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South Australia

Gene Technology Variation Regulations 2007

under the *Gene Technology Act 2001*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Gene Technology Variation Regulations 2007*.

2—Commencement

These regulations will come into operation on 31 March 2007.

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—Substitution of regulation 3

Regulation 3—delete the regulation and substitute:

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;

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 6—an expert adviser appointed under section 113(1) of the Commonwealth Act;

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

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

known means known within the scientific community;

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

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

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

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

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.

5—Substitution of regulation 4

Regulation 4—delete the regulation and substitute:

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.

6—Variation of regulation 6—Dealings exempt from licensing

Regulation 6(1)(c) and (d)—delete paragraphs (c) and (d) and substitute:

(c) it is conducted in accordance with applicable technical and procedural guidelines, as in force from time to time under section 27(d) of the Act, relating to—

(i) containment of the GMO; and

(ii) if the dealing involves transporting the GMO—transport; and

(d) it does not involve an intentional release of the GMO into the environment; and

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

7—Substitution of regulation 7

Regulation 7—delete the regulation (including the notes) and substitute:

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—Variation of regulation 9—Prescribed authorities

(1) Regulation 9(a)—delete paragraph (a) and substitute:

(a) Food Standards Australia New Zealand;

(2) Regulation 9(d) and (e)—delete paragraphs (d) and (e) and substitute:

(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;

9—Variation of regulation 10—Risk assessment—matters to be taken into account

(1) Regulation 10(1)(a)—delete paragraph (a) and substitute:

(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

(2) Regulation 10(1)(b)(v)—delete "selective advantage" and substitute:

an advantage

10—Substitution of regulation 13

Regulation 13—delete the regulation and substitute:

13—Requirements in relation to notifiable low risk dealings

(1) A person must not undertake a notifiable low risk dealing unless an Institutional Biosafety Committee has—

(a) notified the Regulator, in the form approved by the Regulator, of the proposed dealing; and

(b) notified the person, and the project supervisor for the proposed dealing, in writing, that—

(i) the proposed dealing is a dealing of a kind mentioned in Part 1 of Schedule 3; and

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

(iii) paragraph (a) has been complied with.

(2) A notifiable low risk dealing, when undertaken, must comply with the following requirements:

(a) the dealing must be conducted in a facility that—

(i) is certified by the Regulator to—

(A) at least physical containment level 2; or

(B) any other containment level that the Regulator considers suitable for conducting the dealing; and

(ii) is of appropriate design for the kind of dealing being undertaken;

(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.

(3) The Regulator may, by notice in writing, require—

(a) the Institutional Biosafety Committee that has notified the Regulator of a proposed notifiable low risk dealing; or

(b) a person or organisation involved with the conduct of a notifiable low risk dealing of which the Regulator has been notified,

to give the Regulator such further information in relation to the dealing as the Regulator requires in order to be satisfied that the dealing is a notifiable low risk dealing.

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

11—Variation of regulation 39—Record of GMO and GM Product Dealings

Regulation 39(2)(c)(ii)—delete "in the GM product; and" and substitute:

in the GMO from which the GM product is derived; and

12—Substitution of Schedules 1 to 4

Schedules 1 to 4 (inclusive)—delete the Schedules and substitute:

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.

Item	Description of technique
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 2243.3:2002 (Safety in laboratories, Part 3: Microbiological aspects and containment facilities) jointly published by Standards Australia and Standards New Zealand, for classification as Risk Group 1; and (ii) are known to exchange nucleic acid by a natural physiological process; and (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

Schedule 2—Dealings exempt from licensing

(regulation 6)

Note—

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

Part 1—Exempt dealings

Item		Description of dealing
1		A dealing with a genetically modified laboratory mouse or a genetically modified laboratory rat, 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.
2		A dealing with a genetically modified *Caenorhabditis elegans*, unless—
		(a) an advantage is conferred on the animal by the genetic modification; or
		(b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.
3		A dealing with an animal into which genetically modified somatic cells have been introduced, if—
		(a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and
		(b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
4	(1)	Subject to subitems (2) and (3), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture in each vessel containing the resultant culture.
	(2)	The donor nucleic acid—
		(a) must satisfy either of the following requirements:
		(i) it must not be derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi; or
		(ii) it must be characterised and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; and
		(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

Item	Description of dealing

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

(i) is missing at least 1 gene essential for viral multiplication that—

(A) is not available in the cell into which the nucleic acid is introduced; and

(B) will not become available during the dealing; and

(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions.

(3) If the vector is able to transduce human cells, the donor nucleic acid must not confer an oncogenic modification.

5 A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either—

(a) a pathogen; or

(b) a toxin-producing organism.

Part 2—Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C—any derivative that does not contain—	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*	

Item	Class	Host	Vector
		(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— (a) *S. aureofaciens* (b) *S. coelicolor* (c) *S. cyaneus* (d) *S. griseus* (e) *S. lividans* (f) *S. parvulus* (g) *S. rimosus* (h) *S. venezuelae*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. None (non-vector systems)
		Agrobacterium radiobacter *Agrobacterium rhizogenes*—disarmed strains *Agrobacterium tumefaciens*—disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. None (non-vector systems)
		Lactobacillus *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Vibrio cholerae* CVD103-HgR	1. Non-conjugative plasmids 2. None (non-vector systems)
2	Fungi	*Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Kluyveromyces lactis* *Trichoderma reesei*	1. All vectors 2. None (non-vector systems)

Item	Class	Host	Vector
3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
			2. None (non-vector systems)
4	Tissue culture	Animal or human cell cultures (including packaging cell lines)	1. Non-conjugative plasmids
			2. Non-viral vectors, or defective viral vectors (other than a retroviral vector that is able to transduce human cells)
			3. Avipox vectors (attenuated vaccine strains)
			4. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus
			5. None (non-vector systems)
		Plant cell cultures	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens, Agrobacterium radiobacter* or *Agrobacterium rhizogenes*
			2. Non-pathogenic viral vectors
			3. None (non-vector systems)

Part 3—Definitions

In this Schedule—

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

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

(a) bacterial artificial chromosomes (BACs);

(b) cosmids;

(c) P1 artificial chromosomes (PACs);

(d) yeast artificial chromosomes (YACs);

non-vector system means a system by which donor nucleic acid is introduced (for example, by electroporation or particle bombardment) into a host in the absence of a nucleic acid-based vector (for example, a plasmid, viral vector or transposon).

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

(regulations 12 and 13)

Part 1—Dealings that are notifiable low risk dealings

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 2 of this Schedule.

1.1—Kinds of dealings

The following kinds of dealings are notifiable low risk 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 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; or

(iii) where the vector is able to transduce human cells—confers an oncogenic modification;

(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 retroviral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2 if the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions.

Part 2—Dealings that are not notifiable low risk dealings

Note 1—

The following list qualifies the list in Part 1, 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).

2.1—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 item 1.1(h) of Part 1 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 items 1.1(h) of Part 1 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 item 1.1(i) of Part 1 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 item 1.1(g) of Part 1 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 item 1.1(g) of Part 1 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 item 1.1(f) of Part 1 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.

13—Transitional provision

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

(2) Despite the substitution of Schedule 3 by regulation 12 but subject to subregulation (3), a dealing (the ***relevant dealing***) that was a notifiable low risk dealing immediately before 31 March 2007 continues to be a notifiable low risk dealing under Part 6 Division 2 of the Act if the dealing is carried on by the same person (the ***affected person***).

(3) This subregulation ceases to apply in relation to an affected person on the earlier of—

(a) the day on which a licence is issued to the person in respect of the relevant dealing; and

(b) 31 March 2008.

(4) In this regulation—

Act means the *Gene Technology Act 2001*;

licence means a licence under Part 5 of the Act;

notifiable low risk dealing means a dealing under Part 3 Division 2 of these regulations.

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

with the advice and consent of the Executive Council
on 15 March 2007

No 20 of 2007

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