South Australia

Gene Technology Regulations 2017

under the *Gene Technology Act 2001*

Contents

Part 1—Preliminary

1—Short title

(1) These regulations may be cited as the *Gene Technology Regulations 2017*.

(2) These regulations may also be referred to as the *Gene Technology Regulations*.

2—Commencement

These regulations will come into operation on 1 August 2017.

3—Definitions

In these regulations—

Act means the *Gene Technology Act 2001*;

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*, as in force on 1 September 2011;

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;

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

expert adviser means—

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

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

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;

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;

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 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
- 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.

3A—Numbering

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

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

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

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

Notes—

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

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

3 This regulation does not appear in the Commonwealth Regulations.

3B—Notes

Notes do not form part of these regulations.

Note—

This regulation does not appear in the Commonwealth Regulations.

Part 2—Interpretation and general operation

4—Techniques not constituting gene technology

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

Part 3—Dealings with GMOs

Division 1—Licensing system

6—Dealings exempt from licensing

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

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

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

(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.

Notes—

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

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

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

7—Application for licence—prescribed fee

Note—

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

8—Time limit for deciding an application

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

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

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

(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 1 of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment—170 days after the day 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 section 50(3) or 52(3) of the Act, or from the Ethics and Community Committee, may specify a reasonable period within which the advice must be received, and, if the advice is not received within that period, must proceed without regard to that advice.

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

(a) Food Standards Australia New Zealand;

(b) Australian Quarantine and Inspection Service;

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

(e) Australian Pesticides and Veterinary Medicines Authority;

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

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

For the purposes of section 51(1)(a) of the Act, the Regulator must have regard to the following matters:

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

(b) the effect, or the expected effect, of the genetic modification that has occurred, or will occur, on the properties of the organism;

(c) provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;

(d) the potential for spread or persistence of the GMO or its genetic material in the environment;

(e) the extent or scale of the proposed dealings;

(f) any likely impacts of the proposed dealings on the health and safety of people.

10—Risk assessment—matters to be taken into account

(1) For the purposes of sections 51(1)(g) and 51(2)(g) of the Act, other matters to be taken into account in relation to dealings proposed to be authorised by a licence include—

(a) subject to section 45 of the Act, any previous assessment by a regulatory authority, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and

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

11—Prescribed conditions of licence

Note—

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

11A—Time limit for deciding variation application

(1) For section 71(7) of the Act, the Regulator must vary the licence, or refuse to vary the licence, within 90 days after the day an application for 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 or a public holiday in South Australia;

(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, will not be counted.

Note—

This subregulation differs from regulation 11A(2) of the Commonwealth regulations.

Division 2—Notifiable low risk dealings

12—Notifiable low risk dealings

(1) For the purposes of section 74(1) of the Act, a dealing with a GMO is a notifiable low risk dealing if—

(a) it is a dealing of a kind mentioned in Part 1 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.

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

Notes—

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

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

13—Requirements for undertaking notifiable low risk dealings

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

(a) the 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 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 only 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 dealing is undertaken in facilities mentioned in the Institutional Biosafety Committee's record of assessment as being appropriate for the dealing; 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; and

(i) 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 of assessment as having the appropriate training and experience to undertake the dealing. Similarly, a person complies with paragraph (f) if the facility in which the person undertakes the dealing is in a class of facilities that an Institutional Biosafety Committee has included in the record of assessment as being appropriate for 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 Part 2 of Schedule 3—

(i) that is not a dealing mentioned in subparagraph (ii)—in a facility certified by the Regulator to at least physical containment level 2 and that is appropriate for the dealing; or

(ii) that involves a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 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) However, if a notifiable low risk dealing involves the transportation, storage or disposal of a GMO, the transportation, storage or disposal—

(a) may only be undertaken before the day mentioned in regulation 13A as being the day on or before which the dealing must stop being undertaken; and

(b) may happen outside a facility mentioned in subregulation (2), but in that case must be conducted in accordance with—

(i) the *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force on 1 September 2011, that have been issued by the Regulator for this purpose under section 27(d) of the Act; or

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

(4) For subregulation (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 regulation 13(1)(d), the day on or before which the dealing described in the record of assessment of 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 1 September 2011; and

(b) 31 August 2016, if the dealing is assessed by an Institutional Biosafety Committee in the period 31 March 2008 to 31 August 2011 (inclusive); and

(c) 31 March 2015, if the dealing is assessed by an Institutional Biosafety Committee before 31 March 2008.

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

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

(iii) its assessment whether the dealing is a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3;

(iv) if the Committee has assessed the dealing as being a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3, the kind of notifiable low risk dealing that the dealing is, in terms of those Parts;

(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;

(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 name of the person or accredited organisation 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 an 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 by the Committee as a notifiable low risk dealing, give the Regulator a record of the proposed dealing, in the form approved by the Regulator, that includes—

(a) the particulars, prescribed under regulation 39(1) in relation to the dealing, to be included in the Record of GMO and GM Product Dealings; and

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

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

(2) The record of the proposed dealing mentioned in subregulation (1) must be given to the Regulator in the financial year in which the Institutional Biosafety Committee made the assessment—

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

(b) by any other person—in a report for the financial year to be given by the person to the Regulator, in the form approved by the Regulator.

(3) A person or accredited organisation given a copy of a record of assessment by an Institutional Biosafety Committee 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

Note—

The Commonwealth Regulations provide the period within which the Regulator must consider and decide an application for certification of a facility.

15—Application for certification—failure to provide section 85 information

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

Note—

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

16—Regulator to decide accreditation application within 90 days

Note—

The Commonwealth Regulations provide the period within which the Regulator must consider and decide an application for accreditation of an organisation.

17—Application for accreditation—failure to provide section 93 information

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

Note—

A refusal to accredit an organisation is a reviewable decision (see Division 2 of Part 12 of the Act).

Part 4—Gene Technology Technical Advisory Committee

Division 1—Conditions of appointment

18—GTTAC members and advisers—term of appointment

Note—

Regulation 18 of the Commonwealth Regulations provides for the term of appointment of members of the Gene Technology Technical Advisory Committee and expert advisers to the GTTAC.

19—GTTAC members and advisers—resignation

Note—

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

20—GTTAC members—disclosure of interests

Note—

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

21—GTTAC members and advisers—termination of appointment

Note—

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

22—GTTAC members—leave of absence

Note—

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

23—Expert advisers—disclosure of interests

Note—

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

Division 2—Committee procedures

24—Committee procedures generally

Note—

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

25—Committee meetings

Note—

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

26—Presiding member

Note—

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

27—Quorum

Note—

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

28—Voting

Note—

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

29—Records and Reports

Note—

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

Division 3—Subcommittees

30—Operation of subcommittees

Note—

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

Part 5—Ethics and Community Committee

31—Ethics and Community Committee—conditions of appointment

Note—

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

32—Ethics and Community Committee—Committee procedures

Note—

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

33—Ethics and Community Committee—operation of subcommittees

Note—

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

Part 7—Miscellaneous

37—Reviewable State decisions

Note—

The scheme for reviewable State decisions under the Commonwealth Act does not apply under the South Australian legislation.

38—Review of decisions

Note—

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

39—Record of GMO and GM Product Dealings

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

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

(b) in terms of Part 1 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.

(2) For the purposes of section 138(3) of the Act, the following particulars are prescribed in relation to a GM product mentioned in a designated notification:

(a) the name of the organisation producing the GM product;

(b) a description of the GM product, with reference to—

(i) the ***applicable Act***, being the *Agricultural and Veterinary Chemicals (South Australia) Act 1994*; and

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

(c) information about the GM product, including—

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

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

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

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

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

Note—

This regulation differs from regulation 39 of the Commonwealth Regulations.

40—Inspector identity card

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

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

(b) state the date of issue; and

(c) state the period of its validity.

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.

Item	Description of technique
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.

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 2243.3:2010, 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.

Schedule 2—Dealings exempt from licensing

(regulation 6)

Note—

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

Part 1—Exempt dealings

Item	Description of dealing
2	A dealing with a genetically modified *Caenorhabditis elegans*, unless— (a) an advantage is conferred on the animal by the genetic modification; or (b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.

Item		Description of dealing
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 (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 µg/kg; and (c) must not code for a toxin with an LD_{50} of 100 µg/kg or more, if the intention is to express the toxin at high levels; and (d) must not be uncharacterised nucleic acid from a toxin-producing organism; and (e) must not include a viral sequence unless the donor nucleic acid— (i) is missing at least 1 gene essential for viral multiplication that—

Item	Description of dealing
	(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 duplication 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 item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either—
	(a) a pathogen; or
	(b) a toxin-producing organism.

Part 2—Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	*Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917—any derivative that does not contain—	1. Non-conjugative plasmids
		(a) generalised transducing phages; or	2. Bacteriophage
		(b) genes able to complement the conjugation defect in a non-conjugative plasmid	(a) lambda (b) lambdoid (c) Fd or F1 (eg M13)
			3. None (non-vector systems)
		Bacillus—specified species—asporogenic strains with a reversion frequency of less than 10^{-7}—	1. Non-conjugative plasmids
		(a) *B. amyloliquefaciens*	2. Plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus*
		(b) *B. licheniformis*	3. None (non-vector systems)
		(c) *B. pumilus*	
		(d) *B. subtilis*	
		(e) *B. thuringiensis*	
		Pseudomonas putida—strain KT 2440	1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264
			2. None (non-vector systems)
		Streptomyces—specified species—	1. Non-conjugative plasmids
		(a) *S. aureofaciens*	2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives
		(b) *S. coelicolor*	3. Actinophage phi C31 and derivatives
		(c) *S. cyaneus*	4. None (non-vector systems)
		(d) *S. griseus*	
		(e) *S. lividans*	

Item	Class	Host	Vector
		(f) *S. parvulus*	
		(g) *S. rimosus*	
		(h) *S. venezuelae*	
		Agrobacterium radiobacter *Agrobacterium rhizogenes*—disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors
		Agrobacterium tumefaciens—disarmed strains	2. None (non-vector systems)
		Lactobacillus *Lactococcus lactis* *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicata* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Streptococcus thermophilus* *Synechococcus*—specified strains: (a) PCC 7002 (b) PCC 7942 (c) WH 8102 *Synechocystis* species—strain PCC 6803 *Vibrio cholerae* CVD103-HgR	1. Non-conjugative plasmids 2. None (non-vector systems)
2	Fungi	*Kluyveromyces lactis* *Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei* *Yarrowia lipolytica*	1. All vectors 2. None (non-vector systems)
3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. None (non-vector systems)
4	Tissue culture	Any of the following if they cannot spontaneously generate a whole animal:	1. Non-conjugative plasmids

Item	Class	Host	Vector
		(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*	2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells 3. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems)
		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	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens*, *Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. None (non-vector systems)

Part 3—Definitions

In this Schedule—

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

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

(a) bacterial artificial chromosomes (BACs);

(b) cosmids;

(c) P1 artificial chromosomes (PACs);

(d) yeast artificial chromosomes (YACs);

non-vector system means a system 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 regulation 12(1), a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3 of this Schedule.

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

The following kinds of notifiable low risk dealings must be undertaken, unless regulation 13(2)(c) or 13(3)(b) 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 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—

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

(ii) does not—

(A) confer an oncogenic modification in humans; or

(B) encode a protein with immunomodulatory activity in humans.

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

Note—

Because of regulation 12(1), a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3 of this Schedule.

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

The following kinds of notifiable low risk dealings must be undertaken, unless regulation 13(2)(c) or 13(3)(b) 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 clause 1.1(c) of Part 1 of this Schedule 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 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;

(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 item 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 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 dealing mentioned in clause 1.1(c) of Part 1 of this Schedule, 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—

(A) confer an oncogenic modification in humans; or

(B) encode a protein with immunomodulatory activity 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—

(A) confer an oncogenic modification in humans; or

(B) encode a protein with immunomodulatory activity 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.

2.2—Kinds of dealings suitable for at least physical containment level 3

Any kind of dealing mentioned in this Part involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 must be undertaken, unless regulation 13(2)(c) or 13(3)(b) applies, in facilities that are—

(a) certified to at least physical containment level 3; and

(b) appropriate for the dealing.

Part 3—Dealings that are not notifiable low risk dealings

Note 1—

The following list qualifies the list in Part 1 and Part 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 section 32 of the Act).

3.1—Kinds of dealings

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

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

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

(c) a dealing (other than a dealing mentioned in clause 2.1(h) of Part 2 of this Schedule) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;

(d) 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 clause 2.1(i) of Part 2 of this Schedule), if the donor nucleic acid—

(i) confers an oncogenic modification in humans; or

(ii) encodes a protein with immunomodulatory activity in humans;

(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—

(i) confers an oncogenic modification in humans; or

(ii) encodes a protein with immunomodulatory activity 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) humans; or

(B) animals; or

(C) plants; or

(D) fungi; and

(ii) none of the following subsubparagraphs apply:

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

(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;

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

Example—

Donor nucleic acid would not comply with subsubparagraph (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 clause 2.1(g) of Part 2 of this Schedule; or

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

(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 clause 2.1(l) or (m) of Part 2 of this Schedule, 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 clause 2.1(f) of Part 2 of this Schedule;

(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 subsubparagraph (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.

Schedule 4—Revocation of *Gene Technology Regulations 2002*

The *Gene Technology Regulations 2002* are revoked.

Legislative history

Notes

- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes or www.legislation.sa.gov.au.

Principal regulations

Year	No	Reference	Commencement
2017	196	*Gazette 4.7.2017 p2763*	1.8.2017: r 2