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South Australia

# Gene Technology Variation Regulations 2009

under the *Gene Technology Act 2001*

## Contents



# Part 1—Preliminary

## 1—Short title

These regulations may be cited as the *Gene Technology Variation Regulations 2009*.

### 2—Commencement

These regulations will come into operation on the day on which the *Gene Technology (Miscellaneous) Amendment Act 2008* comes into operation.

### 3—Variation provisions

In these regulations, a provision under a heading referring to the variation of specified regulations varies the regulations so specified.

## Part 2—Variation of *Gene Technology Regulations 2002*

### 4—Variation of regulation 3—Definitions

Regulation 3, definition of ***expert adviser***—delete the definition and substitute:

***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;

### 5—Variation of regulation 6—Dealings exempt from licensing

Regulation 6(1)(c)—delete paragraph (c)

### 6—Variation of regulation 8—Time limit for deciding an application

(1) Regulation 8(1)(b)—delete paragraph (b) and substitute:

(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) Regulation 8(2)(e)—delete "Gene Technology Ethics Committee" and substitute:

Ethics and Community Committee

(3) Regulation 8(3)—delete "Gene Technology Ethics Committee" and substitute:

Ethics and Community Committee

(4) Regulation 8—after subregulation (3) insert:

(4) In subregulation (1)—

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

## 7—Variation of regulation 9—Prescribed authorities

Regulation 9(c)—delete paragraph (c)

## 8—Insertion of regulation 9A

After regulation 9 insert:

### 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.

## 9—Insertion of regulation 11A

After regulation 11 insert:

### 11A—Time limit for deciding variation application

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

## 10—Substitution of regulation 13

Regulation 13—delete the regulation and substitute:

### 13—Requirements in relation to undertaking notifiable low risk dealings

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

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

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

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

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

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

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

(a) the dealing must be conducted—

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

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

(iii) in another facility in accordance with any technical and procedural guidelines relating to containment of GMOs, as in force from time to time under section 27(d) of the Act, that the Regulator has determined in writing are appropriate for conducting the dealing;

(b) to the extent that the dealing involves transporting a GMO, the transporting must be conducted in accordance with applicable technical and procedural guidelines, as in force from time to time under section 27(d) of the Act.

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

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

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

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

(c) give a copy of the record to—

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

(ii) the project supervisor for the proposed dealing.

(2) The person or accredited organisation must—

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

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

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

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

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

(a) the Committee; or

(b) the person or accredited organisation; or

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

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

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

## 11—Substitution of Parts 5 and 6

Parts 5 and 6—delete the Parts and substitute:

# 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.

## 12—Variation of Schedule 2—Dealings exempt from licensing

(1) Schedule 2, Part 1, item 1—delete item 1

(2) Schedule 2, Part 1, item 4(1)—delete "subitems (2) and (3)" and substitute:

subitem (2)

(3) Schedule 2, Part 1, item 4(2)—after paragraph (e) insert:

and

(f) must not confer an oncogenic modification.

(4) Schedule 2, Part 1, item 4(3)—delete subitem (3)

(5) Schedule 2, Part 2, item 4, column 4, 2.—delete "(other than a retroviral vector that is able to transduce human cells)" and substitute:

unable to transduce human cells

## 13—Substitution of Schedule 3

Schedule 3—delete the Schedule and substitute:

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

(regulations 12 and 13)

# Part 1—Notifiable low risk dealing suitable for physical containment level 1

**Note—**

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

### 1.1—Kinds of dealings

The following kinds of notifiable low risk dealings may be conducted in physical containment level 1 facilities:

(a) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, unless—

(i) an advantage is conferred on the animal by the genetic modification; or

(ii) because of the genetic modification, the animal is capable of secreting or producing an infectious agent;

(b) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid confers an oncogenic modification;

(c) a dealing involving a defective viral vector able to transduce human cells in a host mentioned in item 4 of Part 2 of Schedule 2 (animal or human cell culture), unless—

(i) the vector is a retroviral vector; or

(ii) the donor nucleic acid confers an oncogenic modification.

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

**Note—**

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

## 2.1—Kinds of dealings

The following kinds of notifiable low risk dealings may be conducted in physical containment level 2 facilities:

(a) a dealing involving whole animals (including non-vertebrates) that—

(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and

(ii) does not involve any of the following:

(A) a genetically modified laboratory mouse;

(B) a genetically modified laboratory rat;

(C) a genetically modified *Caenorhabditis elegans*;

(aa) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, if—

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) either—

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

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

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

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

(i) encodes a pathogenic determinant; or

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

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

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

(A) as a large scale facility; and

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

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

(g) a dealing involving complementation of knocked out genes, if the complementation does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of the parent organism before the genes were knocked out;

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

(i) a pathogen; or

(ii) a toxin-producing organism;

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

(i) the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions; and

(ii) either—

(A) the vector is a retroviral vector; or

(B) the donor nucleic acid confers an oncogenic modification.

# Part 3—Dealings that are not notifiable low risk dealings

**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) unless the viral vector is part of a host/vector system mentioned in Part 2 of Schedule 2 or in clause 1.1(c) of Part 1 or clause 2.1(i) of Part 2 of this Schedule—a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid—

(i) confers an oncogenic modification; or

(ii) encodes—

(A) immunomodulatory molecules; or

(B) cytokines; or

(C) growth factors, or components of a signal transduction pathway, that, when expressed, may lead to cell proliferation;

(e) a dealing involving, as host or vector, a micro-organism that has been implicated in, or has a history of causing, disease in humans, animals, plants or fungi, unless—

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

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

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

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

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

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

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

(h) a dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility in relation to any parent or donor organism;

(i) a dealing involving a lentiviral vector able to transduce human cells unless—

(i) all structural and accessory genes have been removed from the vector to render it incapable of replication or assembly into a virion without these functions being supplied *in trans*; and

(ii) the vector includes a deletion that results in a transcriptionally inactive vector which, even when packaging functions are supplied *in trans*, cannot be converted into full length viral RNA; and

(iii) the packaging cell line and packaging plasmids used contain only viral genes *gag*, *pol*, *rev* and a gene encoding an envelope protein;

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

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

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

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

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

**Note—**

As required by section 10AA(2) of the *Subordinate Legislation Act 1978*, the Minister has certified that, in the Minister's opinion, it is necessary or appropriate that these regulations come into operation as set out in these regulations.

## Made by the Governor's Deputy

with the advice and consent of the Executive Council
on 22 October 2009

No 250 of 2009

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