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**THE LEGISLATIVE ASSEMBLY FOR THE**

**AUSTRALIAN CAPITAL TERRITORY**

# GENE TECHNOLOGY LEGISLATION AMENDMENT BILL 2007

# EXPLANATORY STATEMENT

**Presented by**
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**Health Minister**

Gene Technology Legislation Amendment Bill 2007

# EXPLANATORY STATEMENT

## OVERVIEW

The purpose of this Bill is to amend the *Gene Technology Act 2003* (the Act) in order to improve its operation without changing the underlying policy intent or overall legislative framework of the regulatory scheme.

The Act is the ACT Government's component of the nationally consistent regulatory scheme for gene technology. Under the Gene Technology Agreement 2001, all States and Territories have committed to maintaining corresponding legislation. The object of the Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

## BACKGROUND

In 2005-06, an independent review of the Act and the intergovernmental Gene Technology Agreement 2001 (the Review) was conducted. The Review found that the Act and the national regulatory scheme had worked well in the five years following introduction, and that no major changes were required. However, it suggested a number of minor changes, aimed at improving the operation of the Act at the margin.

On 27 October 2006, the Gene Technology Ministerial Council (GTMC), an intergovernmental body comprised of State, Territory and Australian Government Ministers, agreed to proposals to implement the recommendations of the Review. This Bill proposes to implement the recommendations requiring legislative change.

# NOTES ON CLAUSES

## PART 1 PRELIMINARY

**Clause 1: Name of Act**
Clause 1 provides that the Act may be cited as the *Gene Technology Amendment Act 2007*. This is a formal provision that sets out the name (also called the short title) of the Proposed Act.

**Clause 2: Commencement**
Clause 2 provides that the Act will take effect on a day fixed by the Minister by written notice.

## PART 2 GENE TECHNOLOGY ACT 2003

**Clause 3: Legislation amended-pt 2**
Clause 3 provides that each Act specified in a Schedule to the Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule, has effect according to its terms. This part amends the *Gene Technology Act 2003*.

**Clause 4: Simplified outline-pt 4**
Clause 4 would insert a new paragraph 31(b)(ia) into the simplified outline at the beginning of Part 4 of the Act. The proposed new paragraph makes clear that `a dealing specified in an emergency dealing determination' is not prohibited under the Part.

**Clause 5: Substitute Section 32**
Clause 5 would repeal the existing subsection 32 and substitute a new subsection 32 into the Act. The new subsection would provide that a person commits an offence if he or she deals with a GMO, knowing that it is a GMO and without a licence authorising the dealing, unless the dealing is specified in an emergency dealing determination, it is a notifiable low risk dealing, it has been specifically exempted from the application of the legislation under the Regulations, or it has been placed on the GMO register. The person must either have known, or have been reckless about all of these things to have committed an offence.

The new subsection 32 is substantially the same as the existing subsection 32 except that it inserts an additional paragraph providing that the dealing with the GMO must not be specified in an emergency dealing determination, and the person must know or be reckless as to this fact for an offence to be committed. In addition, the subsection has been redrafted to clarify that an offence is only committed if the dealing with the GMO is not authorised by a licence.

The penalties throughout the proposed amending legislation are in the form that are consistent with the existing ACT *Gene Technology Act 2003*.

**Clauses 6 and 7: New Section 33(1)(ba)**
Clauses 6 and 7 would insert a new paragraph 33(1)(ba) into the Act and insert a reference to the new paragraph 33(1)(ba) into subsection 33(2) of the Act. These amendments would make clear that a person will commit a strict liability offence under subsection 33(1) of the Act if the person deals with a GMO, knowing that it is a GMO, the dealing is not authorised by a licence, it is not specified in an emergency dealing determination, it is not a notifiable low risk dealing, it has not been specifically exempted from the application of the legislation under the Regulations, and it is not on the GMO register. The application of strict liability to this offence is considered appropriate because any dealings with a GMO conducted in an unauthorised or unregulated manner could cause serious harm to the health and safety of people and the environment.

**Clause 8: Substitute Section 34(1)**
Clause 8 would repeal the existing subsection 34(1) and substitute a new subsection 34(1). The subsection has been redrafted to clarify that in order to commit an offence a person's actions must contravene a licence and the person must know or be reckless as to that fact.

**Clause 9: Substitute Section 34(2)(b) and (c)**
Clause 9 would repeal the existing paragraphs 34(2)(b) and (c) and substitute new paragraphs 34(2)(b) and (c). The paragraphs have been redrafted to clarify that in order to commit an offence a person's actions must contravene the conditions of a licence and the person must know or be reckless as to that fact.

**Clause 10: New Sections 35A and 35B**
Clause 10 would insert two new offence provisions into the Act:

Section 35A: the proposed new section 35A is similar to existing section 34 of the Act. Proposed subsection 35A creates an offence for intentionally breaching the conditions of an emergency dealing determination. Proposed paragraph 35A(a) provides that the penalty for an aggravated offence is 5 years imprisonment or 2,000 penalty units. Proposed paragraph 35A(b) provides that if it is not an aggravated offence the penalty will be 2 years imprisonment or 500 penalty units. These penalties are consistent with those contained in section 34.

Section 35B: the proposed new section 35B creates a strict liability offence for breaching the conditions of an emergency dealing determination. It is similar to the existing section 35 of the Act. In order to have committed an offence under proposed new subsection 35B(1), the person must have knowledge of the conditions to which the emergency dealing determination is subject, but need not know that he or she is breaching that condition. Proposed paragraph 35B(1)(a) provides that the penalty for an aggravated offence is 200 penalty units. Proposed paragraph 35B(1)(b) provides that if it is not an aggravated offence the penalty is 50 penalty units. These penalties are consistent with those contained in section 35. Proposed subsection 35B(2) provides that strict liability applies to paragraphs 35B(1).

**Clause 11: New Section 40A**
Clause 11 proposes to insert a new section 40A into the Act. This would provide for a new category of licence: licences relating to inadvertent dealings.

Subsection 40A(1): the proposed new subsection 40A(1) provides that a person does not need to apply for a licence in respect of inadvertent dealings with GMO. The Regulator may treat a person as having applied for a GMO licence without having received an application, as long as that person agrees. This recognises that a person who inadvertently deals with GMOs may not be aware of the legislative framework for GMOs, and hence may not be equipped to apply for a licence under the Act.

Subsection 40A(2): the proposed new subsection 40A(2) makes clear that a person may also apply for a licence under section 40 of the Act in respect of an inadvertent dealing.

**Clause 12: New Section 42(3)**
Clause 4 would add a new subsection 42(3) to the Act with the intention of removing any doubt as to when the Regulator may request further information in respect of an application. It would provide that the Regulator may request further information at any time before the application is decided, whether before or after the Regulator has begun to consider the application.

**Clause 13: Omit "application if-" and substitute "application, or may cease considering the application, if-" in Section 43(2)**
Clause 13 would amend subsection 43(2) of the Act with the intention of expressly allowing the Regulator to cease (as well as to not commence) the consideration of an application if one of the ensuing paragraphs applies to the application.

**Clause 14: New Section 43(2)(f)**
Clause 14 would insert a new paragraph 43(2)(f) into the Act providing that where the Regulator is satisfied that an applicant is not a suitable person to hold a licence (having regard to the matters listed in section 58 of the Act such as whether the applicant has any relevant convictions or licence revocations, and the capacity of the person to meet the conditions of the licence) then the Regulator is not required to consider the application.

**Clauses 15 and 16: New Section 46A and substitute Section 49**
Clauses 15 and 16 would insert new sections 46A and 49 into the Act. These sections would make clear that if:

- the Regulator is satisfied that the licence applied for will only authorise the disposal of the GMO; and
- the Regulator is satisfied that the applicant has come into the possession of the GMO inadvertently;

the normal processes for the initial consideration of licences, which are set out in Divisions 3 and 4 of Part 5 of the Act, will not apply.

An example of a situation in which the new sections 46A and 49 could apply is where a particular GMO has been licensed for use in a certain restricted area and remnants of the GMO become lodged in transporting or handling equipment. In this situation, the GMO crop could conceivably become mixed with non-genetically modified seeds. Thus, a farmer could purchase what he or she believes to be non-genetically modified seeds but subsequently discover GMOs growing amongst his or her crop. A farmer in this situation could apply to the Regulator under section 40 for a licence to dispose of the GMO. If the Regulator was satisfied that the farmer had come into possession of the GMO inadvertently, and the licence sought was only for the purposes of disposal of the GMO, then sections 46A and 49 would apply, meaning that the Regulator could issue a licence for disposal without having to observe the usual process for the initial consideration of licences.

**Clause 17: Omit Section 50(2)**
Clause 17 would make a consequential amendment to the Act by repealing subsection 50(2) which relates to actions required by section 49, which has been substituted.

**Clause 18: Omit "The" in Section 50(3) and substitute "Unless section 50A applies in relation to the application for the licence, the"**
Clause 18 would amend subsection 50(3) of the Act to make clear that if an application is a limited and controlled release application, the Regulator does not need to seek advice from the States (including the Australian Capital Territory and the Northern Territory), the Gene Technology Advisory Committee, prescribed agencies, the Environment Minister, or local councils on the preparation of an RARMP.

**Clause 19: Insert new Section 50A**
Clause 19 would insert a new section 50A into the Act. This section would create a new category of licence application, to be known as `limited and controlled release' applications.

Subsection 50A(1): the proposed subsection 50A(1) provides that the new section 50A will apply if the Regulator is satisfied of three things: firstly, that the principal purpose of the licence sought is to enable experiments to be conducted; secondly, that the release of the GMO under the licence would be limited and that controls would be in place to limit the dissemination of the organism; and thirdly, that it is appropriate for section 50(3) of the Act not to apply to the licence.

Subsection 50A(2): the proposed subsection 50A(2) provides that in determining whether the principal purpose of the licence is to conduct experiments (or, in other words, in determining whether subsection 50A(1) applies to a licence), the Regulator must have regard to whether the applicant proposes to test hypotheses; to gain scientific or technical knowledge; or to gain data for regulatory purposes or for product development or marketing. An undertaking to conduct any of these forms of research would help establish that a licence is for the purposes of conducting experiments. However, the Regulator still needs to consider whether conducting experiments is the principal purpose of the licence. Paragraph 50A(2)(b) makes clear that the Regulator may also consider any other matters that he or she considers to be relevant.

Subsection 50A(3): the proposed subsection 50A(3) gives guidance on the meaning of the terms `controls' and ‘limits’ in subsection 50A(1).

It provides that controls can relate to the dissemination and persistence of the GMO, the disposal of the GMO, the studies that can be conducted on the GMO, the geographic area in which dealings may be conducted, and compliance with a code of practice or a technical and procedural guideline.

It provides that limits can include limits on the scope, scale, location and duration of dealings with a GMO, as well as the persons who are permitted to conduct dealings with the GMO.

The amendments in Clauses 18 and 19 recognise that an application for a release of a GMO for the purposes of obtaining experimental data will generally be limited in terms of time, spatial scale and location and have containment measures to restrict dissemination. In contrast, applicants wishing to intentionally release a GMO may wish to produce that GMO commercially and will generally seek a licence with as few restrictions as possible. Hence, licences for intentional release would need to undergo a more rigorous risk assessment process than licences for a limited and controlled release.

**Clause 20: Omit everything after “matters” in Section 51(1)(a) and substitute “prescribed by regulation;”**
Clause 20 would make a consequential amendment to the Act by omitting reference to Section 49 in subsection 51(1)(a).

**Clauses 21 and 22: Omit Sections 51(1)(b) and 51(2)(b)**
Clauses 21 and 22 would make consequential amendments to the Act by omitting reference to Section 49 in paragraphs 51(1)(b) and 51(2)(b) which relate to actions required by section 49.

**Clauses 23: Omit Section 52(1)**
Clause 23 would make a consequential amendment to the Act by omitting the reference to section 49 in subsection 52(1).

**Clauses 24: Insert new Section 52(2)(ba)**
Clause would insert a new paragraph (ba) into subsection 52(2) of the Act. The new paragraph would provide that if the Regulator is satisfied that dealings with a GMO pose a significant risk, then the Regulator should make a statement to that effect in the notice published under subsection 52(1). Thus, under this paragraph, the Regulator is required to assess whether there is a significant risk after the RARMP has been developed under section 50, but before he or she has consulted on it under section 52(3).

**Clauses 25: Insert new Section 52(2)(ba)**
Clause 25 would insert a new paragraph (ba) into subsection 52(2) of the Act. The new paragraph would provide that if the Regulator is satisfied that dealings with a GMO pose a significant risk, then the Regulator should make a statement to that effect in the notice published under subsection 52(1). Thus, under this paragraph, the Regulator is required to assess whether there is a significant risk after the RARMP has been developed under section 50, but before he or she has consulted on it under section 52(3).

**Clause 26: Substitute Sections 56(2)(a) and (b)**
This clause would provide that, for the purposes of being satisfied that any risks posed by the dealings proposed to be licensed are able to be managed in such a way as to protect the health and safety of people and the environment, the Regulator is required to have regard to:

- under new paragraph 56(2)(a), the risk assessments prepared under section 47, for dealings not involving intentional release, or prepared under section 50, for dealings involving intentional release; and
- under new paragraph 56(2)(b), the risk management plans prepared under section 47, for dealings not involving intentional release, or prepared under section 50 for dealings involving intentional release.

**Clause 27: Insert new note in Section 56(2)**
Clause 27 would add a note to section 56 of the Act. The note makes clear that paragraphs 56(2)(a) to (c), which relate to risk assessment and risk management plans, do not apply to inadvertent dealings applications.

**Clause 28: New Section 57(3)**
Clause 28 would insert a new subsection 57(3) into the Act. The new subsection would make clear that subsection 57(2), which requires the Regulator to be satisfied that an applicant is a suitable person before issuing a licence, does not apply to inadvertent dealings applications. This means that section 58 of the Act, which expands upon subsection 57(2), also does not apply.

**Clause 29: New Section 60(3)**
Clause 29 would insert a new subsection 60(3) into the Act. This subsection would provide that a licence issued for an inadvertent dealing cannot be valid for a period of longer than 12 months. This is a maximum time period and the Regulator may specify a shorter time period where appropriate. In determining the relevant time period, the Regulator should bear in mind that a licence for an inadvertent dealing will only be issued for the purposes of disposal of the GMO.

**Clause 30: Omit "or section 66" in Section 67 and substitute ",section 66 or section 72D(2)(h)**
Clause 30 would alter the wording of section 67, to make clear that the section applies to protect persons who provide information under the new paragraph 72D(1)(h) from certain civil liabilities.

**Clause 31: Substitute Section 71(1)**
Clause 31 would repeal the existing subsection 71(1) and insert a revised subsection 71(1) and a new subsection 71(1A) into the Act. The proposed new subsection 71(1) clarifies that the Regulator has the power to vary a licence either unilaterally, or after receiving an application from a licence-holder. The proposed new subsection 71(1A) provides that the licence holder's application must be in writing and include any information prescribed by the Regulations or required by the Regulator in writing.

**Clause 32: Omit "However, the" in Section 71(2) and substitute "The"**
Clause 32 would make a consequential amendment to subsection 71(2) of the Act.

**Clause 33: Insert new Section 71(2A) and 71(2B)**
Clause 33 would insert new subsections 71(2A) and 71(2B) into the Act. These subsections describe circumstances in which the Regulator is not permitted to vary a licence.

Subsection 71(2A): the proposed new subsection 71(2A) provides that the Regulator must not vary a licence if the original application was for a limited and controlled release unless the licence as varied is also for a limited and controlled release. In other words, the object of this section is to prevent a variation turning a licence for a limited and controlled release into a licence permitting intentional release of a GMO into the environment.

Subsection 71(2B): the proposed new subsection 71(2B) provides that the Regulator must not vary a licence if the licence, as varied, would pose new risks which were not covered in the original risk assessment and risk management plans.

**Clause 34: Omit "However, the regulator must not vary the" and substitute "The regulator must not vary a" in Section 71(4)**
Clause 34 would make a consequential amendment to subsection 71(4) of the Act.

**Clause 35: Insert new Sections 71(5) to 71(8)**
Clause 35 would insert four new subsections into the Act.

Subsection 71(5): the proposed new subsection 71(5) provides that the Regulator must consult with any appropriate local council before varying a licence.

Subsection 71(6): the proposed new subsection 71(6) provides that the Regulations may impose additional limitations on the Regulator's power to vary the licence.

Subsection 71(7): the proposed new subsection 71(7) provides that the Regulations may set a time limit in which the Regulator must vary a licence.

Subsection 71(8): the proposed new subsection 71(8) makes clear that the terms `controls' and `limits' have the same meaning in subsection 71(2A) as in the proposed section 50A of the Act.

**Clause 36: Insert new Section 72(8)**
Clause 36 would add a new subsection 72(8) which provides that section 72 of the Act, which includes, among other things, requirements of notice of proposed variations to licences, does not apply where the proposed variation is of minor significance or complexity.

**Clause 37: Renumber Section 72A as Section 72AA**
Clause 37 would make a consequential amendment to the Act as a new Section 72A is inserted in part 5A.

**Clause 38: Insert new part 5A Sections 72A to 72E**
Clause 38 would add new subsections 72A to 72E in accordance with amendments to the Commonwealth legislation which creates a system whereby the Commonwealth Minister can make a determination relating to GMOs in an emergency. Section 72A: the proposed new section 72A provides that section 72B under the Commonwealth Act applies, as far as applicable, as a law of the Territory.

Section 72B: the proposed new section 72B permits the Commonwealth Minister the power to make an emergency dealing determination in respect of specified dealings with a GMO, by legislative instrument, for the purposes of the Commonwealth Act, Part 5A.

Section 72C: the proposed new subsection 72C sets out when a determination can take effect, when a determination ceases to have effect and how the period of effect may be extended by the Commonwealth Minister responsible for emergency dealing determinations.

Section 72D: the proposed new section 72D allows for conditions to be imposed on an emergency dealing determination. These include conditions relating to the quantity of GMO, the scope of dealings, the source of GMO, the person who may deal with the GMO, information required to be given to persons permitted to deal with a GMO, additional information that must be provided to the Regulator, and the storage and security of the GMO amongst other things.

Section 72E: the proposed new subsection 72E provides that the Commonwealth Minister may vary the conditions of an emergency dealing determination by legislative instrument, including by imposing new conditions on a determination.

**Clause 39: Omit Subsection 78(4)**
Clause 39 would amend subsection 78 of the Act to remove the requirement that a registration of a dealing, made on the application of a licence holder, can only take effect if the licence authorising the dealing ceases to be in force.

**Clause 40: After "Licence conditions" in Sections 82(2) and (4) insert ", or conditions to which an emergency dealing determination is subject,"**
Clause 40 would amend the simplified outline to make clear that the conditions of an emergency dealing determination could require a facility to be certified and accredited under Division 7.2 of the Act, or an organisation to be accredited under Division 7.3 of the Act.

**Clause 41: After "licence" in Section 83(2) note insert ",or conditions to which an emergency dealing determination is subject"**
Clause 41 would insert words into the note in subsection 83(2) to make clear that the conditions of an emergency dealing determination could require a facility to be certified under Division 7.2.

**Clause 42: Insert new Section 89(8)**
Clause 42 would add subsection 89(8), which provides that section 89 of the Act, which includes, among other things, requirements of notice of proposed variations of certification, does not apply where the proposed variation is of minor significance or complexity.

**Clause 43: Insert new Section 89A**
Clause 43 would provide for the insertion of new Section 89A, subsections 89A(1) to (5).

- Subsection 89A(1), which provides for transfers of certification by way of a joint application between the holder of the certification and the transferee;
- Subsection 89A(2), which requires the application to be in writing and contain information prescribed by the regulations or specified in writing by the Regulator;
- Subsection 89A(3), which prohibits the Regulator from transferring certification unless satisfied that the conditions to which the certification is subject will continue to be met;
- Subsection 89A(4), which requires the Regulator to give written notice of his or her decision to the applicants; and
- Subsection 89A(5), which provides for the transfer, if approved, to take effect on the date specified in the notice, for the certification to continue in force and for certification to be subject to the same conditions which applied before the transfer.

**Clause 44: Substitute note 1 and amend note 2 in Section 91(1)**
Clause 44 would replace the note in subsection 91(1) to make clear that the conditions of an emergency dealing determination could require supervision by an Institutional Biosafety Committee. Note 2 has been amended to clarify that the section referred to relates to the Commonwealth legislation.

**Clause 45: Omit ",or proposes to establish," from Section 92(2)(a)**
Clause 45 would amend paragraph 92(2)(a) of the Act to remove the obligation for the Regulator to have regard to whether or not an organisation proposes to establish an Institutional Biosafety Committee (IBC) for the purposes of deciding whether to accredit an organisation.

**Clause 46: Substitute Sections 92(2)(b) and (c) with new Sections 92(2)(b), (c) and (ca)**
Clause 46 would amend paragraph 92(2)(b) of the Act to require the Regulator, for purposes of accrediting organisations, to have regard to whether an organisation will be able to maintain an IBC already established.

This clause would amend paragraph 92(2)(c) of the Act to require the Regulator, for the purposes of accrediting organisations, to have regard to whether an organisation has appropriate indemnity arrangements if the organisation has established an IBC.

This clause would also insert a new paragraph 92(2)(ca) into the Act which includes a consideration of whether or not the organisation will be in a position to use an IBC established by another accredited organisation as a matter to which the Regulator must have regard in deciding whether to accredit an organisation.

**Clause 47: Insert new Section 97(8)**
Clause 47 would add a new subsection 97(8) which provides that section 97 of the Act, which includes, among other things, requirements of notice of proposed variations of accreditation, does not apply where the proposed variation is of minor significance or complexity.

**Clause 48: Substitute Part 8 heading**
Part 8 proposes amendments which will combine the Gene Technology Ethics Committee (the Ethics Committee) and the Gene Technology Community Consultative Committee (the Consultative Committee) into one advisory committee. The combined committee will be known as the Gene Technology Ethics and Community Consultative Committee (the Ethics and Community Committee) and will carry out the combined functions of both committees as well as providing advice on risk communication and community consultation in relation to intentional release licence applications.

The object of these proposed amendments is to increase efficiency by addressing the overlap between the roles of the Ethics Committee and the Consultative Committee. The new committee would also allow relevant skills to be distributed across its membership so that the committee is able to provide clear, balanced, appropriate, and more coordinated advice.

The GTMC will review the performance of the new advisory committee after 18 months, but before it has been operating for two years.

**Clauses 49 to 52: After "technology" insert "ethics and"**
Clauses 49 to 52 would repeal references to the Gene Technology Consultative Committee and the Gene Technology Ethics Committee in the Act and replace them with references to the Gene Technology Ethics and Community Committee in line with the amendment proposed in clause 48.

**Clause 53: Substitute Section 107**
Section 107: the proposed new section 107 provides that the function of the Ethics and Community Committee will be to provide advice, at the request of the Regulator or the Ministerial Council, on:

- matters on which the Ethics Committee currently advises;
- matters on which the Consultative Committee currently advises;
- community consultation matters relating to intentional release licence applications; and
- risk communication matters relating to dealings that involve the intentional release of a GMO into the environment.

Risk communication involves an interactive dialogue between risk assessors, risk managers and stakeholders. It underpins the processes of risk assessment and risk management.

The proposed new section 107 is not intended to mandate the examination of every intentional release application, instead it is intended to permit the Regulator to seek advice in relation to certain types of releases that might be precipitated by such an application.

The matters on which the Ethics Committee currently advises are set out in section 112 of the existing Act. These are: ethical issues relating to gene technology; the need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs; and the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons. It is proposed that these matters will be incorporated into proposed paragraphs 107(a), (b) and (c) of the Act.

The matters on which the Consultative Committee currently advises are set out in existing section 107 of the Act. These are: matters of general concern identified by the Regulator in relation to applications, matters of general concern in relation to GMOs, and the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the conduct of such principles, guidelines and codes. It is proposed that these matters will be incorporated into proposed paragraphs 107(d), (g), and (h) of the Act.

**Clause 54: Omit "consultative" in Sections 108 and 109, notes, and substitute "ethics and community"**
Clause 54 would repeal references to the Consultative Committee in the notes of Sections 108 and 109 of the Act and replace them with references to the Ethics and Community Committee.

**Clause 55: Omit everything after "membership" in Section 110 and substitute "and procedures of the ethics and community committee."**
Amended Clause 55 would provide that the regulations may prescribe matters relating to the membership and procedures of the Ethics and Community Committee.

**Clause 56: Omit Section 110A**
This would make a consequential amendment to clause 48 which proposed amendments which will combine the Gene Technology Ethics Committee (the Ethics Committee) and the Gene Technology Community Consultative Committee (the Consultative Committee) into one advisory committee. Clause 58 allows for the establishment of the subcommittees relevant to the new advisory committee.

**Clause 57: New Sections 111 and 112 in division 8.3**
The proposed new sections 111 and 112 in division 8.3 provide for the establishment of subcommittees and the appointment of expert advisers. The sections are the same as the existing sections 116, 110A, and 113 of the Act except that they refer to the Ethics and Community Committee instead of the Ethics Committee or the Consultative Committee.

**Clause 58: Omit Division 8.4**
Clause 58 would repeal provisions relating to the gene technology ethics committee as a consequential amendment.

**Clause 59: New sections 136A(2)(ba) and (bc)**
Clause 59 would insert two new paragraphs 136A(2)(ba) and 136A(2)(bc) into the Act providing that quarterly reports prepared by the Regulator and given to the Minister must include information about any emergency dealing determinations issued by the Minister and any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the quarter.

**Clause 60: New Section 138(1A)**
Clause 60 would insert a new subsection 138(3A) into the Act providing that the Record of GMO and GM Product dealings required under Division 6, must include comprehensive information, except confidential commercial information, on the content of emergency dealing determinations.

**Clause 61: After "1," insert (1A)," in Section 138(5)**
Clause 61 would make a consequential amendment to the Act as a new Section 138(1A) is inserted in Clause 60.

**Clause 62: After "environment" insert ", or for certain other reasons" in Section 145(a)(ii)**
Clause 62 would add the phrase "or for certain other reasons" to the end of paragraph 145(a)(ii) in the simplified outline at the start of Part 10 of the Act. This would make clear that the circumstances under which the Regulator may give directions have been expanded.

**Clause 63: New Section 145(aa)**
Clause 63 would insert a new paragraph into the simplified outline in section 145 of the Act. This makes clear that Part 10 of the Act authorises the Regulator to give directions to a person permitted to deal with a GMO under an emergency dealing determination. This is consistent with existing subsections (a) and (b) although "enables" is used in place of "authorises" in the corresponding Commonwealth legislation.

**Clause 64: Substitute Section 146(1)(b)**
Clause 64 would insert a new subparagraph 146(1)(b) into the Act. This subparagraph provides that the Regulator may give directions to a person, requiring that he or she take steps to comply with the Act and Regulations, if it is desirable in the public interest to do so.

**Clause 65: Substitute Section 146(2)(a)**
Clause 65 would amend paragraph 146(2)(a) to provide that the Regulator may give directions to a person dealing with, or who has dealt with, a GMO specified in an emergency dealing determination.

**Clause 66: Substitute Section 146(2)(b)**
Clause 64 would insert a new subparagraph 146(2)(b) into the Act. This subparagraph provides that the Regulator may give directions to a person, requiring that he or she take steps to comply with the Act and Regulations, if it is desirable in the public interest to do so.

**Clause 67: Insert new Section 146(2A)**
Clause 67 would insert a new paragraph 146(2A) into the Act, setting out the matters that the Regulator should consider in deciding whether it is in the public interest to make a direction. These matters would include:

- the type of the GMO dealing and whether it is a one-off or ongoing dealing;
- whether any steps have been taken to address the non-compliance issue;
- the likelihood of a repeat of the non-compliance;
- the severity of the non-compliance issue;
- the compliance history of the licensee or the person covered by the licence;
- whether it would be more appropriate to address the non-compliance by another means such as variation, suspension or cancellation of the licence;
- whether the non-compliance was deliberate; and
- the need for deterrence.

These matters are similar to those listed in the OGTR's Non-Compliance Protocol of 10 May 2002. The protocol gives the Regulator guidance on what matters he or she should consider in deciding whether to conduct a criminal investigation.

**Clause 68: After "licence" insert ""or an emergency dealing determination" in Section 149(e)**
Clause 68 would insert a reference to emergency dealing determinations into the simplified outline in section 149 of the Act. This makes clear that Part 11 does not limit the conditions to which an emergency dealing determination can be subject.

**Clause 69: Insert new Section 152(2)(d)**
Clause 69 would insert a new paragraph into subsection 152(2) of the Act to make clear that an inspector may enter premises and exercise the monitoring powers set out in section 153, for the purpose of finding out whether the Act or regulations have been complied with, if the occupier of the premises is a person dealing with, or who has dealt with, a GMO specified in an emergency dealing determination and entry is at a reasonable time.

**Clause 70: Omit "subsection (2)(c) does not" and substitute "subsection (2)(c) or (d) does not in Section 152(3)**
Clause 70 would make a consequential amendment to include reference to the new Section 152(2)(d) inserted in Clause 69.

**Clause 71: Substitute Section 177**
Clause 71 would insert a reference to the Minister's power to impose conditions on an emergency dealing determination into section 177 of the Act. This clarifies that Part 11 does not limit the Minister's power to impose conditions on an emergency dealing determination.

**Clause 72: New Item 1A, table, Section 179**
Clause 72 would insert Item 1A into the table at section 179 of the Act, which adds to the list of reviewable decisions under section 179, a decision by the Regulator under paragraph 43(2)(f) to refuse to consider an application on the basis that the applicant is not a suitable person to hold a licence.

**Clause 73: New Item 4A, table, Section 179**
Clause 73 would insert a new item 4A into the table in section 179 of the Act. This makes clear that the Regulator's decision to refuse to vary a licence is a reviewable decision, and that the licence holder can apply to the Administrative Appeals Tribunal under section 183 of the Act for review of the decision.

**Clause 74: New Item 7A, table, Section 179**
Clause 74 would insert Item 7A into the table at section 179 of the Act which adds to the list of reviewable decisions under section 179, a decision by the Regulator under section 89A to refuse to transfer a certification.

**Clause 75: Substitute Section 182(a)**
Clause 75 would amend the wording of paragraph 182(a) so as to extend the application of section 182 to all applications to the Regulator, not just applications to the Regulator to make a reviewable decision.

**Clause 76: Omit “decision to refuse the application” and substitute “reviewable decision to refuse the application, and the person may seek internal review of the reviewable decision under section 181” in Section 182**
Clause 76 would insert into section 182 of the Act wording as indicated above, thereby removing any doubt that a deemed rejection of an application on account of elapse of time is reviewable under the Act.

**Clause 77: Insert new Section 185(5A)**
Clause 77 would add a new subsection 185(5A) into the Act which would provide that information specified for purposes of an application for a declaration that information is confidential commercial information (`CCI'), is treated as CCI until the Regulator has made a decision on the application.

**Clause 78: Insert new paragraph (aa) in Section 192A(2)**
Clause 78 would insert a new paragraph into subsection 192A(2) of the Act to provide that authorised GMO dealings include dealings 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 emergency dealing determination.

**Clause 79: Insert “dealings” after “are” in Section 192A(2)(d)**
Clause 79 would amend paragraph (d) of the definition of authorised GMO dealings in subsection 192A(2) of the Act, to refer to `dealings included on the GMO Register'.

**Clause 80: Omit dictionary definition of *consultative committee***
Clause 80 would repeal the definition of Consultative Committee in the Dictionary of the Act, a consequential amendment.

**Clause 81: Amend dictionary definition of *deal with***
Clause 81 would amend the definition of "deal with" in relation to a GMO by including transport of a GMO, and disposal of a GMO, as a dealing. Possession, supply and use of the GMO remain dealings when used for the purposes of, or in the course of a dealing described in the definition.

**Clause 82: Insert new dictionary definition of *ethics and community committee***
Clause 82 would insert a definition of Ethics and Community Committee into the Dictionary of the Act. It would be defined to mean the Gene Technology Ethics and Community Consultative Committee established by section 107 of the Act.

**Clause 83: Omit dictionary definition of *ethics committee***
Clause 83 would repeal the definition of Ethics Committee in the Dictionary of the Act, a consequential amendment.

**Clause 84: Insert new dictionary definition of *inadvertent dealings application***
Clause 84 would insert a dictionary definition for inadvertent dealings application to mean 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.

**Clause 85: Substitute dictionary definition of *institutional biosafety committee***
Clause 85 would amend the Dictionary of the Act with the intention of clarifying the meaning of Institutional Biosafety Committee by defining it as a committee established in accordance with guidelines issued by the Regulator under section 98 of the Act.