2011, that was then an exempt dealing but that is now likely to be a notifiable low risk dealing, to have a proposal assessed by an Institutional Biosafety Committee as to whether the dealing is a notifiable low risk dealing.
- (5) Subject to subregulation (6), despite the amendments made to Schedules 2 and 3 by these Regulations, a dealing mentioned in subregulation (4) that was an exempt dealing immediately before 1 March 2011 continues to be an exempt dealing under the Act if the dealing is undertaken by the same person.

(6) Subregulation (5) ceases to apply on the earlier of:

(a) the day on which an Institutional Biosafety Committee assesses the dealing; and

(b) 1 March 2012.

(7) In this regulation:

Act means the *Gene Technology Act 2000*.

exempt dealing has the meaning given by subsection 32 (3) of the Act.

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*.