

House of Assembly

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South Australia

Gene Technology (Miscellaneous) Amendment Bill 2008

A BILL FOR

An Act to amend the *Gene Technology Act 2001*.

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The Parliament of South Australia enacts as follows:

Part 1—Preliminary

1—Short title

This Act may be cited as the *Gene Technology (Miscellaneous) Amendment Act 2008*.

2—Commencement

This Act will come into operation on a day to be fixed by proclamation.

3—Amendment provisions

In this Act, a provision under a heading referring to the amendment of a specified Act amends the Act so specified.

Part 2—Amendment of *Gene Technology Act 2001*

4—Amendment of section 8B—Notes

Section 8B—delete "do not"

5—Amendment of section 10—Definitions

- (1) Section 10(1), definition of *Consultative Committee*—delete the definition
- (2) Section 10(1)—after the definition of *containment level* insert:

corresponding Commonwealth emergency dealing determination, in relation to an emergency dealing determination under this Act, means a determination under section 72B of the Commonwealth Act that specifies the same kind of dealings as those proposed to be specified in, or specified in, the emergency dealing determination under this Act;
- (3) Section 10(1), definition of *deal with*—after paragraph (g) insert:
 - (h) transport the GMO;
 - (i) dispose of the GMO,
- (4) Section 10(1), definition of *deal with*—delete ", use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (g)" and substitute:

or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i)

- (5) Section 10(1)—after the definition of *eligible person* insert:

emergency dealing determination means a determination in force under section 72B;

- (6) Section 10(1), definition of *Ethics Committee*—delete the definition and substitute:

Ethics and Community Committee means the Gene Technology Ethics and Community Consultative Committee established by section 106 of the Commonwealth Act;

- (7) Section 10(1)—after the definition of *GM product* insert:

inadvertent dealings application means an application for a GMO licence to which Division 3 or 4 of Part 5 does not apply because of the operation of section 46A or 49;

- (8) Section 10(1), definition of *Institutional Biosafety Committee*—delete "by an accredited organisation as an Institutional Biosafety Committee" and substitute:

as an Institutional Biosafety Committee in accordance with written guidelines issued by the Regulator under section 98

- (9) Section 10—after subsection (2) insert:

Note—

This section differs from section 10 of the Commonwealth Act.

6—Amendment of section 31—Simplified outline

Section 31(b)—after subparagraph (i) insert:

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

7—Amendment of section 32—Person not to deal with a GMO without a licence

Section 32(1)—delete subsection (1) and substitute:

- (1) A person is guilty of 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 as to that fact; and
 - (c) the dealing with the GMO is not specified in an emergency dealing determination, and the person knows or is reckless as to that fact; and
 - (d) the dealing is not a notifiable low risk dealing, and the person knows or is reckless as to that fact; and
 - (e) the dealing is not an exempt dealing, and the person knows or is reckless as to that fact; and
 - (f) the dealing is not included on the GMO Register, and the person knows or is reckless as to that fact.

8—Amendment of section 33—Person not to deal with a GMO without a licence—strict liability offence

- (1) Section 33(1)—after paragraph (b) insert:
- (ba) the dealing with the GMO is not specified in an emergency dealing determination; and
- (2) Section 33(2)—after "(1)(b)," insert:
- (ba),

9—Amendment of section 34—Person must not breach conditions of a GMO licence

- (1) Section 34(1)—delete subsection (1) and substitute:
- (1) The holder of a GMO licence is guilty of 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 as to that fact.
- (2) Section 34(2)(b) and (c)—delete paragraphs (b) and (c) and 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 as to that fact.

10—Insertion of sections 35A and 35B

After section 35 insert:

35A—Person must not breach conditions of emergency dealing determination

- (1) A person is guilty of 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 as to that fact.
- (2) An offence under this section is punishable on conviction by whichever of the following applies:
- (a) in the case of an aggravated offence—imprisonment for a term not exceeding 5 years or a fine not exceeding \$220 000;
 - (b) in any other case—imprisonment for a term not exceeding 2 years or a fine not exceeding \$55 000.

Notes—

- 1 Section 38 defines *aggravated offence*.
- 2 This section differs from section 35A of the Commonwealth Act.

35B—Person must not breach conditions of emergency dealing determination—strict liability offence

- (1) A person is guilty of 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.
- (2) Strict liability applies to subsection (1)(a) and (c).
- (3) An offence under this section is punishable on conviction by a fine of not more than whichever of the following amounts applies:
 - (a) in the case of an aggravated offence—\$22 000;
 - (b) in any other case—\$5 500.

Notes—

- 1 Section 38 defines *aggravated offence*.
- 2 This section differs from section 35B of the Commonwealth Act.

11—Insertion of section 40A

After section 40 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 avoid doubt, subsection (1) does not prevent a person from making an application under section 40 in respect of a GMO that has inadvertently come into the person's possession.

Note—

Sections 46A and 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 section 40, or is taken to have been made under this section.

12—Amendment of section 42—Regulator may require applicant to give further information

Section 42—after subsection (2) 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—Amendment of section 43—Regulator must consider applications except in certain circumstances

- (1) Section 43(2)—after "consider the application" insert:

, or may cease considering the application,

- (2) Section 43(2)—after paragraph (e) insert:

or

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

14—Insertion of section 46A

After section 46 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.

15—Substitution of section 49

Section 49—delete section 49 and 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.

16—Amendment of section 50—Regulator must prepare risk assessment and risk management plan

- (1) Section 50(2)—delete subsection (2)
- (2) Section 50(3)—delete "The" and substitute:

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

17—Insertion of section 50A

After section 50 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 persons covered by the licence, to conduct experiments; and
 - (b) the application proposes, in relation to any GMO in respect of 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 referred to in section 50(3).
- (2) For the purposes of subsection (1)—

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

 - (a) specified 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.

- (3) For the purposes of subsection (1)—
- 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 persons who are to be permitted to conduct the dealings with the GMO.
- (4) In deciding whether the principal purpose of an application is to enable the licence holder, and persons 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 any other matter that the Regulator considers to be relevant.

Note—

This section differs from section 50A of the Commonwealth Act.

18—Amendment of section 51—Matters Regulator must take into account in preparing risk assessment and risk management plan

- (1) Section 51(1)(a)—delete "mentioned in section 49(2)(a) to (f)" and substitute:

prescribed by the regulations
- (2) Section 51(1)(b)—delete paragraph (b)
- (3) Section 51(2)(b)—delete paragraph (b)

19—Amendment of section 52—Public notification of risk assessment and risk management plan

- (1) Section 52(1)—delete "49 (if applicable),"
- (2) Section 52(2)—after paragraph (b) 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

- (3) Section 52(2)(d)—delete "than 30 days after the date on which the notice was published" and 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.

20—Amendment of section 56—Regulator must not issue the licence unless satisfied as to risk management

- (1) Section 56(2)(a) and (b)—delete paragraphs (a) and (b) and substitute:

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

- (2) Section 56—after subsection (2) insert:

Note—

Paragraphs (a), (b) and (c) of subsection (2) do not apply to an inadvertent dealings application.

21—Amendment of section 57—Other circumstances in which Regulator must not issue the licence

Section 57—after subsection (2) insert:

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

22—Amendment of section 60—Period of licence

Section 60—after subsection (2) 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.

23—Amendment of section 67—Protection of persons who give information

Section 67—delete "or 66" and substitute:

, 66 or 72D(2)(h)

24—Amendment of section 71—Variation of licence

- (1) Section 71(1)—delete subsection (1) and substitute:

- (1) The Regulator may vary a licence, by notice in writing 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) such information as is prescribed by the regulations (if any); and
 - (b) such information as is specified in writing by the Regulator.
- (2) Section 71(2)—delete "However, the" and substitute:
The
- (3) Section 71—after the note to subsection (2) 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 persons covered by the licence, to conduct experiments; and
 - (b) the application for variation proposes, in relation to any GMO in respect of 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 referred to 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 respect of the original application for the licence did not cover the risks posed by the dealings proposed to be authorised by the licence as varied.
- (4) Section 71(4)—delete "However, the Regulator must not vary the" and substitute:
The Regulator must not vary a
- (5) Section 71—after subsection (4) insert:
- (5) The Regulator must not vary a licence unless any local council that the Regulator considers appropriate has been consulted on the proposed variation.
 - (6) The Regulator must not vary a licence in the circumstances (if any) prescribed by the regulations.

- (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 the regulations.
- (8) For the purposes of subsection (2A)—
controls has the same meaning as in section 50A(2);
limits has the same meaning as in section 50A(3).

25—Amendment of section 72—Regulator to notify of proposed suspension, cancellation or variation

Section 72—after subsection (6) insert:

- (7) 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.

26—Redesignation of section 72A

Section 72A—redesignate the section as section 72AA

27—Insertion of Part 5A

After section 72AA insert:

Part 5A—Emergency dealing determinations

Division 1—Simplified outline

72A—Simplified outline

In outline, this Part provides a system under which the Minister can make determinations relating to dealings with GMOs in emergencies.

Note—

This section differs from section 72A of the Commonwealth Act.

Division 2—Making of emergency dealing determination

72B—Minister may make emergency dealing determination

- (1) The Minister may, by order published in the Gazette (an *emergency dealing determination*), specify dealings with a GMO for the purposes of this Part.
- (2) The Minister may make an emergency dealing determination only if the Minister administering section 72B of the Commonwealth Act has made, or is proposing to make, a corresponding Commonwealth emergency dealing determination.

Note—

Section 72B of the Commonwealth Act includes a subsection (3) dealing with threats of a kind mentioned in subsection (2) of that section.

- (3) The dealings in respect of which the Minister may make an emergency dealing determination may be—
- (a) all dealings with a GMO or with a specified class of GMOs;
or
 - (b) a specified class of dealings with a GMO or with a specified class of GMOs; or
 - (c) 1 or more specified dealings with a GMO or with a specified class of GMOs.

Note—

This section differs from section 72B of the Commonwealth Act.

72C—Period of effect of emergency dealing determination

- (1) An emergency dealing determination takes effect—
- (a) on the day on which the emergency dealing determination is made; or
 - (b) on a later day that is specified in the emergency dealing determination.
- (2) An emergency dealing determination ceases to have effect—
- (a) subject to subsection (3), at the end of the period of 6 months starting when the emergency dealing determination takes effect; or
 - (b) at the end of the period specified by the Minister in the emergency dealing determination; or
 - (c) when the emergency dealing determination is revoked,
- whichever occurs first.
- (3) The Minister may, by order published in the Gazette, extend the period of effect of an emergency dealing determination.
- (4) The Minister may extend the period of effect of an emergency dealing determination under subsection (3) more than once, but each single such extension must not exceed 6 months.
- (5) The Minister may extend the period of effect of an emergency dealing determination only if the Minister administering section 72C of the Commonwealth Act has under that section extended, or is proposing to extend under that section, the period of effect of the corresponding Commonwealth emergency dealing determination.
- (6) An order extending the period of effect of an emergency dealing determination takes effect at the time when the determination would have ceased to have effect but for the extension.

Note—

This section differs from section 72C of the Commonwealth Act.

Division 3—Effect and conditions of emergency dealing determination

72D—Emergency dealing determination authorises dealings, subject to conditions

- (1) If an emergency dealing determination is in force in respect of dealings with a GMO, those dealings are authorised, subject to the conditions (if any) specified in the emergency dealing determination.
- (2) Conditions may relate to, but are not limited to, the following:
 - (a) the quantity of GMO in relation to which dealings are covered;
 - (b) the scope of the dealings covered;
 - (c) the purposes for which the dealings may be undertaken;
 - (d) variations to the scope or purposes of the dealings;
 - (e) the source of the GMO;
 - (f) the persons who may deal with the GMO;
 - (g) the information that is required to be given by a person and the person to whom that information is to be given;
 - (h) obligations about informing the Regulator if—
 - (i) a person becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings specified in the emergency dealing determination; or
 - (ii) a person becomes aware of any contraventions of the conditions to which the emergency dealing determination is subject by any person; or
 - (iii) a person becomes aware of any unintended effects of the dealings specified in the emergency dealing determination;
 - (i) the storage and security of the GMO;
 - (j) the required level of containment in respect of the dealings, including requirements relating to the certification of facilities to specified containment levels;
 - (k) waste disposal requirements;
 - (l) the manner in which any quantity of the GMO is to be dealt with if a condition of the emergency dealing determination is breached;
 - (m) measures to manage risks posed to the health and safety of people, or to the environment;
 - (n) data collection, including studies to be conducted;

- (o) auditing and reporting;
 - (p) the keeping and disclosure of, and access to, records about the GMO;
 - (q) actions to be taken in case of the release of the GMO from a contained environment;
 - (r) the geographic area in which the dealings specified in the emergency dealing determination may occur;
 - (s) requirements for compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27;
 - (t) supervision by, and monitoring by, Institutional Biosafety Committees;
 - (u) contingency planning in respect of unintended effects of the dealings specified in the emergency dealing determination;
 - (v) limiting the dissemination or persistence of the GMO or its genetic material in the environment;
 - (w) any other matters that the Minister thinks appropriate.
- (3) A condition under subsection (2)(f) may permit dealings with a GMO by, or may impose obligations on—
- (a) a specified person or persons; or
 - (b) a specified class of person.
- (4) It is a condition of an emergency dealing determination that if—
- (a) a dealing with a GMO is specified in the emergency dealing determination; and
 - (b) a particular condition of the emergency dealing determination applies to the dealing by a person,
- the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.
- (5) Subsection (4) does not limit the conditions that may be specified in an emergency dealing determination.

Division 4—Variation, suspension and revocation of emergency dealing determination

72E—Variation, suspension and revocation of emergency dealing determination

- (1) The Minister may, by order published in the Gazette, vary the conditions to which an emergency dealing determination is subject, including by imposing new conditions, if the Minister administering section 72E of the Commonwealth Act has made, or is proposing to make, the same variation to the corresponding Commonwealth emergency dealing determination.
- (2) The Minister may, by order published in the Gazette, suspend or revoke an emergency dealing determination if the Minister administering section 72E of the Commonwealth Act has suspended or revoked, or is proposing to suspend or revoke, (as the case requires) the corresponding Commonwealth emergency dealing determination.

Note—

Section 72E of the Commonwealth Act includes a subsection (3) dealing with consultation with the States in relation to the variation, suspension or revocation of an emergency dealing determination.

- (3) A variation, suspension or revocation of an emergency dealing determination takes effect—
 - (a) if the Minister states in the variation, suspension or revocation that the variation, suspension or revocation is necessary to prevent imminent risk of death, serious illness, serious injury or serious environmental damage—on the day on which the variation, suspension or revocation is made; or
 - (b) in any other case—on the day specified by the Minister in the variation, suspension or revocation.
- (4) The day specified as mentioned in subsection (3)(b) must not be earlier than 30 days after the day on which the variation, suspension or revocation is made.

Note—

This section differs from section 72E of the Commonwealth Act.

28—Amendment of section 78—Regulator may include dealings with GMOs on GMO register

Section 78(3)—delete the second sentence

29—Amendment of section 82—Simplified outline

- (1) Section 82(a)—after "Licence conditions" insert:
, or conditions to which an emergency dealing determination is subject,

(2) Section 82(b)—after "Licence conditions" insert:

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

30—Amendment of section 83—Application for certification

Section 83(2), note—after "licence" insert:

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

31—Amendment of section 89—Regulator to notify of proposed suspension, cancellation or variation

Section 89—after subsection (6) insert:

- (7) 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.

32—Insertion of section 89A

After section 89 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) such information as is prescribed by the regulations (if any); and
 - (b) such information as is specified in writing by the Regulator.
- (3) The Regulator must not transfer the certification unless the Regulator is 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 specified 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.

33—Amendment of section 91—Application for accreditation

Section 91(1), note—delete the note and substitute:

Notes—

- 1 The conditions of a licence may require supervision of dealings by an Institutional Biosafety Committee (see section 62(2)(m)) and the regulations may require such supervision of notifiable low risk dealings (see section 75(2)(c)).

- 2 The conditions to which an emergency dealing determination is subject may require supervision of dealings by an Institutional Biosafety Committee (see section 72D(2)(t)).

34—Amendment of section 92—Regulator may accredit organisations

- (1) Section 92(2)(a)—delete ", or proposes to establish,"
- (2) Section 92(2)(b) and (c)—delete paragraphs (b) and (c) and 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 such guidelines; and
 - (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

35—Amendment of section 97—Regulator to notify of proposed suspension, cancellation or variation

Section 97—after subsection (6) insert:

- (7) 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.

36—Substitution of heading to Part 8

Heading to Part 8—delete the heading and substitute:

Part 8—The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee

37—Amendment of section 99—Simplified outline

Section 99—delete "Advisory's Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee" and substitute:

Advisory Committee and the Gene Technology Ethics and Community Consultative Committee

38—Amendment of heading to Part 8 Division 3

Heading to Part 8 Division 3—after "**Technology**" insert:

Ethics and

39—Amendment of section 106—The Gene Technology Ethics and Community Consultative Committee

Section 106, note—after "Technology" insert:

Ethics and

40—Substitution of section 107

Section 107—delete the section and substitute:

107—Function of Ethics and Community Committee

The function of the Ethics and Community Committee under this Act is to provide advice, on the 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 in respect of 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 in respect of the process for applications for licences covering dealings that involve the 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.

41—Amendment of section 108—Membership

Section 108, note—delete "Consultative Committee" and substitute:

Ethics and Community Committee

42—Amendment of section 109—Remuneration

Section 109, note—delete "Consultative Committee" and substitute:

Ethics and Community Committee

43—Amendment of section 110—Regulations

(1) Section 110, note—delete "operation" and substitute:

procedures

- (2) Section 110, note—delete "Consultative Committee" and substitute:

Ethics and Community Committee

44—Repeal of section 110A

Section 110A—delete the section

45—Repeal of heading

Part 8 Division 4, heading—delete the heading to Division 4

46—Substitution of sections 111 to 116

Sections 111 to 116 (inclusive)—delete the sections and substitute:

111—Subcommittees

Note—

Section 111 of the Commonwealth Act deals with the establishment of subcommittees by the Ethics and Community Committee.

112—Expert advisers

Note—

Section 112 of the Commonwealth Act provides for the appointment of expert advisers to the Ethics and Community Committee.

47—Amendment of section 136A—Quarterly reports

Section 136A(2)—after paragraph (b) 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;

48—Amendment of section 138—Record of GMO and GM Product Dealings

- (1) Section 138—after subsection (1) insert:

- (1A) The 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.

- (2) Section 138(5)—after "(1)," insert:

(1A),

49—Amendment of section 145—Simplified outline

- (1) Section 145(a)(ii)—after "environment" insert:
 - , or for certain other reasons
- (2) Section 145—after paragraph (a) insert:
 - (ab) enables 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 or the regulations; 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;

50—Amendment of section 146—Regulator may give directions

- (1) Section 146(1)(b)—delete paragraph (b) and 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 specified in subsection (2A), for the Regulator to exercise powers under this section,
- (2) Section 146(2)(a) and (b)—delete paragraphs (a) and (b) and substitute:
 - (a) 1 of the following kinds of persons is not complying with this Act or the regulations in respect of 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
 - (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 specified in subsection (2A), for the Regulator to exercise powers under this section,

(3) Section 146—after subsection (2) insert:

- (2A) For the purposes of deciding under subsection (1)(b)(ii) or (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 or the regulations 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 or the regulations at a future time;
 - (d) the severity of the suspected non-compliance;
 - (e) whether, on 1 or more occasions, the licence holder or the 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 non-compliance (including, but not limited to, by cancelling, varying or suspending a licence, accreditation or certification);
 - (g) whether, in the Regulator's opinion, the suspected non-compliance was deliberate;
 - (h) the desirability of deterring future non-compliance with this Act or the regulations.

51—Amendment of section 149—Simplified outline

Section 149(e)—after "licence" insert:

or an emergency dealing determination

52—Amendment of section 152—Powers available to inspectors for monitoring compliance

Section 152(2)—after paragraph (c) insert:

or

- (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.

53—Amendment of section 177—Part does not limit power to impose conditions

Section 177—after "conditions" insert:

or the Minister's power to impose conditions on an emergency dealing determination

54—Amendment of section 179—Meaning of terms

(1) Section 179—before item 1 in the table insert:

1A	To refuse to consider an application on the basis that the applicant is not a suitable person to hold a licence	section 43(2)(f)	the applicant
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(2) Section 179—after item 3 in the table insert:

3A	To refuse to transfer a licence	section 70	an applicant for the transfer
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(3) Section 179—after item 4 in the table insert:

4A	To refuse to vary a licence	section 71	the licence holder
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(4) Section 179—after item 7 in the table insert:

7A	To refuse to transfer a certification	section 89A	an applicant for the transfer
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55—Amendment of section 182—Deadlines for making reviewable decisions

(1) Section 182(a)—delete paragraph (a) and substitute:

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

(2) Section 182—delete "decision to reject the application" and substitute:

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

56—Amendment of section 185—Regulator may declare that information is confidential commercial information

Section 185—after subsection (3A) insert:

(3B) If—

(a) a person has made an application under section 184 for a declaration that specified 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.

57—Amendment of section 192A—Interference with dealings with GMOs

- (1) Section 192A(2), definition of *authorised GMO dealings*—after paragraph (a) insert:
 - (ab) 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
- (2) Section 192A(2), definition of *authorised GMO dealings*, (d)—after "are" insert:

dealings