Queensland

Gene Technology Amendment Regulation (No. 1) 2008

Subordinate Legislation 2008 No. 109

made under the

Gene Technology Act 2001

Contents

Contents

1 Short title

This regulation may be cited as the *Gene Technology Amendment Regulation (No. 1) 2008*.

2 Regulation amended

This regulation amends the *Gene Technology Regulation 2002*.

3 Amendment of s 6 (Dealings exempt from licensing)

Section 6(1)(c)—

omit.

4 Amendment of s 8 (Time limit for deciding an application)

(1) Section 8(1)(b)—

omit, insert—

'(b) for an application to which part 5, division 4 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 on which the regulator receives the application; 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 on which the regulator receives the application; and

(iii) otherwise—255 days after the day on which the regulator receives the application.'.

(2) Section 8(2)(e) and (3), 'ethics committee'—

omit, insert—

'ethics and community committee'.

(3) Section 8(4)—

insert—

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

5 Amendment of s 9 (Prescribed authorities)

Section 9(c)—

omit.

6 Insertion of new s 9A

After section 9—

insert—

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

'For 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.'.

7 Insertion of new s 11A

Part 3, division 1—

insert—

'11A Time limit for deciding variation application

'For section 71(7) of the Act, the prescribed period for the regulator to vary, or refuse to vary, the licence is 90 days after the day on which the regulator receives the application for the variation.

Note—

This section differs from regulation 11A of the Commonwealth regulations.'.

8 Amendment of s 12 (Notifiable low risk dealings)

Section 12(1)(a)—

omit, insert—

'(a) it is a dealing of a kind mentioned in schedule 3, part 1 or 2 (other than a dealing of a kind also mentioned in schedule 3, part 3); and'.

9 Replacement of s 13 (Requirements for notifiable low risk dealings)

Section 13—

omit, insert—

'13 Requirements for 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 the personnel to be involved in the proposed dealing have appropriate training and experience.

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

(a) the dealing must be conducted—

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

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

(iii) in another facility in accordance with any technical and procedural guidelines about 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 for 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 stated 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 institutional biosafety 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) otherwise—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 on which 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) another person involved with the conduct of the proposed dealing;

to give the regulator any further information about 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 accredited organisation receiving a notice under subsection (3) must, by the end of the period stated in the notice, give the regulator the information required by the notice.'.

10 Replacement of pt 5 (Gene technology community consultative committee)

Part 5—

omit, insert—

'Part 5 Ethics and community committee

'31 Ethics and community committee—conditions of appointment

Note—

Regulation 31 of the Commonwealth regulations states that part 4, division 1 of the Commonwealth regulations applies to the conditions of appointment of a member of the ethics and community committee, or an expert adviser.

'32 Ethics and community committee—consultative committee procedures

Note—

Regulation 32 of the Commonwealth regulations states that part 4, division 2 of the Commonwealth regulations applies to the procedures of the ethics and community committee.

'33 Ethics and community committee—operation of subcommittees

Note—

Regulation 33 of the Commonwealth regulations states that regulations 24 to 26 and 28 of the Commonwealth regulations apply to a

subcommittee established under section 111(1) of the Commonwealth Act.'.

11 Omission of pt 6 (Gene technology ethics committee)

Part 6—

omit.

12 Amendment of s 38 (Review of decisions)

Section 38, 'the consultative committee and the ethics committee'—

omit, insert—

'or an expert adviser'.

13 Amendment of s 39 (Record of GMO and GM product dealings)

Section 39(1)(b), 'part 1,'—

omit, insert—

'parts 1 and 2,'.

14 Amendment of sch 2 (Dealings exempt from licensing)

(1) Schedule 2, part 1, section 1—

omit.

(2) Schedule 2, part 1, section 4(1), 'subsections (2) and (3)'—

omit, insert—

'subsection (2)'.

(3) Schedule 2, part 1, section 4(2)—

insert—

'(f) must not confer an oncogenic modification.'.

(4) Schedule 2, part 1, section 4(3)—

omit.

(5) Schedule 2, part 2, item 4, column 4, from 'vectors', first mention, to 'cells)'—

omit, insert—

'vectors, or defective viral vectors unable to transduce human cells'.

15 Amendment of sch 3 (Notifiable low risk dealings in relation to a GMO)

(1) Schedule 3, parts 1 and 2—

renumber as schedule 3, parts 2 and 3.

(2) Schedule 3—

insert—

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

Note—

Under section 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 schedule 2, part 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, item 4 (animal or human cell cultures), unless—

(i) the vector is a retroviral vector; or

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

(3) Schedule 3, part 2, as renumbered, heading—

omit, insert—

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

(4) Schedule 3, part 2, as renumbered, note, 'part 2'—

omit, insert—

'part 3'.

(5) Schedule 3, section 1.1—

renumber as schedule 3, section 2.1.

(6) Schedule 3, section 2.1, as renumbered, from 'The' to 'dealings—'—

omit, insert—

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

(7) Schedule 3, section 2.1(e)(iii), as renumbered—

omit.

(8) Schedule 3, section 2.1(i), as renumbered—

omit, insert—

‘(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, 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.’.

(9) Schedule 3, part 3, as renumbered, note 1, ‘part 1’—

omit, insert—

‘parts 1 and 2’.

(10) Schedule 3, section 2.1—

renumber as schedule 3, section 3.1.

(11) Schedule 3, section 3.1(a) and (c), as renumbered, ‘part 1, section 1.1(h)’—

omit, insert—

‘part 2, section 2.1(h)’.

(12) Schedule 3, section 3.1(d), as renumbered, ‘section 1.1(i)’—

omit, insert—

‘section 1.1(c) or part 2, section 2.1(i)’.

(13) Schedule 3, section 3.1(e)(iii), as renumbered, from ‘this schedule’—

omit, insert—

‘in this schedule, part 2, section 2.1(g);’.

(14) Schedule 3, section 3.1(f)(i), as renumbered, ‘part 1, section 1.1(g)’—

omit, insert—

‘part 2, section 2.1(g)’.

(15) Schedule 3, section 3.1(i), as renumbered, ‘able to transduce human cells’—

omit.

(16) Schedule 3, section 3.1(k), as renumbered, ‘part 1, section 1.1(f)’—

omit, insert—

‘part 2, section 2.1(f)’.

16 Amendment of sch 5 (Dictionary)

Schedule 5, definitions *competitive advantage, gene-knockout mice, inclusion-negative* and *selective advantage—*

omit.

ENDNOTES

1 Made by the Governor in Council on 1 May 2008.

2 Notified in the gazette on 2 May 2008.

3 Laid before the Legislative Assembly on . . .

4 The administering agency is the Department of Tourism, Regional Development and Industry.