

Gene Technology Amendment Act 2008

A2008-10

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Gene Technology Amendment Act 2008

A2008-10

An Act to amend the Gene Technology Act 2003

The Legislative Assembly for the Australian Capital Territory enacts as follows:

1 Name of Act

This Act is the Gene Technology Amendment Act 2008.

2 Commencement

This Act commences on a day fixed by the Minister by written notice.

- *Note 1* The naming and commencement provisions automatically commence on the notification day (see Legislation Act, s 75 (1)).
- Note 2 A single day or time may be fixed, or different days or times may be fixed, for the commencement of different provisions (see Legislation Act, s 77 (1)).
- Note 3 If a provision has not commenced within 6 months beginning on the notification day, it automatically commences on the first day after that period (see Legislation Act, s 79).

3 Legislation amended

This Act amends the Gene Technology Act 2003.

4 Simplified outline—pt 4 New section 31 (b) (ia)

insert

(ia) the dealing is specified in an emergency dealing determination; or

5 Section 32

substitute

32 Person not to deal with GMO without licence

A person commits an offence if—

(a) the person deals with a GMO, knowing that it is a GMO; and

- (b) the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless about that fact; and
- (c) the dealing with the GMO is not specified in an emergency dealing determination, and the person knows or is reckless about that fact; and
- (d) the dealing is not a notifiable low risk dealing, and the person knows or is reckless about that fact; and
- (e) the dealing is not an exempt dealing and the person knows or is reckless about that fact; and
- (f) the dealing is not included on the GMO Register, and the person knows or is reckless about that fact.

Maximum penalty:

- (a) for an aggravated offence—2 000 penalty units, imprisonment for 5 years or both; or
- (b) in any other case—500 penalty units, imprisonment for 2 years or both.
- Note 1 Aggravated offence is defined in s 38.
- Note 2 For provisions corresponding to the Commonwealth Act, s 32 (4), see the Legislation Act, s 48.

Person not to deal with GMO without licence—strict liability offence New section 33 (1) (ba)

insert

(ba) the dealing with the GMO is not specified in an emergency dealing determination; and

7 Section 33 (2)

after

subsection (1) (b),

insert

(ba),

Person must not breach conditions of GMO licence Section 34 (1)

substitute

- (1) The holder of a GMO licence commits an offence if—
 - (a) the holder intentionally takes an action or omits to take an action; and
 - (b) the action or omission contravenes the licence, and the holder knows or is reckless about that fact.

Maximum penalty:

- (a) for an aggravated offence—2 000 penalty units, imprisonment for 5 years or both; or
- (b) in any other case—500 penalty units, imprisonment for 2 years or both.

9 Section 34 (2) (b) and (c)

substitute

- (b) the person has knowledge of the conditions of the licence; and
- (c) the action or omission contravenes a condition of the licence, and the person knows or is reckless about that fact.

10 New sections 35A and 35B

insert

35A Person must not breach conditions of emergency dealing determination

A person commits an offence if—

- (a) the person intentionally takes an action or omits to take an action; and
- (b) the person has knowledge of the conditions to which an emergency dealing determination is subject; and
- (c) the action or omission contravenes such a condition, and the person knows or is reckless about that fact.

Maximum penalty:

- (a) for an aggravated offence—2 000 penalty units, imprisonment for 5 years or both; or
- (b) in any other case—500 penalty units, imprisonment for 2 years or both.

Note This section differs from the Commonwealth Act, s 35A.

Person must not breach conditions of emergency dealing determination—strict liability offence

- (1) A person commits an offence if—
 - (a) the person takes an action or omits to take an action; and
 - (b) the person has knowledge of the conditions to which an emergency dealing determination is subject; and

(c) the action or omission by the person contravenes such a condition.

Maximum penalty:

- (a) for an aggravated offence—200 penalty units; or
- (b) in any other case—50 penalty units.
- (2) Strict liability applies to subsection (1) (a) and (c).

Note This section differs from the Commonwealth Act, s 35B.

11 New section 40A

insert

40A Licences relating to inadvertent dealings

- (1) If the regulator is satisfied that a person has come into possession of a GMO inadvertently the regulator may, with the agreement of the person, treat the person as having made an inadvertent dealings application.
- (2) To remove any doubt, subsection (1) does not prevent a person from making an application under section 40 in relation to a GMO that has inadvertently come into the person's possession.

Note Section 46A and s 49 have the effect that the regulator may expedite consideration of an application to dispose of a GMO that has come into a person's possession inadvertently. These sections have effect whether the application is made under s 40, or is taken to have been made under this section.

12 Regulator may require applicant to give further information New section 42 (3)

insert

(3) The regulator may require information to be given under this section at any time before the regulator decides the application, whether before or after the regulator has begun to consider the application.

13 Regulator must consider applications except in certain circumstances Section 43 (2)

omit

application if—

substitute

application, or may cease considering the application, if—

14 New section 43 (2) (f)

insert

(f) the regulator is satisfied (having regard to the matters mentioned in section 58) that the applicant is not a suitable person to hold a licence.

15 New section 46A

insert

46A Division does not apply to an application relating to inadvertent dealings

Despite section 46, this division does not apply to an application for a GMO licence if the regulator is satisfied that—

- (a) the dealings proposed to be authorised by the licence are limited to dealings to be undertaken for the purposes of, or for purposes relating to, disposing of a GMO; and
- (b) the applicant for the licence came into possession of the GMO inadvertently.

16 Section 49

substitute

49 Division does not apply to an application relating to inadvertent dealings

Despite section 48, this division does not apply to an application for a GMO licence if the regulator is satisfied that—

- (a) the dealings proposed to be authorised by the licence are limited to dealings to be undertaken for the purposes of, or for purposes relating to, disposing of a GMO; and
- (b) the applicant for the licence came into possession of the GMO inadvertently.

17 Regulator must prepare risk assessment and risk management plan Section 50 (2)

omit

18 Section 50 (3)

omit

The

substitute

Unless section 50A applies in relation to the application for the licence, the

19 New section 50A

insert

50A Limited and controlled release applications

- (1) This section applies to an application for a licence if the regulator is satisfied that—
 - (a) the principal purpose of the application is to enable the licence holder, and people covered by the licence, to conduct experiments; and
 - (b) the application proposes in relation to any GMO for which dealings are proposed to be authorised—
 - (i) controls to restrict the dissemination or persistence of the GMO and its genetic material in the environment; and
 - (ii) limits on the proposed release of the GMO; and
 - (c) the regulator is satisfied that the controls and limits are of such a kind that it is appropriate for the regulator not to seek the advice mentioned in section 50 (3).

- (2) In deciding whether the principal purpose of an application is to enable the licence holder, and people covered by the licence, to conduct experiments, the regulator—
 - (a) must have regard to whether the applicant proposes that any or all of the following be authorised by, and done under, the licence:
 - (i) testing hypotheses;
 - (ii) gaining scientific or technical knowledge;
 - (iii) gaining data for regulatory purposes, or for product development or marketing; and
 - (b) may have regard to anything else the regulator considers to be relevant.
- (3) In this section:

controls, in relation to restricting the dissemination or persistence of a GMO and its genetic material in the environment, include the following:

- (a) stated methods for disposal of the GMO or its genetic material;
- (b) data collection requirements, including studies to be conducted about the GMO or its genetic material;
- (c) a restricted geographic area in which the proposed dealings with the GMO or its genetic material may occur;
- (d) compliance, in relation to dealings with the GMO or its genetic material, with—
 - (i) a code of practice issued under section 24; or
 - (ii) a technical or procedural guideline issued under section 27.

limits, in relation to the release of a GMO that is proposed to be authorised by a licence, includes limits on any of the following:

- (a) the scope of the dealings with the GMO;
- (b) the scale of the dealings with the GMO;
- (c) the locations of the dealings with the GMO;
- (d) the duration of the dealings with the GMO;
- (e) the people who are to be permitted to conduct of the dealings with the GMO.

Note This section differs from the Commonwealth Act, s 50A.

20 Matters regulator must take into account in preparing risk assessment and risk management plan Section 51 (1) (a)

omit everything after

matters

substitute

prescribed by regulation;

21 Section 51 (1) (b)

omit

22 Section 51 (2) (b)

omit

Public notification of risk assessment and risk management plan Section 52 (1)

omit

sections 49 (if applicable), 50 and 51

substitute

section 50 and section 51

24 New section 52 (2) (ba)

insert

(ba) if the regulator is satisfied that 1 or more dealings proposed to be authorised by the licence may pose a significant risk to the health and safety of people or to the environment—state that the regulator is so satisfied; and

25 Section 52 (2) (d)

omit everything after

earlier

substitute

than-

- (i) if the notice states that the regulator is satisfied that the dealings proposed to be authorised by the licence may pose a significant risk to the health and safety of people or to the environment—50 days after the date on which the notice was published; or
- (ii) in any other case—30 days after the date on which the notice was published.

26 Regulator must not issue the licence unless satisfied as to risk management Section 56 (2) (a) and (b)

substitute

- (a) the risk assessment prepared under section 47 or section 50 in relation to the dealings;
- (b) the risk management plan prepared under section 47 or section 50 in relation to the dealings;

27 Section 56 (2), new note

insert

Note Subsections (2) (a) to (c) do not apply to an inadvertent dealings application.

Other circumstances in which regulator must not issue the licence New section 57 (3)

insert

(3) Subsection (2) does not apply to an inadvertent dealings application.

29 Period of licence New section 60 (3)

insert

(3) A licence issued as a result of an inadvertent dealings application must not be expressed to be in force for a period of longer than 12 months.

30 Protection of persons who give information Section 67

omit

or section 66

substitute

, section 66 or the Commonwealth Act, section 72D (2) (h)

Variation of licence Section 71 (1)

substitute

- (1) The regulator may vary a licence, by written notice given to the licence holder—
 - (a) at any time, on the regulator's own initiative; or
 - (b) on application by the licence holder.
- (1A) An application for a variation must be in writing, and must contain—
 - (a) any information prescribed by regulation; and
 - (b) any information specified in writing by the regulator.

32 Section 71 (2)

omit

However, the

substitute

The

33 New section 71 (2A)

insert

- (2A) The regulator must not vary a licence if the original application for the licence was an application to which section 50A applied, unless—
 - (a) the regulator is satisfied that the principal purpose of the licence as proposed to be varied is to enable the licence holder, and people covered by the licence, to conduct experiments; and
 - (b) the application for variation proposes, in relation to any GMO for which dealings are proposed to be authorised as a result of the variation—
 - (i) controls to restrict the dissemination or persistence of the GMO and its genetic material in the environment; and
 - (ii) limits on the proposed release of the GMO; and
 - (c) the regulator is satisfied that the controls and limits are of such a kind that it is appropriate for the regulator not to seek the advice mentioned in section 50 (3).

Note Section 50A applies to an application that proposes controls and limits on the dissemination, persistence and release of the GMO concerned and is for the purpose of conducting experiments.

(2B) The regulator must not vary a licence if the regulator is satisfied that the risk assessment and the risk management plan in relation to the original application for the licence did not cover the risks posed by the dealings proposed to be authorised by the licence as varied.

34 Section 71 (4)

omit

However, the regulator must not vary the

substitute

The regulator must not vary a

35 New section 71 (5) to (8)

insert

- (5) The regulator must not vary a licence unless any local council that the regulator considers appropriate has been consulted about the proposed variation.
- (6) The regulator must not vary a licence in the circumstances (if any) prescribed by regulation.
- (7) If an application has been made for variation of a licence, the regulator must vary the licence or refuse to vary the licence, within the period (if any) prescribed by regulation.
- (8) In this section:

controls—see section 50A (3).

limits—see section 50A (3).

36 Regulator to notify of proposed suspension, cancellation or variation New section 72 (8)

insert

(8) This section does not apply to a variation of a licence if the regulator is satisfied that the variation is of minor significance or complexity.

37 GMO licence—annual charge Section 72A

renumber as section 72AA

38 New part 5A

insert

Part 5A Emergency dealing determinations

Note to pt 5A

This part differs from the Commonwealth Act, pt 5A.

72A Application of Commonwealth emergency dealing determinations

An emergency dealing determination in force under the Commonwealth Act, section 72B applies, as far as applicable, as a law of the Territory.

Note This section differs from the Commonwealth Act, s 72A.

72B Minister may make emergency dealing determination

Note

The Commonwealth Act, s 72B permits the Commonwealth Minister to make emergency dealing determinations with a GMO for the purposes of the Commonwealth Act, part 5A.

72C Period of effect of emergency dealing determination

Note

The Commonwealth Act, s 72C provides for when an emergency dealing determination takes effect, when it ceases to have effect and how the period of effect may be extended by the Commonwealth Minister responsible for emergency dealing determinations.

Division 5A.3 Effect and conditions of emergency dealing determination

72D Emergency dealing determination authorises dealings, subject to conditions

Note

The Commonwealth Act, s 72D authorises dealings with a GMO subject to conditions, including those referred to in s 72D (2).

Division 5A.4 Variation, suspension and revocation of emergency dealing determination

72E Variation, suspension and revocation of emergency dealing determination

Note

Under the Commonwealth Act, s 72E, the Commonwealth Minister responsible for emergency dealing determinations may suspend an emergency dealing determination, revoke an emergency dealing determination or vary the conditions to which an emergency dealing determination is subject.

Regulator may include dealings with GMOs on GMO register Section 78 (4)

omit

40 Simplified outline—pt 7 Section 82 (2) and (4)

after

Licence conditions

insert

, or conditions to which an emergency dealing determination is subject,

41 Application for certification Section 83 (2), note

after

licence

insert

, or conditions to which an emergency dealing determination is subject,

42 Regulator to notify of proposed suspension, cancellation or variation New section 89 (8)

insert

(8) This section does not apply to a variation of a licence if the regulator is satisfied that the variation is of minor significance or complexity.

43 New section 89A

insert

89A Transfer of certification

- (1) The holder of a certification and another person (the *transferee*) may jointly apply to the regulator for the certification to be transferred from the holder of the certification to the transferee.
- (2) The application must be in writing and must contain—
 - (a) any information prescribed by regulation; and
 - (b) any information required, in writing, by the regulator.
- (3) The regulator must not transfer the certification unless satisfied that, if the certification is transferred, any conditions to which the certification is subject will continue to be met.
- (4) The regulator must give written notice of his or her decision on the application to the holder of the certification and the transferee.

- (5) If the regulator decides to transfer the certification—
 - (a) the transfer takes effect on the date stated in the notice; and
 - (b) the certification continues in force; and
 - (c) the certification is subject to the same conditions as those in force immediately before the transfer.

44 Application for accreditation Section 91 (1), note

substitute

- Note 1 The conditions of a licence may require supervision of dealings by an institutional biosafety committee (see s 62 (2) (m)), and a regulation may require such supervision of notifiable risk dealings (see s 75 (2) (c)).
- Note 2 The conditions to which an emergency dealing determination is subject may require supervision of dealings by an institutional biosafety committee (see the Commonwealth Act, s 72D (2) (t)).

45 Regulator may accredit organisations Section 92 (2) (a)

omit

, or proposes to establish,

46 Section 92 (2) (b) and (c)

substitute

(b) if the organisation has established an institutional biosafety committee—whether the organisation will be able to maintain the institutional biosafety committee in accordance with the guidelines; and

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- (c) if the organisation has established an institutional biosafety committee—whether the organisation has appropriate indemnity arrangements for its institutional biosafety committee members; and
- (ca) if the organisation has not established an institutional biosafety committee as mentioned in paragraph (a)—whether the organisation will be in a position to use an institutional biosafety committee established by an accredited organisation; and

47 Regulator to notify of proposed suspension, cancellation or variation New section 97 (8)

insert

(8) This section does not apply to a variation of an accreditation if the regulator is satisfied that the variation is of minor significance or complexity.

48 Part 8 heading

substitute

Part 8

Gene technology technical advisory committee and gene technology ethics and community consultative committee

49 Simplified outline—pt 8 Section 99 (b) and (c)

substitute

(b) gene technology ethics and community consultative committee.

50 Division 8.3 heading

substitute

Division 8.3 Gene technology ethics and community consultative committee

51 Section 106 heading

substitute

106 Gene technology ethics and community consultative committee

52 Section 106, note

after

technology

insert

ethics and

53 Section 107

substitute

107 Function of ethics and community committee

The function of the ethics and community committee under this Act is to provide advice, on request of the regulator or the ministerial council, on the following:

- (a) ethical issues relating to gene technology;
- (b) the need for, and content of, codes of practice in relation to ethics for conducting dealings with GMOs;
- (c) the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons:
- (d) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes;
- (e) community consultation about the process for applications for licences covering dealings that involve intentional release of a GMO into the environment;
- (f) risk communication matters in relation to dealings that involve the intentional release of a GMO into the environment:
- (g) matters of general concern identified by the regulator in relation to applications made under this Act;
- (h) matters of general concern in relation to GMOs.

54 Sections 108 and 109, notes

omit

consultative

substitute

ethics and community

55 Regulations Section 110, note

omit everything after

membership

substitute

and procedures of the ethics and community committee.

56 Subcommittees Section 110A

omit

57 New sections 111 and 112

in division 8.3, insert

111 Subcommittees

Note The Commonwealth Act, s 111 deals with the establishment of subcommittees by the ethics and community committee.

112 Expert advisers

Note The Commonwealth Act, s 112 provides for the appointment of expert advisers to the ethics and community committee.

58 Gene technology ethics committee Division 8.4

omit

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59 Quarterly reports New sections 136A (2) (ba) and (bc)

insert

- (ba) emergency dealing determinations made by the Minister during the quarter;
- (bb) any breaches of conditions of an emergency dealing determination that have come to the regulator's attention during the quarter;

Record of GMO and GM product dealings New section 138 (1A)

insert

- (1A) The GM record must contain the following information, other than confidential commercial information, in relation to each emergency dealing determination made under section 72B:
 - (a) the dealings specified in the emergency dealing determination and the GMO to which those dealings relate;
 - (b) any conditions to which the emergency dealing determination is subject;
 - (c) the date on which the emergency dealing determination takes effect:
 - (d) the date on which the emergency dealing determination will cease to have effect.

61 Section 138 (5)

after

(1),

insert

(1A),

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62 Simplified outline—pt 10 Section 145 (a) (ii)

after

environment

insert

, or for certain other reasons

63 New section 145 (aa)

insert

- (aa) authorises the regulator to give directions to a person permitted by an emergency dealing determination to deal with a GMO if—
 - (i) the regulator believes that the person is not complying with this Act; and
 - (ii) the regulator believes that it is necessary to do so in order to protect the health and safety of people or to protect the environment or for certain other reasons; and

64 Regulator may give directions Section 146 (1) (b)

substitute

- (b) either of the following applies:
 - (i) it is necessary to exercise powers under this section in order to protect the health and safety of people or to protect the environment;
 - (ii) it is desirable in the public interest, having regard to the matters mentioned in subsection (2A), for the regulator to exercise powers under this section;

65 Section 146 (2) (a)

substitute

- (a) 1 of the following kinds of people is not complying with this Act in relation to a thing:
 - (i) a person covered by a GMO licence;
 - (ii) a person dealing with, or who has dealt with, a GMO specified in an emergency dealing determination; and

66 Section 146 (2) (b)

substitute

- (b) either of the following applies:
 - (i) it is necessary to exercise powers under this section in order to protect the health and safety of people or to protect the environment;
 - (ii) it is desirable in the public interest, having regard to the matters mentioned in subsection (2A), for the regulator to exercise powers under this section;

67 New section 146 (2A)

insert

- (2A) For the purposes of deciding under subsection (1) (b) (ii) or subsection (2) (b) (ii) whether it is desirable to exercise powers under this section to give directions to a licence holder or another person, the regulator must have regard to the following:
 - (a) the types of dealings with GMOs authorised by the licence or specified in the emergency dealing determination concerned, and, in particular, whether the dealings are ongoing;

- (b) whether measures have been, or are being, taken to address the non-compliance with this Act that the regulator believes is occurring (the *suspected non-compliance*);
- (c) the likelihood of the licence holder or other person not complying with this Act at a future time;
- (d) the severity of the suspected noncompliance;
- (e) whether, on 1 or more occasions, the licence holder or other person—
 - (i) has been charged with or convicted of an offence against this Act; or
 - (ii) has been given a direction under this section;
- (f) other means available to the regulator to address the suspected noncompliance (including, but not limited to, by cancelling, varying or suspending a licence, accreditation or certification);
- (g) whether, in the regulator's opinion, the suspected noncompliance was deliberate;
- (h) the desirability of deterring future noncompliance with this Act or the regulations.

68 Simplified outline—pt 11 Section 149 (e)

after

licence

insert

or an emergency dealing determination

Powers available to inspectors for monitoring compliance New section 152 (2) (d)

insert

(d) the occupier of the premises is a person dealing with, or who has dealt with, a GMO specified in an emergency dealing determination, and the entry is at a reasonable time.

70 Section 152 (3)

omit

subsection (2) (c) does not

substitute

subsection (2) (c) or (d) does not

71 Section 177

substitute

177 Pt 11 does not limit power to impose conditions

This part does not limit the regulator's power to impose licence conditions or the Minister's power to impose conditions on an emergency dealing determination.

72 Meaning of *reviewable decision* and *eligible person* Section 179, table, new item 1A

before item 1, insert

to refuse to consider an application on the basis that the applicant is not a suitable person to hold a licence under

the applicant

section 43 (2) (f)

73 Section 179, table, new item 5A

insert

5A to refuse to vary a licence

the licence holder

under section 71

74 Section 179, table, new item 7A

insert

7A to refuse to transfer a

an applicant for the transfer

certification under section 89A

75 Deadlines for making reviewable decisions Section 182 (a)

substitute

(a) this Act provides for a person to make an application of any kind to the regulator; and

76 Section 182

omit

decision to refuse the application

substitute

reviewable decision to refuse the application, and the person may seek internal review of the reviewable decision under section 181

77 Regulator may declare information is confidential commercial information New section 185 (5A)

insert

(5A) If—

- (a) a person has made an application under section 184 for a declaration that stated information is confidential commercial information; and
- (b) the regulator has not yet made a decision on the application;

the information is to be treated as confidential commercial information until the regulator makes a decision on the application.

78 Interference with dealings with GMOs Section 192A (2), definition of authorised GMO dealings, new paragraph (aa)

insert

(aa) that are specified in an emergency dealing determination and are not prohibited from being undertaken at the premises or facility by a condition of the determination; or

79 Section 192A (2), definition of *authorised GMO dealings*, paragraph (d)

after

are

insert

dealings

80 Dictionary, definition of consultative committee

omit

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81 Dictionary, definition of *deal with*

omit everything after paragraph (g), substitute

- (h) transport the GMO;
- (i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

Dictionary, new definition of *ethics and community* committee

insert

ethics and community committee means the gene technology ethics and community consultative committee established by the Commonwealth Act, section 106.

83 Dictionary, definition of ethics committee

omit

Dictionary, new definition of *inadvertent dealings* application

insert

inadvertent dealings application means an application for a GMO licence to which division 5.3 or division 5.4 does not apply because of the operation of section 46A or section 49.

85 Dictionary, definition of *institutional biosafety committee*

substitute

institutional biosafety committee means a committee established as an institutional biosafety committee in accordance with the guidelines issued by the regulator under section 98.

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Endnotes

1 Presentation speech

Presentation speech made in the Legislative Assembly on 6 December 2007.

2 Notification

Notified under the Legislation Act on 21 April 2008.

3 Republications of amended laws

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

I certify that the above is a true copy of the Gene Technology Amendment Bill 2008, which originated in the Legislative Assembly as the Gene Technology Amendment Bill 2007 and was passed by the Assembly on 8 April 2008.

Clerk of the Legislative Assembly

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