2004-2005-2006-2007

The Parliament of the
Commonwealth of Australia

THE SENATE

Presented and read a first time

Gene Technology Amendment Bill 2007

No. , 2007

(Health and Ageing)

A Bill for an Act to amend the law relating to gene technology, and for related purposes

Contents

A Bill for an Act to amend the law relating to gene technology, and for related purposes

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Gene Technology Amendment Act 2007*.

2 Commencement

(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provision(s)	**Commencement**	**Date/Details**
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day on which this Act receives the Royal Assent.	
2. Part 1 of Schedule 1	The later of: (a) 1 July 2007; and (b) the day after the day on which this Act receives the Royal Assent.	
3. Part 2 of Schedule 1	A single day to be fixed by Proclamation. However, if any of the provision(s) do not commence before 1 January 2008, they commence on that day.	
4. Parts 3, 4, 5 and 6 of Schedule 1	At the same time as the provision(s) covered by table item 2.	
5. Schedule 2	At the same time as the provision(s) covered by table item 2.	

Note: This table relates only to the provisions of this Act as originally passed by both Houses of the Parliament and assented to. It will not be expanded to deal with provisions inserted in this Act after assent.

(2) Column 3 of the table contains additional information that is not part of this Act. Information in this column may be added to or edited in any published version of this Act.

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Gene Technology Act 2000

Part 1—Emergency dealing determinations

1 Subsection 10(1)

Insert:

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

2 Section 31

After:

> (a) the person undertaking the dealing is authorised to do so by a GMO licence; or

insert:

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

3 Subsection 32(1) (not including the note)

Repeal the subsection, 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.

4 After paragraph 33(1)(b)

Insert:

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

5 Subsection 33(2)

After "paragraphs (1)(b),", insert "(ba),".

6 Subsection 34(1) (not including the note)

Repeal the subsection, 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.

7 Paragraphs 34(2)(b) and (c) (not including the note)

Repeal the paragraphs, 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.

8 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.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(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 5 years or 2,000 penalty units;

(b) in any other case—imprisonment for 2 years or 500 penalty units.

Note: Section 38 defines ***aggravated offence***.

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.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) Strict liability applies to paragraphs (1)(a) and (c).

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(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—200 penalty units;

(b) in any other case—50 penalty units.

Note: Section 38 defines ***aggravated offence***.

9 Section 67

Omit "or 66", substitute ", 66 or paragraph 72D(2)(h)".

10 After Part 5

Insert:

Part 5A—Emergency dealing determinations

Division 1—Simplified outline

72A Simplified outline

The following is a simplified outline of this Part:

> This Part provides a system under which the Minister can make determinations relating to dealings with GMOs in emergencies.

Division 2—Making of emergency dealing determination

72B Minister may make emergency dealing determination

(1) The Minister may, by legislative instrument (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:

(a) the Minister has received advice from:

(i) the Commonwealth Chief Medical Officer; or

(ii) the Commonwealth Chief Veterinary Officer; or

(iii) the Commonwealth Chief Plant Protection Officer; or

(iv) a person prescribed by the regulations;

that there is an actual or imminent threat to the health and safety of people or to the environment, and that the dealings proposed to be specified in the emergency dealing determination would, or would be likely to, adequately address the threat; and

(b) the Minister is satisfied that there is an actual or imminent threat to the health and safety of people or to the environment, and that the dealings proposed to be specified in the emergency dealing determination would, or would be likely to, adequately address the threat; and

(c) the Minister has received advice from the Regulator that any risks posed by the dealings proposed to be specified in the

emergency dealing determination are able to be managed in such a way as:

(i) to protect the health and safety of people; and

(ii) to protect the environment; and

(d) the Minister is satisfied that any risks posed by the dealings proposed to be specified in the emergency dealing determination are able to be managed in such a way as:

(i) to protect the health and safety of people; and

(ii) to protect the environment; and

(e) the States have been consulted in relation to the making of the proposed emergency dealing determination.

(3) An actual or imminent threat of a kind mentioned in paragraph (2)(a) or (b) may include, but is not limited to, any of the following:

(a) a threat from the outbreak of a plant, animal or human disease;

(b) a threat from a particular plant or animal, such as a pest or an alien invasive species;

(c) a threat from an industrial spillage.

(4) 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) one or more specified dealings with a GMO or with a specified class of GMOs.

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 legislative instrument, 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:

(a) the Minister has received advice from the original adviser in relation to the emergency dealing determination that the threat to which the determination relates still exists, and that the proposed extension would, or would be likely to, adequately address the threat; and

(b) the Minister is satisfied that the threat still exists, and that the proposed extension would, or would be likely to, adequately address that threat; and

(c) the Minister has received advice from the Regulator that any risks posed by the proposed extension are able to be managed in such a way as:

(i) to protect the health and safety of people; and

(ii) to protect the environment; and

(d) the Minister is satisfied that any risks posed by the proposed extension are able to be managed in such a way as:

(i) to protect the health and safety of people; and

(ii) to protect the environment; and

(e) a majority of jurisdictions agree to the extension.

(6) A legislative instrument 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.

(7) In subsection (5):

original adviser, in relation to an emergency dealing determination, means the person who gave the advice mentioned in paragraph 72B(2)(a) in relation to the determination.

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 a 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 paragraph (2)(f) may permit dealings with a GMO by, or may impose obligations upon:
(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 legislative instrument, vary the conditions to which an emergency dealing determination is subject, including by imposing new conditions.

(2) The Minister may, by legislative instrument, suspend or revoke an emergency dealing determination if:

(a) the Minister becomes aware of risks to the health and safety of people, or to the environment, associated with the continuation of the dealings authorised by the emergency dealing determination, and is satisfied that adequate measures to address those risks are not able to be implemented; or

(b) the Minister is satisfied that the threat to which the emergency dealing determination relates:

(i) no longer exists; or

(ii) is no longer sufficiently actual or imminent as to require the determination to be in force to address that threat; or

(c) the Minister is no longer satisfied that the dealings specified in the emergency dealing determination adequately address the threat.

(3) The Minister must not:

(a) vary an emergency dealing determination (unless the variation is of a minor technical nature); or

(b) suspend or revoke an emergency dealing determination;

unless the States have been consulted in relation to the variation, suspension or revocation, as the case requires.

(4) 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.

(5) The day specified as mentioned in paragraph (4)(b) must not be earlier than 30 days after the day on which the variation, suspension or revocation is made.

11 Section 82 (first paragraph of the simplified outline)

After "Licence conditions", insert ", or conditions to which an emergency dealing determination is subject,".

12 Section 82 (second paragraph of the simplified outline)

After "Licence conditions", insert ", or conditions to which an emergency dealing determination is subject,".

13 Subsection 83(2) (note)

After "conditions of a licence", insert ", or conditions to which an emergency dealing determination is subject,".

14 Subsection 91(1) (note)

Repeal the note, substitute:

Note 1: The conditions of a licence may require supervision of dealings by an Institutional Biosafety Committee established by an accredited organisation (see paragraph 62(2)(m)), and the regulations may require such supervision of notifiable low risk dealings (see paragraph 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 established by an accredited organisation (see paragraph 72D(2)(t)).

15 After paragraph 136A(2)(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;

16 After subsection 138(3)

Insert:

(3A) 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.

17 Section 145

Before:

> The Part also empowers the Federal Court to issue injunctions, and contains a forfeiture provision.

insert:

> This Part enables the Regulator to give directions to a person permitted by an emergency dealing determination to deal with a GMO, if:
>
> (a) the Regulator believes that the person is not complying with this Act or the regulations; and
>
> (b) 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.

18 Paragraph 146(2)(a)

Repeal the paragraph, substitute:

(a) one 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

19 Section 149 (fifth paragraph of the simplified outline)

After "a licence", insert "or an emergency dealing determination".

20 At the end of subsection 152(2)

Add:

; 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.

21 Section 177

After "licence conditions", insert "or the Minister's power to impose conditions on an emergency dealing determination".

Note: The heading to section 177 is altered by omitting "licence".

22 Subsection 192A(2) (after paragraph (a) of the definition of *authorised GMO dealings*)

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

23 Subsection 192A(2) (paragraph (d) of the definition of *authorised GMO dealings*)

Omit "deregulated GMO dealings", substitute "dealings included on the GMO Register".

Part 2—Creation of Gene Technology Ethics and Community Consultative Committee

24 Subsection 10(1) (definition of *Consultative Committee*)

Repeal the definition.

25 Subsection 10(1)

Insert:

> ***Ethics and Community Committee*** means the Gene Technology Ethics and Community Consultative Committee established by section 106.

26 Subsection 10(1) (definition of *Ethics Committee*)

Repeal the definition.

27 Paragraphs 17(1)(c) and (d)

Repeal the paragraphs, substitute:

(c) the Ethics and Community Committee;

28 Paragraphs 22(1)(c) and (d)

Repeal the paragraphs, substitute:

(c) the Ethics and Community Committee;

29 Paragraphs 24(2)(b) and (c)

Repeal the paragraphs, substitute:

(b) the Ethics and Community Committee;

30 Part 8 (heading)

Repeal the heading, substitute:

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

31 Section 99 (first paragraph of the simplified outline)

Omit ", the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee", substitute "and the Gene Technology Ethics and Community Consultative Committee".

32 Subsection 100(5)

Omit "subsection (6)", substitute "subsections (6) and (7A)".

33 Subsection 100(7A)

Repeal the subsection, substitute:

(7A) The Minister must ensure that the Committee includes at least one person who is a member of the Ethics and Community Committee. The Minister is not required to be satisfied that this person has skills or experience in an area mentioned in subsection (5).

34 Divisions 3 and 4 of Part 8

Repeal the Divisions, substitute:

Division 3—The Gene Technology Ethics and Community Consultative Committee

106 The Gene Technology Ethics and Community Consultative Committee

The Gene Technology Ethics and Community Consultative Committee (the ***Ethics and Community Committee***) is established.

107 Function of Ethics and Community Committee

The function of the Ethics and Community Committee 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.

108 Membership

(1) The Minister is to appoint up to 12 members of the Ethics and Community Committee, and must appoint one of the members to chair the Ethics and Community Committee.

(2) Before appointing a member of the Ethics and Community Committee, the Minister must consult the following:
(a) the States;
(b) the Regulator;
(c) such scientific, consumer, health, environmental and industry groups as the Minister considers appropriate;
(d) such other Ministers as the Minister considers appropriate.

(3) The Minister must not appoint a person as a member of the Ethics and Community Committee (other than as a member mentioned in subsection (4)) unless the Minister is satisfied that the person has skills or experience of relevance to gene technology in relation to one or more of the following:
(a) community consultation;

(b) risk communication;
(c) the impact of gene technology on the community;
(d) issues relevant to businesses developing or using biotechnology;
(e) issues relevant to gene technology research;
(f) issues relevant to local government;
(g) issues of concern to consumers;
(h) law;
(i) religious practices;
(j) human health;
(k) animal health and welfare;
(l) primary production;
(m) ethics;
(n) environmental issues;
(o) issues specified by the regulations for the purposes of this paragraph.

(4) The Minister must ensure that the Ethics and Community Committee includes the following members:
(a) a person who is a member of the Gene Technology Technical Advisory Committee;
(b) a person who is a member of the Australian Health Ethics Committee.

(5) The members of the Ethics and Community Committee hold office on a part-time basis.

(6) The Minister must not appoint a member to chair the Ethics and Community Committee unless a majority of jurisdictions agree to the appointment.

109 Remuneration

(1) A person who is a member of the Ethics and Community Committee or an expert adviser is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed by the regulations.

(2) A person who is a member of the Ethics and Community Committee or an expert adviser is to be paid the allowances that are prescribed by the regulations.

(3) This section has effect subject to the *Remuneration Tribunal Act 1973*.

110 Membership and Procedures

(1) The regulations may prescribe matters relating to the members of the Ethics and Community Committee, including, but not limited to, the following:

(a) term of appointment;

(b) resignation;

(c) disclosure of interests;

(d) termination of appointment;

(e) leave of absence.

(2) The regulations may prescribe matters relating to the operation of the Ethics and Community Committee, including, but not limited to, the following:

(a) procedures for convening meetings of the Ethics and Community Committee;

(b) the constitution of a quorum for a meeting of the Ethics and Community Committee;

(c) the way in which matters are to be resolved by the Ethics and Community Committee;

(d) Ethics and Community Committee records;

(e) reporting requirements, including, but not limited to, reports to the Regulator and to the public.

(3) If no regulations are in force under subsection (2), the Ethics and Community Committee must operate in the way determined in writing by the Regulator.

(4) If no regulations are in force under subsection (2) and no determination is in force under subsection (3), the Ethics and Community Committee may operate in the way determined in writing by the Ethics and Community Committee.

(5) A determination made under subsection (3) or (4) is not a legislative instrument.

111 Subcommittees

(1) The Ethics and Community Committee may, with the Regulator's consent, establish subcommittees to assist in the performance of its functions.

(2) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

112 Expert advisers

(1) The Minister may appoint one or more persons (***expert advisers***) to give expert advice to the Ethics and Community Committee to assist it in the performance of its functions. Expert advisers may be appointed on a continuing or an ad hoc basis.

(2) Expert advisers are not members of the Ethics and Community Committee.

35 Transitional provision

(1) This item applies if functions are conferred by a corresponding State law upon the Ethics Committee or the Consultative Committee.

(2) Despite the repeals and amendments made by this Part:

(a) the Ethics Committee and the Consultative Committee that were in existence immediately before the commencement of this item:

(i) continue in existence after the commencement of this item; and

(ii) the members of the Ethics and Community Committee are taken to constitute the Ethics Committee and the Consultative Committee, respectively; and

(b) if, after the commencement of this item, the Ethics and Community Committee performs a function corresponding to a function conferred on the Ethics Committee or the Consultative Committee by a corresponding State law, the Ethics Committee or the Consultative Committee, as continued in existence by this item, is taken to have performed the function.

(3) Despite the repeals and amendments made by this Part, the authority:

(a) given by section 17 of the *Gene Technology Act 2000* (as in force immediately before the commencement of this item); and

(b) that permits a corresponding State law to confer functions, powers and duties on the Ethics Committee or the Consultative Committee;

continues in effect as if those repeals and amendments had not happened.

(4) In this item:

Consultative Committee has the meaning given by the *Gene Technology Act 2000*, as in force immediately before the commencement of this item.

Ethics Committee has the meaning given by the *Gene Technology Act 2000*, as in force immediately before the commencement of this item.

Part 3—Assessment of applications: limited and controlled release and consultation on significant risk

36 Section 49

Repeal the section.

37 Subsection 50(2)

Repeal the subsection.

38 Subsection 50(3)

Omit "The", substitute "Unless section 50A applies in relation to the application for the licence, the"

39 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 subsection 50(3).

(2) For the purposes of subsection (1):

controls, in relation to a GMO and its genetic material, include the following:

(a) methods to restrict the dissemination or persistence of the GMO or its genetic material in the environment;
(b) methods for disposal of the GMO or its genetic material;
(c) data collection, including studies to be conducted about the GMO or its genetic material;
(d) the geographic area in which the proposed dealings with the GMO or its genetic material may occur;
(e) 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.

40 Paragraph 51(1)(a)

Omit "mentioned in paragraphs 49(2)(a) to (f)", substitute "prescribed by the regulations".

41 Paragraph 51(1)(b)

Repeal the paragraph.

42 Paragraph 51(2)(b)

Repeal the paragraph.

43 Subsection 52(1)

Omit "49 (if applicable),".

44 After paragraph 52(2)(b)

Insert:

(ba) if the Regulator is satisfied that one 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

45 Paragraph 52(2)(d)

Omit all the words 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.

Part 4—Provisions relating to variation

46 Subsection 71(1)

Repeal the subsection, 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.

47 Subsection 71(2)

Omit "However, the", substitute "The".

48 After subsection 71(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 subsection 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.

49 Subsection 71(4)

Omit "However, the Regulator must not vary the", substitute "The Regulator must not vary a".

50 At the end of section 71

Add:

(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 subsection 50A(2).

limits has the same meaning as in subsection 50A(3).

51 Section 179 (after table item 4)

Insert:

4A	To refuse to vary a licence	section 71	the licence holder

Part 5—Regulator's power to direct

52 Section 145 (at the end of paragraph (b) of the first paragraph of the simplified outline)

Add ", or for certain other reasons".

53 Paragraphs 146(1)(b) and 146(2)(b)

Repeal the paragraphs, 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;

54 After subsection 146(2)

Insert:

(2A) For the purposes of deciding under subparagraph (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 one 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.

Part 6—Inadvertent dealings

55 Subsection 10(1)

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.

56 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.

57 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.

58 After section 48

Insert:

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.

59 At the end of section 56

Add:

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

60 At the end of section 57

Add:

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

61 At the end of section 60

Add:

(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.

Schedule 2—Technical amendments

Gene Technology Act 2000

1 Subsection 10(1) (after paragraph (g) of the definition of *deal with)*

Insert:

(h) transport the GMO;

(i) dispose of the GMO;

2 Subsection 10(1) (definition of *deal with*)

Omit all the words after "possession,", substitute "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)".

3 Subsection 10(1) (definition of *Institutional Biosafety Committee*)

Omit all the words after "established", substitute "as an Institutional Biosafety Committee in accordance with written guidelines issued by the Regulator under section 98".

4 At the end of section 42

Add:

(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.

5 Subsection 43(2)

After "application" (first occurring), insert ", or may cease considering the application,".

6 At the end of subsection 43(2)

Add:

; 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.

7 Paragraphs 56(2)(a) and (b)

Repeal the paragraphs, 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;

8 At the end of section 72

Add:

(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.

9 Subsection 78(3)

Omit all the words after "specified in the determination".

10 At the end of section 89

Add:

(7) This section does not apply to a variation of a certification if the Regulator is satisfied that the variation is of minor significance or complexity.

11 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.

12 Paragraph 92(2)(a)

Omit ", or proposes to establish,".

13 Paragraph 92(2)(b)

Omit "whether the organisation will be able to maintain an", substitute "if the organisation has established an Institutional Biosafety Committee—whether the organisation will be able to maintain the".

14 Paragraphs 92(2)(c)

Omit "whether the organisation has, or will have,", substitute "if the organisation has established an Institutional Biosafety Committee—whether the organisation has".

15 After paragraph 92(2)(c)

Insert:

(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

16 At the end of section 97

Add:

(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.

17 Section 179 (before table item 1)

Insert:

1A	To refuse to consider an application on the basis that the applicant is not a suitable person to hold a licence	paragraph 43(2)(f)	the applicant

18 Section 179 (after table item 3)

Insert:

3A	To refuse to transfer a licence	section 70	an applicant for the transfer

19 Section 179 (after table item 7)

Insert:

7A	To refuse to transfer a certification	section 89A	an applicant for the transfer

20 Paragraph 182(a)

Repeal the paragraph, substitute:

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

21 Section 182

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

22 After subsection 185(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.