Gene Technology Amendment Regulations 2007 (No. 1)[1]

Select Legislative Instrument 2007 No. 128

I, PHILIP MICHAEL JEFFERY, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Gene Technology Act 2000*.

Dated 23 May 2007

P. M. JEFFERY
Governor-General

By His Excellency's Command

BRETT MASON
Parliamentary Secretary to the Minister for Health and Ageing

Federal Register of Legislative Instruments F2007L01317

1 Name of Regulations

These Regulations are the *Gene Technology Amendment Regulations 2007 (No. 1)*.

2 Commencement

These Regulations commence as follows:

(a) on the commencement of Part 1 of Schedule 1 to the *Gene Technology Amendment Act 2007* — Schedule 1;

(b) immediately after the commencement of Schedule 1 — Schedule 2;

(c) on the commencement of Part 2 of Schedule 1 to the *Gene Technology Amendment Act 2007* — Schedule 3.

3 Amendment of *Gene Technology Regulations 2001*

Schedules 1, 2 and 3 amend the *Gene Technology Regulations 2001*.

Schedule 1 Amendments commencing on commencement of Part 1 of Schedule 1 to the *Gene Technology Amendment Act 2007*

(regulation 3)

[1] Paragraph 6 (1) (c)

omit

[2] Paragraph 8 (1) (b)

substitute

(b) for an application to which Division 4 of Part 5 of the Act applies:

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

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

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

[3] After subregulation 8 (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.

[4] Paragraph 9 (c)

omit

[5] After regulation 9

insert

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

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

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

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

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

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

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

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

[6] After regulation 11

insert in Division 1

11A Time limit for deciding variation application

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

[7] Regulation 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 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 paragraph 27 (d) of the Act, that the Regulator has determined in writing are appropriate for conducting the dealing; and

(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 paragraph 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 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 subregulation (3) must, by the end of the period mentioned in the notice, give the Regulator the information required by the notice.

[8] Schedule 2, Part 1, item 1

omit

[9] Schedule 2, Part 1, subitem 4 (1)

omit

subitems (2) and (3),

insert

subitem (2),

[10] Schedule 2, Part 1, subparagraph 4 (2) (e) (ii)

omit

virions

insert

virions; and

[11] Schedule 2, Part 1, after paragraph 4 (2) (e)

insert

(f) must not confer an oncogenic modification.

[12] Schedule 2, Part 1, subitem 4 (3)

omit

[13] Schedule 2, Part 2, item 4, column 3

omit

(other than a retroviral vector that is able to transduce human cells)

insert

unable to transduce human cells

[14] Schedule 3, Part 1

renumber as Part 2

[15] Schedule 3, Part 1, item 1.1

renumber as item 2.1

[16] Schedule 3, Part 2

renumber as Part 3

[17] Schedule 3, Part 2, item 2.1

renumber as item 3.1

Schedule 2 Amendments commencing immediately after commencement of Schedule 1

(regulation 3)

[1] Schedule 3, before Part 2

insert

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

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

[2] Schedule 3, Part 2, heading

substitute

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

[3] Schedule 3, Part 2, note

omit

Part 2

insert

Part 3

[4] Schedule 3, Part 2, item 2.1

omit all words before paragraph (a), insert

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

[5] Schedule 3, Part 2, subparagraph 2.1 (e) (ii)

omit

fungi; or

insert

fungi;

[6] Schedule 3, Part 2, subparagraph 2.1 (e) (iii)

omit

[7] Schedule 3, Part 2, paragraph 2.1 (i)

substitute

(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.

[8] Schedule 3, Part 3, note 1

omit

Part 1

insert

Parts 1 and 2

[9] Schedule 3, Part 3, paragraphs 3.1 (a) and (c)

omit

paragraph 1.1 (h) of Part 1

insert

paragraph 2.1 (h) of Part 2

[10] Schedule 3, Part 3, paragraph 3.1 (d)

omit

paragraph 1.1 (i) of Part 1

insert

paragraph 1.1 (c) of Part 1 or 2.1 (i) of Part 2

[11] Schedule 3, Part 3, subparagraphs 3.1 (e) (iii) and (f) (i)

omit

paragraph 1.1 (g) of Part 1

insert

paragraph 2.1 (g) of Part 2

[12] Schedule 3, Part 3, paragraph 3.1 (i)

omit

able to transduce human cells

[13] Schedule 3, Part 3, paragraph 3.1 (k)

omit

paragraph 1.1 (f) of Part 1

insert

paragraph 2.1 (f) of Part 2

Schedule 3 Amendments commencing on commencement of Part 2 of Schedule 1 to the *Gene Technology Amendment Act 2007*

(regulation 3)

[1] Regulation 3, definition of *expert adviser*

substitute

expert adviser means:

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

(b) in Part 5 — an expert adviser appointed under subsection 112 (1) of the Act.

[2] Regulation 3, note

after

- environment

insert

- Ethics and Community Committee

[3] Paragraph 8 (2) (e)

omit

Gene Technology Ethics Committee

insert

Ethics and Community Committee

[4] Subregulation 8 (3)

omit

Gene Technology Ethics Committee,

insert

Ethics and Community Committee,

[5] Parts 5 and 6

substitute

Part 5 Ethics and Community Committee

31 Ethics and Community Committee — conditions of appointment

Division 1 of Part 4 applies to the conditions of appointment of a member of the Ethics and Community Committee, or an expert adviser, as if:

(a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Ethics and Community Committee; and

(b) a reference to a member of the Gene Technology Technical Advisory Committee were a reference to a member of the Ethics and Community Committee; and

(c) the reference, in paragraph 21 (2) (b), to section 101 of the Act were a reference to section 107 of the Act.

32 Ethics and Community Committee — Committee procedures

Division 2 of Part 4 applies to the procedures of the Ethics and Community Committee as if:

(a) a reference to the Gene Technology Technical Advisory Committee were a reference to the Ethics and Community Committee; and

(b) a reference to a member or Chairperson of the Gene Technology Technical Advisory Committee were a reference to a member or Chairperson of the Ethics and Community Committee; and

(c) the reference, in paragraph 26 (1) (b), to paragraph 100 (7A) (a) or (b) of the Act were a reference to paragraph 108 (4) (a) or (b) of the Act; and

(d) the reference, in regulation 27, to subsection 100 (2) of the Act were a reference to subsection 108 (1) of the Act.

33 Ethics and Community Committee — operation of subcommittees

(1) Regulations 24, 25, 26 and 28 apply to a subcommittee established under subsection 111 (1) of the Act as if a reference in those regulations to the Gene Technology Technical Advisory Committee were a reference to the subcommittee.

(2) At a meeting of a subcommittee, a quorum exists if half of the members of the subcommittee are present.

(3) A subcommittee must keep a record of its proceedings, and must give to the Ethics and Community Committee a copy of each resolution passed by the subcommittee.

[6] Regulation 38

omit

or Part 6

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See www.frli.gov.au.