Australian Capital Territory

Gene Technology Amendment Regulation 2008 (No 1)

Subordinate Law SL2008-17

The Australian Capital Territory Executive makes the following regulation under the *Gene Technology Act 2003*.

Dated 14 April 2008.

KATY GALLAGHER
Minister

SIMON CORBELL
Minister

J2007-573

Australian Capital Territory

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made under the

Gene Technology Act 2003

Contents

J2007-573

1 Name of regulation

This regulation is the *Gene Technology Amendment Regulation 2008 (No 1)*.

2 Commencement

This regulation commences on the commencement of the *Gene Technology Amendment Act 2008*, section 3.

Note The naming and commencement provisions automatically commence on the notification day (see Legislation Act, s 75 (1)).

3 Legislation amended

This regulation amends the *Gene Technology Regulation 2004*.

4 Section 4

omit

somatic cell nuclear transfer if the transfer does not involve genetically modified material

substitute

a technique in schedule 1A

5 Section 6 (1) (c)

omit

6 Section 6 (1) (d)

substitute

(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 Section 6 (3)

omit

8 Section 7

substitute

7 Application for licence—prescribed fee

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

9 Section 8 (1) (b)

substitute

(b) for an application to which the Act, division 5.4 applies—

(i) for a limited and controlled release application for which the regulator is satisfied that the dealings proposed to be authorised by the licence do not pose significant risks to the health and safety of people or to the environment—150 days after the day the application is received by the regulator; and

(ii) for a limited and controlled release application for which the regulator is satisfied that at least one of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment—170 days after the day the application is received by the regulator; and

(iii) in any other case—255 days after the day the application is received by the regulator.

10 Section 8 (2) (e)

omit

gene technology ethics committee

substitute

ethics and community committee

11 Section 8 (3)

omit

gene technology ethics committee

substitute

ethics and community committee

12 New section 8 (4)

insert

(4) In this section:

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

13 Section 9 (c)

omit

14 Section 9 (d) and (e)

substitute

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

(e) Australian Pesticides and Veterinary Medicines Authority;

15 New section 9A

insert

9A Risks posed by dealings proposed to be authorised by licence—Act, s 51 (1) (a)

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.

16 Section 10 (1) (a)

substitute

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

17 Section 10 (1) (b) (v)

omit

selective advantage

substitute

an advantage

18 New section 11A

in division 3.1, insert

11A Time limit for deciding variation application—Act, s 71 (7)

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.

19 Section 13

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 schedule 3, part 3.1—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 schedule 3, part 3.2—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 the Act, section 27 (d) 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 the Act, section 27 (d).

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 by the organisation 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 subsection (3) must, by the end of the period mentioned in the notice, give the regulator the information required by the notice.

20 Parts 5 and 6

substitute

Part 5 Ethics and community committee

31 Ethics and community committee—conditions of appointment

Note The Commonwealth regulations, reg 31 provides for the Commonwealth Act, pt 4, div 1 to apply to the conditions of appointment of a member of the ethics and community committee.

32 Ethics and community committee—committee procedures

Note The Commonwealth regulations, reg 32 provides for the Commonwealth Act, pt 4, div 2 to apply to the procedures of the ethics and community committee.

33 Ethics and community committee—operation of subcommittees

Note The Commonwealth regulations, reg 33 provides for the matters covered by the Commonwealth Act, pt 4, div 2 for subcommittees established under the Commonwealth Act, s 111 (1).

21 Section 39 (2) (c) (ii)

omit

in the GM product; and

substitute

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

22 Part 8

omit

23 Schedules 1 to 4

substitute

Schedule 1A Techniques that are not gene technology

(see s 4)

column 1 item	column 2 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

column 1 item	column 2 description of technique
9	zygote implantation
10	a natural process, if the process does not involve genetically modified material **Examples—natural processes** Conjugation, transduction, transformation and transposon mutagenesis. *Note* An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Schedule 1 Organisms that are not genetically modified organisms

(see s 5)

column 1 item	column 2 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

column 1 item	column 2 description of organism
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

(see s 6)

Note For this schedule, s 6 (1) sets out other requirements for exempt dealings.

Part 2.1 Exempt dealings

column 1 item	column 2 description of dealing
2	a dealing with a genetically modified *Caenorhabditis elegans*, unless— (a) an advantage is conferred on the animal by the genetic modification; or (b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent
3	a dealing with an animal into which genetically modified somatic cells have been introduced, if— (a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and (b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells

column 1 item	column 2 description of dealing
4	a dealing involving a host/vector system mentioned in part 2.2 and producing not more than 10 litres of GMO culture in each vessel containing the resultant culture if the donor nucleic acid— (a) is— (i) not derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi; or (ii) 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) does not code for a toxin with an LD_{50} of less than 100µg/kg; and (c) does not code for a toxin with an LD_{50} of 100µg/kg or more, if the intention is to express the toxin at high levels; and (d) is not an 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— (A) is not available in the cell into which the nucleic acid is introduced; and (B) will not become available during the dealing; and

column 1 item	column 2 description of dealing
	(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and
	(f) does not confer an oncogenic modification
5	a dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in part 2.2, item 1, if the donor nucleic acid is not derived from either—
	(a) a pathogen; or
	(b) a toxin-producing organism

Part 2.2 Host/vector systems for exempt dealings

column 1 item	column 2 class	column 3 host	column 4 vector
1	bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C—any derivative that does not contain— (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1 non-conjugative plasmids 2 bacteriophage— (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}: (a) *B. amyloliquefaciens* (b) *B. licheniformis* (c) *B. pumilus* (d) *B. subtilis* (e) *B. thuringiensis*	1 non-conjugative plasmids 2 plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *bacillus* 3 none (non-vector systems)

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*	1 non-conjugative plasmids 2 none (non-vector systems)

		Photobacterium angustum *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Vibrio cholerae* CVD103-HgR	
2	fungi	*Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Kluyveromyces lactis* *Trichoderma reesei*	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	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 2.3 Definitions—sch 2

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).

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Schedule 3 Notifiable low risk dealings in relation to a GMO

(see s 12 and s 13)

Part 3.1 Notifiable low risk dealings suitable for physical containment level 1

Note For this part, because of s 12 (1), a dealing mentioned in this part is not a notifiable risk dealing if it is also a dealing of a kind mentioned in this schedule, pt 3.3.

3.1 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 schedule 2, part 2.2, 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 schedule 2, part 2.2, item 4 (animal or human cell culture), unless—

(i) the vector is a retroviral vector; or

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

Part 3.2 Notifiable low risk dealings suitable for physical containment level 2

Note For this part, because of s 12 (1), a dealing mentioned in this part is not a notifiable risk dealing if it is also a dealing of a kind mentioned in this schedule, pt 3.3.

3.2 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 schedule 2, part 2.2, 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 schedule 2, part 2.2, 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 schedule 2, part 2.2, 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 schedule 2, part 2.2, 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 schedule 2, part 2.1, item 4;

(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 shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in schedule 2, part 2.2, item 1, 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 schedule 2, part 2.2, 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 3.3 Dealings that are not notifiable low risk dealings

Note 1 For this part, the following list qualifies the list in pt 3.1 and pt 3.2 and is not an exhaustive list of dealings that are not notifiable low risk dealings.

Note 2 For this part, a dealing that is not a notifiable low risk dealing, or an exempt dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see Act, s 32).

3.3 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 this schedule, part 3.2, section 3.2 (h)) 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 this schedule, part 3.2, section 3.2 (h)) 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 schedule 2, part 2.2 or in this schedule, part 3.1, section 3.1 (c) or part 3.2, section 3.2 (i)—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 schedule 2, part 2.2; 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 this schedule, part 3.2, section 3.2 (g);

(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 this schedule, part 3.2, section 3.2 (g); or

(ii) the micro-organism is a host mentioned in schedule 2, part 2.2;

(g) a dealing involving the introduction into a micro-organism, other than a host mentioned in schedule 2, part 2.2, of genes whose expressed products have a heightened risk of inducing an auto-immune 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 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 this schedule, part 3.2, section 3.2 (f);

(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.

24 Dictionary, note 3, new dot point

insert

- ethics and community committee

25 Dictionary, definition of *advantage*

substitute

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.

26 Dictionary, definition of *characterised*

substitute

characterised, in relation to nucleic acid, means nucleic acid that has been sequenced and in relation to which there is an understanding of potential gene products or potential functions.

27 Dictionary, definitions of *division 5.3 application* and *division 5.4 application*

omit

28 Dictionary, definition of *expert advisor*

substitute

expert adviser means—

(a) for part 4 (Gene technology technical advisory committee)—an expert adviser appointed under the Act, section 102 (1); and

(b) for part 5 (Ethics and community committee)—an expert adviser appointed under the Act, section 112 (1).

29 Dictionary, definition of *gene-knockout mice*

omit

30 Dictionary, definition of *genetic manipulation advisory committee*

omit

31 Dictionary, new definitions

insert

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.

32 Dictionary, definition of *inclusion-negative*

omit

33 Dictionary, new definitions

insert

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—see schedule 2, part 2.3.

non-vector system, for schedule 2—see schedule 2, part 2.3.

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.

34 Dictionary, new definition of *plasmid*

insert

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

35 Dictionary, definition of *recombinant*

omit

36 Dictionary, definition of *shotgun cloning*

substitute

shotgun cloning means the production of a large random collection of cloned fragments of nucleic acid from which genes of interest can later be selected.

37 Dictionary, new definitions

insert

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.

Endnotes

1 Notification

Notified under the Legislation Act on 17 April 2008.

2 Republications of amended laws

For the latest republication of amended laws, see www.legislation.act.gov.au.