Gene Technology Regulations 2001

Statutory Rules No. 106, 2001

made under the

Gene Technology Act 2000

Compilation No. 9

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About this compilation

This compilation

This is a compilation of the *Gene Technology Regulations 2001* that shows the text of the law as amended and in force on 8 October 2020 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1 Name of Regulations

These Regulations are the *Gene Technology Regulations 2001*.

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.

AS/NZS 2243.3:2010 means the Australian/New Zealand Standard *Safety in laboratories Part 3: Microbiological safety and containment*, jointly published by Standards Australia and Standards New Zealand, as in force on 1 September 2011.

characterised means:

(a) in relation to a nucleic acid—the nucleic acid has been sequenced and there is an understanding of potential gene products or potential functions of the nucleic acid; or

(b) in relation to a genetic modification—the gene or genomic region which is modified has been sequenced and there is an understanding of:

(i) potential gene products or potential functions of the gene or genomic region; and

(ii) the likely effect of the genetic modification on the gene products or 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.

host/vector system has a meaning affected by subclause 2.1(3) of Schedule 2.

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 has the meaning given in Part 3 of Schedule 2.

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

oncogenic modification means a genetic modification capable of contributing to tumour formation, including modifications that cause at least 1 of the following:

(a) defects in DNA proofreading and repair;
(b) defects in chromosome maintenance;
(c) defects in cell cycle checkpoint mechanisms;
(d) uncontrolled cell proliferation;
(e) resistance to apoptosis;
(f) cellular immortalisation.

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.

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 micrograms per kilogram.

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
- 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 subsection 10(1) of the Act, gene technology does not include a technique mentioned in Schedule 1A.

4A Organisms that are genetically modified organisms

For the purposes of paragraph (c) of the definition of ***genetically modified organism*** in subsection 10(1) of the Act, an organism is a genetically modified organism if an item in Schedule 1B applies to the organism.

5 Organisms that are not genetically modified organisms

For the purposes of paragraph (e) of the definition of ***genetically modified organism*** in subsection 10(1) of the Act, an organism is not a genetically modified organism if:

(a) one or more items in Schedule 1 applies to the organism; and

(b) the organism has not been modified by gene technology except for any modifications described in those items; and

(c) the organism has not inherited any traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology, except as described in item 9 in Schedule 1; and

(d) none of the items in Schedule 1B applies to the organism.

Part 2A—Gene Technology Regulator

5A Functions of the Regulator

For paragraph 27(l) 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*.

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.

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 awaiting information that the applicant has been requested, in writing, to give;

(c) if, in relation to the application, the Regulator publishes notice of a public hearing under section 53 of the Act, a day in the period that:

(i) begins on the day of publication; and

(ii) ends on the day when the public hearing ends;

(d) a day on which the Regulator cannot proceed with the decision-making process, or a related function, because:

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

(ii) the Regulator is:

(A) considering the application; or

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

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

(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) the Department administered by the Minister administering Part 1 of Chapter 8 of the *Biosecurity Act 2015*;

(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) that part of the Department known as the Therapeutic Goods Administration.

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; and

(aa) it is not a dealing of a kind mentioned in Part 3 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 for undertaking notifiable low risk dealings

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

(a) a person or an accredited organisation has 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 kind of dealing mentioned in Part 1 or 2 of Schedule 3, and not mentioned in Part 3 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 only undertaken no later than the day 5 years after the date of the assessment; and

(e) the person is mentioned in, or is in a class of persons mentioned in, the Institutional Biosafety Committee's record of assessment as having the appropriate training and experience to undertake the dealing; and

(f) subject to subregulation (3), the dealing is undertaken in facilities that:

(i) are mentioned in, or are in a class of facilities mentioned in, the Institutional Biosafety Committee's record of assessment as being appropriate for the dealing; and

(ii) are facilities in which subregulation (2) permits the dealing to be undertaken; and

(g) the person keeps or can give, on request, a copy of the Institutional Biosafety Committee's record of assessment to an inspector; and

(h) the person does not compromise the containment of a GMO involved in the dealing.

(2) A notifiable low risk dealing must be undertaken:

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

(b) for a kind of dealing mentioned in clause 2.1 of Schedule 3 (but not clause 2.2)—in a facility certified by the Regulator to at least physical containment level 2 and that is appropriate for the dealing; or

(ba) for a kind of dealing mentioned in clause 2.2 of Schedule 3—in a facility certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or

(c) in a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken.

(3) If a notifiable low risk dealing involves the transportation, storage or disposal of a GMO, the transportation, storage or disposal may happen outside a facility that complies with paragraph (1)(f) and subregulation (2), if it is conducted in accordance with:

(a) the *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force from time to time, that have been issued by the Regulator under paragraph 27(d) of the Act; or

(b) transportation, storage or disposal requirements that the Regulator has agreed in writing are appropriate for the containment of the GMO.

(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.

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) the identifying name of the dealing to be undertaken that was given to the dealing by the person or accredited organisation that submitted the proposal;

(ii) a description of the dealing to be undertaken;

(iii) its assessment whether the dealing is a kind of dealing mentioned in Part 1 or 2 of Schedule 3, and not mentioned in Part 3 of Schedule 3;

(iv) if the Committee has assessed the dealing as being a kind of dealing mentioned in Part 1 or 2 of Schedule 3 (and not mentioned in Part 3 of Schedule 3)—which kind of dealing in those Parts that the dealing is;

(v) the date of the Committee's assessment of the dealing;

(vi) the persons or classes of persons considered by the Committee to have the appropriate training and experience to undertake the dealing;

(vii) the facilities or classes of facilities the Committee considers to be of the appropriate physical containment level and type for the dealing, having regard to the requirements of subregulation 13(2);

(viii) the name of the Committee that assessed the proposal;

(ix) the name of the person or accredited organisation that submitted the proposal;

(x) the person or persons proposing 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.

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 under paragraph 13B(b) must, if the dealing has been assessed by the Committee as a notifiable low risk dealing, give the Regulator a record of the dealing.

(2) A record of a dealing for the purposes of subregulation (1) must include:

(a) the particulars, prescribed under regulation 39 in relation to the dealing, to be included in the Record of GMO Dealings; and

(b) the name of the Committee that assessed the proposal relating to the dealing; and

(c) the name of the person or accredited organisation that submitted the proposal to the Committee for assessment.

(2A) The record must be given to the Regulator:

(a) in a form approved by the Regulator; and

(b) no later than 30 September in the financial year following the one in which the Institutional Biosafety Committee made the assessment.

(2B) An accredited organisation that is required, as a condition of accreditation, to give an annual report to the Regulator, must:

(a) include the record in the annual report for the year in which the Institutional Biosafety Committee made the assessment; or

(b) certify in the annual report that the record has previously been given to the Regulator.

(3) A person or accredited organisation given a copy of a record of assessment by an Institutional Biosafety Committee under paragraph 13B(b) must keep a copy of the Committee's record of assessment for 8 years after the date of the assessment.

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

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

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

(5) A person or organisation given a notice under subregulation (4) 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).

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.

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 who is also a member of the Ethics and Community Committee) 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 the Ethics and Community Committee were a reference to the Gene Technology Technical Advisory Committee or the Australian Health Ethics Committee; 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 Dealings

For the purposes of 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 person or persons that proposed to undertake the dealing, as recorded by the Institutional Biosafety Committee that assessed the dealing as a notifiable low risk dealing;

(b) the kind of notifiable low risk dealing, in terms of Part 1 or 2 of Schedule 3;

(c) the identifying name given to the dealing by the person or accredited organisation that submitted the dealing to the Institutional Biosafety Committee for assessment;

(d) the date of assessment by the Institutional Biosafety Committee that the dealing is a notifiable low risk dealing.

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.

Part 8—Application and transitional provisions

Division 1—Amendments made by the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019

41 Changed requirements for dealings

Former exempt dealings

(1) If:
  (a) a person was undertaking a dealing before the amending day; and
  (b) the dealing was an exempt dealing under the old Regulations; and
  (c) the dealing is not (apart from this provision) an exempt dealing under the new Regulations;

then, despite the amendments, the dealing is an exempt dealing when undertaken by the person.

(2) Subregulation (1) applies until:
  (a) the dealing is assessed, under the new Regulations, as a notifiable low risk dealing by an Institutional Biosafety Committee; or
  (b) the person is issued a GMO licence for the dealing; or
  (c) 1 year after the amending day if neither of the events in paragraphs (a) and (b) occurs before then.

Former notifiable low risk dealings

(3) If:
  (a) a person was undertaking a dealing before the amending day; and
  (b) the dealing was a notifiable low risk dealing under the old Regulations; and
  (c) the dealing:
    (i) is not (apart from this provision) a notifiable low risk dealing under the new Regulations; and
    (ii) is not an exempt dealing;

then, despite the amendments, the dealing is a notifiable low risk dealing when undertaken by the person.

(4) Subregulation (3) applies until:
  (a) the person is issued a GMO licence for the dealing; or
  (b) 1 year after the amending day if the person is not issued a GMO licence before then.

Changed requirements for notifiable low risk dealings

(5) If a person was undertaking a notifiable low risk dealing before the amending day, the dealing is, for the purposes of section 37 of the Act, undertaken in accordance with the regulations if:

(a) it is undertaken in accordance with the old Regulations; or
(b) it is undertaken in accordance with the new Regulations.

(6) Subregulation (5) ceases to be in force 1 year after the amending day.

Definitions

(7) In this regulation:

amending day means the day that Schedule 1 to the amending Regulations commences.

amending Regulations means the *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019*.

new Regulations means these Regulations as amended by the amending Regulations.

old Regulations means these Regulations as in force immediately before the amending day.

42 Previous assessment by an Institutional Biosafety Committee

(1) This regulation applies if:
(a) before 1 July 2020, an Institutional Biosafety Committee assessed a dealing as being a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3; and
(b) the record of the Committee's assessment does not indicate that the Committee assessed whether the dealing is of a kind mentioned in Part 3 of Schedule 3.

(2) The Committee is taken to have assessed the dealing as being a kind of dealing that is not mentioned in Part 3 of Schedule 3.

43 New requirements for giving records to Regulator apply to notifiable low risk dealing assessed in previous financial year

Regulation 13C as amended by Schedule 2 to the *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019* applies in relation to a dealing that has been assessed by an Institutional Biosafety Committee as a notifiable low risk dealing on or after 1 July 2019.

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.
11	Introduction of RNA into an organism, if: (a) the RNA cannot be translated into a polypeptide; and (b) the introduction of the RNA cannot result in an alteration of the organism's genome sequence; and (c) the introduction of the RNA cannot give rise to an infectious agent.

Schedule 1B—Organisms that are genetically modified organisms

Note: See regulation 4A.

1.1 Genetically modified organisms

For the purposes of regulation 4A, an organism is a genetically modified organism if an item in the following table applies to the organism.

Organisms that are genetically modified organisms

Item	Description of organism
1	An organism that has had its genome modified by oligonucleotide-directed mutagenesis
2	An organism modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was added to guide homology-directed repair

Schedule 1—Organisms that are not genetically modified organisms

(regulation 5)

Item	Description of organism
2	A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.
3	Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.
4	An organism modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was not added to guide homology-directed repair.
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 2243.3:2010 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.
8	An organism that is descended from a genetically modified organism (the ***initial organism***), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology.
9	An organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology, if: (a) the initial organism was not a genetically modified organism (because of the application of regulation 5); or (b) all such inherited traits are traits that occurred in the initial organism as a result of a modification described in an item in this Schedule.
10	An organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present.
11	*Agrobacterium radiobacter* strain K1026.
12	*Pasteurella multocida* strain PMP1.

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.
3A	A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if: (a) the *in vivo* modification occurred as part of a previous dealing; and (b) the replication defective viral vector is no longer in the animal; and (c) no germ line cells have been genetically modified; and (d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and (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.
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. (2) The donor nucleic acid: (a) must meet either of the following requirements: (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; (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 Example: Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it: (a) provides an advantage; or

Item	Description of dealing
	(b) adds a potential host species or mode of transmission; or (c) increases its virulence, pathogenicity or transmissibility. (b) must not code for a toxin with an LD_{50} of less than 100 micrograms per kilogram; and (c) must not code for a toxin with an LD_{50} of 100 micrograms per kilogram 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) if the donor nucleic acid includes a viral sequence—cannot give rise to infectious agents when introduced into any potential host species, without additional non-host genes or gene products that: (i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and (ii) will not become available during the dealing; and (f) if the donor nucleic acid includes a viral sequence—cannot restore replication competence to the vector.
5	A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in 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

2.1 Hosts and vectors

(1) A reference to a host mentioned in this Part is a reference to a host mentioned in column 2 of an item of the table in this clause.

(2) A reference to a vector mentioned in this Part is a reference to a vector mentioned in column 3 of an item of the table in this clause.

(3) A reference to a ***host/vector system*** mentioned in this Part is a reference to any of the following:

(a) a system involving a host mentioned in column 2 of an item of the table in this clause and a vector mentioned in column 3 of the same item;

(b) a non-vector system involving a host mentioned in column 2 of an item of the table;

(c) a system involving a GMO mentioned as a vector in column 3 of an item of the table (except item 7), without a host.

Note: Column 1 of the table is included for information only.

Hosts and vectors

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
1	Bacteria	*Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917—any derivative that does not contain: (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	Any of the following: (a) non-conjugative plasmids; (b) lambda bacteriophage; (c) lambdoid bacteriophage; (d) Fd, F1 or M13 bacteriophage
2	Bacteria	*Bacillus*—asporogenic strains of the following species with a reversion frequency of less than 10^{-7}: (a) *B. amyloliquefaciens*; (b) *B. licheniformis*; (c) *B. pumilus*; (d) *B. subtilis*; (e) *B. thuringiensis*	Any of the following: (a) non-conjugative plasmids; (b) other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus*
3	Bacteria	*Pseudomonas putida* strain KT2440	Non-conjugative plasmids
4	Bacteria	The following *Streptomyces* species: (a) *S. aureofaciens*; (b) *S. coelicolor*; (c) *S. cyaneus*; (d) *S. griseus*;	Any of the following: (a) non-conjugative plasmids; (b) plasmids SCP2, SLP1, SLP2, pIJ101 and derivatives; (c) actinophage phi C31 and derivatives

Hosts and vectors			
Item	**Column 1** **Host class**	**Column 2** **Hosts**	**Column 3** **Vectors**
		(e) *S. lividans*; (f) *S. parvulus*; (g) *S. rimosus*; (h) *S. venezuelae*	
5	Bacteria	Any of the following: (a) *Agrobacterium radiobacter*; (b) *Agrobacterium rhizogenes* (disarmed strains only); (c) *Agrobacterium tumefaciens* (disarmed strains only)	Disarmed Ri or Ti plasmids
6	Bacteria	Any of the following: (a) *Allorhizobium* species; (b) *Corynebacterium glutamicum*; (c) *Lactobacillus* species; (d) *Lactococcus lactis*; (e) *Oenococcus oeni* syn. *Leuconostoc oeni*; (f) *Pediococcus* species; (g) *Photobacterium angustum*; (h) *Pseudoalteromonas tunicata*; (i) *Rhizobium* species; (j) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis*; (k) *Streptococcus thermophilus*; (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102; (m) *Synechocystis* species strain PCC 6803; (n) *Vibrio cholerae* CVD103-HgR; (o) *Zymomonas mobilis*	Non-conjugative plasmids
7	Fungi	Any of the following: (a) *Kluyveromyces lactis*; (b) *Neurospora crassa* (laboratory strains); (c) *Pichia pastoris*; (d) *Saccharomyces cerevisiae*; (e) *Schizosaccharomyces pombe*; (f) *Trichoderma reesei*; (g) *Yarrowia lipolytica*	All vectors
8	Slime moulds	*Dictyostelium* species	*Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2

Hosts and vectors			
Item	**Column 1** **Host class**	**Column 2** **Hosts**	**Column 3** **Vectors**
9	Tissue culture	Any of the following if they cannot spontaneously generate a whole animal: (a) animal or human cell cultures (including packaging cell lines); (b) isolated cells, isolated tissues or isolated organs, whether animal or human; (c) early non-human mammalian embryos cultured *in vitro*	Any of the following: (a) plasmids; (b) replication defective viral vectors unable to transduce human cells; (c) polyhedrin minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV)
10	Tissue culture	Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures; (b) isolated plant tissues or organs	Any of the following: (a) Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes* (disarmed strains only) or *Agrobacterium tumefaciens* (disarmed strains only); (b) non-pathogenic viral vectors

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 were transduced with a replication defective retroviral vector in which no vector particles remain.

Schedule 3—Notifiable low risk dealings in relation to a GMO

(regulations 12 and 13)

Part 1—Notifiable low risk dealings suitable for at least 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.

1.1 Kinds of dealings suitable for at least physical containment level 1

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 1 and that are appropriate for the dealings:

(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;

(c) a dealing involving virions of a replication defective vector derived from *Human adenovirus* or from *Adeno-associated virus*, either without a host or with a host mentioned in item 9 of Part 2 of Schedule 2, if the donor nucleic acid:

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

(ii) does not confer an oncogenic modification or immunomodulatory effect in humans.

Part 2—Notifiable low risk dealings suitable for at least physical containment level 2 or 3

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.

2.1 Kinds of dealings suitable for at least physical containment level 2

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 2 and 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;

(c) a dealing involving a host/vector system not mentioned in paragraph 1.1(c) or Part 2 of Schedule 2, if neither 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/vector system not mentioned 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 genetic modification is characterised; and

(iii) the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;

Example: A genetic modification 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) is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; 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;

(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:

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

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

(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;

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.

(h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in 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 virions of a replication defective viral vector unable to transduce human cells and 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 virions of a replication defective non-retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

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

(ii) the dealing is not a dealing mentioned in paragraph 1.1(c);

(k) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells and 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 confer an oncogenic modification or immunomodulatory effect in humans;

(l) a dealing involving virions of a replication defective retroviral vector able to transduce human cells, either without a host or with 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 new virions 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 virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acids does not confer an oncogenic modification or immunomodulatory effect in humans; and

(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions 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.

2.2 Kinds of dealing suitable for at least physical containment level 3

(1) A kind of dealing that:

(a) is a kind mentioned in clause 2.1; and

(b) involves a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3;

must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 3 and that are appropriate for the dealings.

(2) For the purposes of paragraph (1)(b), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent micro-organism satisfies those criteria.

(3) However, subclause (2) does not apply in relation to a replication defective retroviral vector that meets the criteria in paragraph 2.1(l) or (m).

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: If a dealing is not a notifiable low risk dealing, or an exempt dealing, as provided by these Regulations, a person undertaking the dealing must be authorised by a GMO licence unless the dealing is within one of the other exceptions to licensing provided by the Act: see section 32 of the Act.

3.1 Kinds of dealings

(1) 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 LD_{50} of less than 100 micrograms per kilogram;

(b) a dealing involving high level expression of toxin genes, even if the LD_{50} is 100 micrograms per kilogram 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 virions of a replication defective viral vector and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid confers an oncogenic modification or immunomodulatory effect in humans; and

(ii) the dealing is not a dealing mentioned in paragraph 2.1(i);

(e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the genetic modification confers an oncogenic modification or immunomodulatory effect 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;

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

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

Example: A genetic modification 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 or mode of transmission; or
(c) increases its 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;

(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;

(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;

Example: A dealing would 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.

(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 a 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 2243.3:2010 for classification as Risk Group 4;

(q) a dealing involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 and that is not undertaken:

(i) in a facility that is certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or

(ii) in a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken;

(r) a dealing involving a GMO capable of sexual reproduction, the sexual progeny of which are, as a result of the genetic modification, more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism);

(s) a dealing involving a viral vector that can modify an organism capable of sexual reproduction, so that the sexual progeny of the organism are more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism).

Note: A modification that increases the likelihood of inheritance of a nucleotide sequence or sequences, as described in paragraphs (r) and (s), is generally known as an engineered gene drive.

(2) For the purposes of paragraph (1)(p), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4 if the unmodified parent micro-organism satisfies those criteria.

(3) For the purposes of paragraph (1)(q), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent micro-organism satisfies those criteria.

(4) However, subclause (3) does not apply in relation to a replication defective retroviral vector that meets the criteria in paragraph 2.1(l) or (m).

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
2001 No. 106	31 May 2001	22 June 2001 (r 2)	
2006 No. 314	1 Dec 2006 (F2006L03558)	31 Mar 2007	r 4
2007 No. 128	24 May 2007 (F2007L01317)	Sch 1: 1 July 2007 (r 2 (a)) Sch 2: 1 July 2007 (r 2 (b)) Sch 3: 1 Jan 2008 (r 2 (c))	—
2009 No. 68	1 May 2009 (F2009L01112)	2 May 2009 (r 2)	—
2011 No. 73	3 June 2011 (F2011L00933)	1 Sept 2011 (r 2)	r 4

Name	Registration	Commencement	Application, saving and transitional provisions
Biosecurity (Consequential Amendments and Transitional Provisions) Regulation 2016	9 May 2016 (F2016L00717)	Sch 2 (item 13) and Sch 3: 16 June 2016 (s 2(1) item 1)	Sch 3
Gene Technology Amendment (2019 Measures No. 1) Regulations 2019	8 Apr 2019 (F2019L00573)	Sch 1: 8 Oct 2019 (s 2(1) item 2) Sch 2: 1 July 2020 (s 2(1) item 3) Sch 3: 8 Oct 2020 (s 2(1) item 4)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
r 2	rep LA s 48D
r 3	rs. 2006 No. 314
	am. 2007 No. 128; 2011 No. 73; F2019L00573
Part 2	
r 4	rs. 2006 No. 314
	am F2019L00573
r 4A	ad F2019L00573
r 5	rs F2019L00573
Part 2A	
Part 2A	ad. 2009 No. 68
r. 5A	ad. 2009 No. 68
	am. 2011 No. 73
Part 3	
Division 1	
r. 6	am. 2006 No. 314; 2007 No. 128; 2011 No. 73
r. 7	rs. 2006 No. 314
r. 8	am. 2007 No. 128
r 9	am. 2006 No. 314; 2007 No. 128; F2016L00717; F2019L00573
r. 9A	ad. 2007 No. 128
r. 10	am. 2006 No. 314
r. 11A	ad. 2007 No. 128
	rs. 2011 No. 73
Division 2	
r 12	am. 2011 No. 73; F2019L00573
r 13	rs. 2006 No. 314; 2007 No. 128; 2011 No. 73
	am F2019L00573
r 13A	ad. 2007 No. 128
	rs. 2011 No. 73
	rep F2019L00573
r 13B	ad. 2011 No. 73
	am F2019L00573
r 13C	ad. 2011 No. 73
	am F2019L00573
Part 4	
Division 1	
r 21	am F2019L00573

Endnote 4—Amendment history

Provision affected	How affected
Division 2	
r 26	am F2019L00573
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
	am F2019L00573
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; 2011 No. 73
	rs F2019L00573
Part 8	
Part 8	rep. 2006 No. 314
	ad F2019L00573
Division 1	
r 41	rep 2006 No. 314
	ad F2019L00573
	(5) exp 8 Oct 2020 (r 41(6))
r 42	rep. 2006 No. 314
	ad F2019L00573
r 43	ad F2019L00573
Schedule 1A	
Schedule 1A	ad. 2006 No. 314
	am F2019L00573
Schedule 1B	
Schedule 1B	ad F2019L00573
Schedule 1	
Schedule 1	rs 2006 No 314
	am 2011 No 73; F2019L00573
Schedule 2	
Schedule 2	rs. 2006 No. 314
	am. 2007 No. 128; 2011 No. 73; F2019L00573
Schedule 3	
Schedule 3	rs. 2006 No. 314
	am. 2007 No. 128

Endnote 4—Amendment history

Provision affected	How affected
	rs. 2011 No. 73
	am F2019L00573
Schedule 4	rep. 2006 No. 314