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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

GENE TECHNOLOGY AMENDMENT BILL 2007

EXPLANATORY MEMORANDUM

(Circulated by authority of the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Honourable Brett Mason)

GENE TECHNOLOGY AMENDMENT BILL 2007

OUTLINE

The purpose of this Bill is to amend the *Gene Technology Act 2000* (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 Australian 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).

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, which include:

- introducing emergency powers, giving the Minister the ability to expedite the approval of a dealing with a GMO in an emergency (Part 1 of Schedule 1 to the Bill);
- improving the mechanism for providing advice to the Gene Technology Regulator (the Regulator) and the GTMC on ethics and community consultations (Part 2 of Schedule 1 to the Bill);
- streamlining the process for the initial consideration of licences (Part 3 of Schedule 1 to the Bill);
- reducing the regulatory burden for low risk dealings (Part 3 of Schedule 1 to the Bill);
- providing clarification on the circumstances in which licence variations can be made (Part 4 of Schedule 1 to the Bill);
- clarifying the circumstances under which the Regulator can direct a person to comply with the Act (Part 5 of Schedule 1 to the Bill);
- providing the Regulator with the power to issue a licence to persons who find themselves inadvertently dealing with an unlicensed GMO, for the purpose of disposing of that organism (Part 6 of Schedule 1 to the Bill); and
- making technical amendments to improve the operation of the Act (Schedule 2 to the Bill).

FINANCIAL IMPACT STATEMENT

The proposed amendments to the Act have no financial impact.

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NOTES ON CLAUSES

Clause 1: Short Title
This clause provides that the Act may be cited as the *Gene Technology Amendment Act 2007*.

Clause 2: Commencement
This clause provides that sections 1 to 3 of the Act would commence on the day on which the Act receives Royal Assent. Parts 1, 3, 4, 5, and 6 of Schedule 1 and Schedule 2 would commence on 1 July 2007, or on the day after the day on which the Act receives Royal Assent, whichever is the later.

Part 2 of Schedule 1 would commence on a single day to be fixed by Proclamation, which must be before 1 January 2008, otherwise this Part commences on 1 January 2008. It is scheduled to commence after the rest of the Bill to allow members of the Gene Technology Ethics Committee to complete their agreed terms of appointment.

Clause 3: Schedule(s)
This clause 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.

SCHEDULE 1: *GENE TECHNOLOGY ACT 2000*

PART 1: Emergency dealing determinations

Part 1 of Schedule 1 to the Bill proposes to introduce emergency provisions into the Act. The object of these provisions is to increase the effectiveness of the gene technology regulatory system by increasing its responsiveness.

The emergency provisions give the Minister power to expedite an approval of a dealing with a GMO in an emergency. This recognises that situations may arise in which approval of a dealing with a GMO may be required in a limited time. The emergency provisions also further the objects of the Act to protect the health and safety of people and to protect the environment.

The introduction of emergency provisions to the Act is also beneficial because it will improve consistency between regulatory schemes. Other relevant product regulators for vaccines, such as the Therapeutic Goods Administration and the Australian Pesticides and Veterinary Medicines Authority, already possess the ability to expedite approvals in an emergency.

Item 1 would insert a definition of ***emergency dealing determination*** into subsection 10(1) of the Act, providing that an emergency dealing determination means a determination in force under section 72B of the Act.

Item 2 would insert a new paragraph 31(2)(aa) 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.

Item 3 would repeal the existing subsection 32(1) and substitute a new subsection 32(1) 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(1) is substantially the same as the existing subsection 32(1) 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.

Items 4 and 5 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.

Item 6 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.

Item 7 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.

Item 8 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(1) creates an offence for intentionally breaching the conditions of an emergency dealing determination. Proposed paragraph 35A(2)(a) provides that the penalty for an aggravated offence is 5 years imprisonment or 2,000 penalty units. Proposed paragraph 35A(2)(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(2)(a) provides that the penalty for an aggravated offence is 200 penalty units. Proposed paragraph 35B(2)(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(3) provides that strict liability applies to paragraphs 35B(1)(a) and (b).

New strict liability offence

Item 6 would create a new strict liability offence for breaching the conditions of an emergency dealing determination. 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. Strong deterrents are needed to discourage persons from dealing with GMOs unless they are fully aware of any relevant regulatory safeguards.

Item 9 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.

Item 10 would insert a new Part 5A with the title 'Emergency dealing determinations' into the Act.

Section 72A: the proposed new section 72A creates a simplified outline for the Part. It provides that the Part creates a system whereby the Minister can make a determination relating to dealings with GMOs in an emergency.

Section 72B

Subsection 72B(1): the proposed new subsection 72B(1) gives the Minister power to make an emergency dealing determination in respect of specified dealings with a GMO, by legislative instrument. The emergency dealing determination will effectively authorise the specified dealings with the GMO so that the penalty provisions in Part 4 of the Act will not apply.

A legislative instrument made under subsection 72B(1) is not to be disallowable because, once States and Territories sign the amended *Gene Technology Agreement 2001,* it would fall under the exemption in subsection 44(1) of the *Legislative Instruments Act 2003* (the LIA). The exemption applies because the Act, in conjunction with the *Gene Technology Agreement 2001,* facilitates an intergovernmental scheme involving the Commonwealth and all States and Territories. A legislative instrument made under subsection 72B(1) would be made for the purposes of this scheme; this is supported by paragraph 72B(2)(e) which provides that States must be consulted about the making of the proposed emergency dealing determination.

Subsection 72B(2): the proposed new subsection 72B(2) sets out the conditions under which the Minister is permitted to make an emergency dealing determination. It provides that before making an emergency dealing determination the Minister must:

- have received advice from the Commonwealth Chief Medical Officer; the Commonwealth Chief Veterinary Officer, the Commonwealth Chief Plant Protection Officer or a person specified in the regulations, that there is an actual or imminent threat to the health and safety of people or 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;

- be satisfied that there is an actual or imminent threat to the health and safety of people or the environment, that the dealings proposed to be covered by the emergency dealing determination would, or would be likely to, adequately address the threat; and
- be satisfied that the risks posed by the proposed dealings can be managed safely, and have received advice from the Regulator to that effect.

In addition, States (which is defined to include the Australian Capital Territory and the Northern Territory) must have been consulted about the proposed emergency dealing determination.

Subsection 72B(3): the proposed new subsection 72B(3) gives examples of situations in which it may be appropriate to issue an emergency dealing determination. These include:

- where there is a threat of disease;
- where there is a threat from an animal or plant (such as a pest or alien invasive species); or
- where there is a threat from industrial spillage.

The Bill makes clear that the threat must be actual and imminent for the emergency provisions to apply. It is expected that the provisions will only be utilised if a threat is serious and immediate.

Hypothetical examples situations in which the powers could be used are if there is a threat of an avian flu pandemic or if there is a threat of major environmental damage from an oil spill. In these situations the Minister may wish to issue an emergency dealing determination in relation to a dealing with a GMO which is intended to address the threat by minimising or eradicating the problem organism and its vectors, or by conveying immunity in humans and/or animals. In the hypothetical situations mentioned above, the determination could cover dealings in relation to a genetically modified vaccine for human or veterinary use; or a genetically modified bacterium to dissolve oil.

Subsection 72B(4): the proposed new subsection 72B(4) sets out the types of dealings for which the Minister may make a determination. It makes clear that the determination may be in respect of all dealings with a GMO, a specified class of dealings, or one or more specified dealings and may relate to a specific GMO or a class of GMOs. A class of dealings or a class of GMOs may be defined by a range of matters. For example, an exempt class of dealings with a GMO may be limited by the type of GMO, who deals with the GMO, how the GMO is dealt with and whether the GMO is regulated under existing legislation. This provision is drafted in similar terms to the existing subsection 32(4) of the Act.

Section 72C

Subsection 72C(1): the proposed new subsection 72C(1) sets out that a determination can take effect on the day on which it is made or at a specified later date. In other words, the determinations cannot apply retrospectively.

Subsection 72C(2): the proposed new subsection 72C(2) provides that a determination ceases to have effect on: a date specified in the determination; when the determination is revoked; or after six months; whichever comes first.

Subsection 72C(3): the proposed new subsection 72C(3) provides that the Minister may extend an emergency dealing determination.

Subsection 72C(4): the proposed new subsection 72C(4) provides that the Minister may extend the emergency dealing determination more than once, for up to six months each time. The process set out in subsection 72C(5) must be repeated for each extension.

Subsection 72C(5): the proposed new subsection 72C(5) provides that the Minister may only extend an emergency dealing determination if:

- he or she has received advice from the person who originally provided advice under paragraph 72B(2)(a) (the "original adviser") that the threat still exists and that extending the emergency dealing determination would, or would be likely to, adequately address the threat; and
- he or she is satisfied that threat still exists and that extending the emergency dealing determination would, or would be likely to, adequately address the threat; and
- he or she is satisfied that the risks posed by the proposed dealings can be managed safely, and have received advice from the Regulator to that effect; and
- the majority of jurisdictions (including States, Territories and the Australian Government) agree to the extension.

Subsection 72C(6): the proposed new subsection 72C(6) provides that the extension of the emergency dealing determination takes effect when the original emergency dealing determination was scheduled to end.

Subsection 72C(7): the proposed new subsection 72C(7) defines original adviser in subsection 72C(5) as the person who gave the advice under paragraph 72B(2)(a).

Section 72D

Subsection 72D(1): the proposed new subsection 72D(1) allows conditions to be imposed on an emergency dealing determination. Paragraphs 72D(2)(a) to (v) give examples of the conditions that may be imposed. 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. The new paragraph (w) clarifies that the conditions the Minister may impose are not limited to the matters listed in paragraphs (a) to (v), but that the Minister may impose conditions over any other matter he or she considers appropriate.

The proposed new paragraphs 72D(2)(a) to (v) correspond to the existing sections 62, 63, 64 of the Act, which relate to the conditions that may be imposed on licences:

- the proposed new paragraphs 72D(2)(b) to (d) correspond to the existing subsections 62(1)(a) to (c);
- the proposed new paragraph 72D(2)(g) is the equivalent of the existing section 63;

- the proposed new paragraph 72D(2)(h) corresponds to the existing section 65;
- the proposed new paragraphs 72D(2)(j) and (k) correspond to the existing paragraphs 62(1)(e) and (f);
- the proposed new paragraphs 72D(2)(m) to (o) correspond to the existing paragraphs 62(1)(g) to (i); and
- the proposed new paragraphs 72D(2)(q) to (v) correspond to the existing paragraphs 62(1)(j) to (o).

Subsection 72D(3): the proposed new paragraph 72D(2)(f) provides that a condition may specify the person who may deal with the GMO. The proposed subsection 72D(3) makes clear that it is not necessary to specify a single person, that a condition can specify persons or a class of persons who may deal with the GMO. There are no restrictions on who may be included in the class of persons who may deal with the GMO, or how large the class may be.

Subsection 72D(4): the proposed new subsection 72D(4) is drafted on similar terms to the existing section 64 of the Act. It provides that it is a condition of an emergency dealing determination that a person permitted to deal with a GMO under an emergency dealing determination, must allow the Regulator (or delegate) to enter premises where the dealing is being undertaken, in order to conduct audits, or monitor the dealings covered by the emergency dealing determination. This allows the Regulator to undertake routine or 'on-the-spot' auditing or monitoring of dealings covered by an emergency dealing determination.

Subsection 72D(5): the proposed new subsection 72D(5) makes clear that subsection 72D(4) does not limit the conditions that may be placed on an emergency dealing determination.

Section 72E

Subsection 72E(1): the proposed new subsection 72E(1) provides that the Minister may vary the conditions of an emergency dealing determination by legislative instrument, including by imposing new conditions on a determination.

A legislative instrument issued under subsection 72E(1) is not disallowable because the exemption in subsection 44(1) of the LIA applies. This exemption applies for the reasons set out in relation to subsection 72B(1), above.

Subsection 72E(2): the proposed new subsection 72E(2) provides that the Minister may suspend or revoke an emergency dealing determination by legislative instrument, in three circumstances:

- if the Minister becomes aware of risks to the health and safety of people or the environment posed by the dealing that cannot be adequately addressed;
- if the Minister is satisfied that the threat no longer exists or is no longer sufficiently serious as to warrant an emergency dealing determination; or
- if the Minister is no longer satisfied that the dealings covered by the determination are likely to adequately address the threat.

Subsection 72E(3): the proposed new subsection 72E(3) provides that the Minister must consult the States (which is defined to include the Territories) before varying, suspending or revoking an emergency dealing determination unless the proposed variation is of a minor technical nature.

Subsections 72E(4) and 72E(5): the proposed new subsection 72E(4) provides that a suspension, revocation, or variation may take effect immediately only if the Minister states that it is necessary to prevent imminent risk of death, serious illness or serious injury or serious damage to the environment. Subsection 72E(5) provides that otherwise, it must take effect on a date specified, which must be 30 days or more after it is made.

Items 11 and 12 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 2 of the Act, or an organisation to be accredited under Division 3 of the Act.

Item 13 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 2.

Item 14 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.

Item 15 would insert two new paragraphs 136A(2)(ba) and 136A(2)(bb) 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.

Item 16 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.

Item 17 would insert a new paragraph into the simplified outline in section 145 of the Act. This makes clear that Part 10 of the Act enables the Regulator to give directions to a person permitted to deal with a GMO under an emergency dealing determination.

Item 18 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.

Item 19 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.

Item 20 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.

Item 21 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.

Item 22 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.

Item 23 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' instead of 'deregulated GMO dealings'.

PART 2: Creation of Gene Technology Ethics and Community Consultative Committee

Part 2 of Schedule 1 to the Bill 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.

Item 24 would repeal the definition of ***Consultative Committee*** in subsection 10(1) of the Act.

Item 25 would insert a definition of ***Ethics and Community Committee*** into subsection 10(1) of the Act. It would be defined to mean the Gene Technology Ethics and Community Consultative Committee established by section 106 of the Act (inserted by tem 34).

Item 26 would repeal the definition of ***Ethics Committee*** in subsection 10(1) of the Act.

Items 27-31 and 33 would repeal references to the Consultative Committee and the Ethics Committee in the Act and replace them with references to the Ethics and Community Committee.

Item 32 would make a consequential amendment to subsection 100(5) of the Act to make clear that subsection 100(5) is subject to both subsection 100(6) and subsection 100(7A).

Item 34 would repeal Divisions 3 and 4 of Part 8 of the Act and insert a new Division 3, which establishes the Ethics and Community Committee, and provides for its functions and membership, as well as the remuneration of its members.

Section 106: the proposed new section 106 establishes the Gene Technology Ethics and Community Consultative Committee, to be known as the Ethics and Community Committee.

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.

Section 108: the proposed new section 108 relates to the membership of the Ethics and Community Committee. The proposed new subsection 108(1) is the same as the existing subsections 108(1) and 111(2) of the Act, except that it refers to the Ethics and Community Committee instead of the Ethics Committee or the Consultative Committee. With the same exception, the proposed new subsection 108(2) is the same as the existing subsections 108(2) and 111(4) of the Act; the proposed new subsection 108(5) is the same as the existing subsections 108(5) and 111(3) of the Act; and the proposed new subsection 108(6) is the same as the existing subsections 108(6) and 111(7) of the Act.

Subsection 108(3): the proposed new subsection 108(3) lists the areas of experience members of the Ethics and Community Committee are required to have. It specifies that, with the exception of a member appointed under the proposed new subsection 108(4), the Minister must not appoint a person as a member of the Ethics and Community Committee unless the Minister is satisfied that the person has skills or experience relevant to gene technology in one or more of the following areas:

- community consultation;
- risk communication (i.e. the facilitation of communication between risk assessors, risk managers and stakeholders);
- the impact of gene technology on the community;
- issues relevant to businesses developing or using biotechnology;
- issues relevant to gene technology research;
- issues relevant to local government;
- issues of concern to consumers;
- law;
- religious practices;
- human health;
- animal health and welfare;
- primary production;
- ethics; and
- environmental issues.

Regulations may also prescribe additional areas of skill or experience. With the exception of community consultation and risk communication, all of these areas of experience were previously listed as areas of experience members of either the Ethics Committee or the Consultative Committee were required to have.

Subsection 108(4): the proposed new subsection 108(4**)** provides that the Minister must ensure that the Ethics and Community Committee includes a member of the Gene Technology Technical Advisory Committee and a member of the Australian Health Ethics Committee.

Section 109: the proposed new section 109 provides for remuneration of the Ethics and Community Committee and its expert advisers. It is the same as existing sections 109 and 114 of the Act, except that it refers to the Ethics and Community Committee instead of the Ethics Committee or the Consultative Committee.

Section 110: the proposed new section 110 relates to the membership and procedures of the Ethics and Community Committee. This section is similar to the existing section 115 of the Act.

Subsections 110(1) and 110(2): the proposed new subsections 110(1) and (2) provide that the regulations may prescribe matters relating to the membership and operation of the Ethics and Community Committee.

Subsection 110(3): the proposed new subsection 110(3) provides that if no regulations are in force, the Ethics and Community Committee must operate in a way determined by the Regulator in writing.

Subsection 110(4): the proposed new subsection 110(4) provides that in the absence of regulations made under subsections 110(1) and (2), or a determination made under subsection 110(3), the Ethics and Community Committee may operate as it, itself, determines in writing.

Subsection 110(5): the proposed new subsection 110(5) makes clear that determinations made under subsections 110(4) and 110(5) are not legislative instruments.

Determinations made under subsections 110(3) and (4) not legislative instruments
Subsection 110(5) is intended to assist readers by making clear that a determination made under subsection 110(3) or 110(4) is not a legislative instrument. This is because the instruments made under these sections would be administrative rather than legislative in nature and therefore would not meet the definition of a legislative instrument in section 5 of the LIA (subsection 15AE(3) of the *Acts Interpretation Act 1901* deals with a provision of a law which requires or permits an instrument that is described as not being a legislative instrument to be made).

Sections 111 and 112: the proposed new sections 111 and 112 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.

Item 35 is a transitional provision. This provision makes clear that where State laws confer functions on the former Ethics Committee or the Consultative Committee, the new Ethics and Community Committee can exercise those functions. This will ensure that the new Committee can perform the functions that are conferred by the State laws on the old Committees until the State laws are amended to refer to the new Committee.

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

Part 3 of Schedule 1 to the Bill proposes two types of amendment. The first type of amendment would alter the order of events during the initial licence consultation process, so that the Regulator is no longer required to consider whether an application poses a significant risk to the health and safety of people or the environment before developing a risk assessment and risk management plan (RARMP). The object of these amendments is to improve the process by which licences are initially considered by giving the Regulator more time to consider whether dealings pose a significant risk. The second type of amendment would introduce a new category of licence to distinguish between licences for a limited and controlled release, and licences for intentional release. The object of these amendments is to increase the efficiency of the regulatory system by streamlining the application process for licences involving a limited and controlled release of a GMO.

Item 36 would repeal section 49 of the Act. Under this section, the Regulator is currently required to assess whether a proposed dealing may pose a significant risk before developing a RARMP. This has proved problematic, as it can be difficult for the Regulator to make a judgment on the risk of a GMO prior to the development of the comprehensive RARMP.

Item 36 would repeal this requirement, thereby allowing the Regulator to identify the significant risk *after* he or she has developed a RARMP under section 50 of the Act.

Items 37 and 40-43 would make consequential amendments to the Act by repealing subsection 50(2), and paragraphs 51(1)(b) and 51(2)(b) which relate to actions required by section 49; and by omitting the references to section 49 in subsection 51(2) and paragraph 51(1)(a).

Item 44 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).

Item 45 would provide for a longer consultation process where the Regulator considers that the GMO poses a significant risk to the health and safety of people or the environment and the RARMP contains a statement to that effect. The item proposes to insert two new subparagraphs into paragraph 52(2)(d) of the Act. The proposed subparagraph 52(2)(d)(i) would provide that the time period for submissions must be at least 50 days if the Regulator is satisfied that the dealings pose a significant risk. The proposed subparagraph 52(2)(d)(ii) would provide for a thirty day time period for all other dealings.

Items 38 and 39

Item 39 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. Item 38 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.

These amendments 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.

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) gives guidance on the meaning of the term 'controls' 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.

Subsection 50A(3): the proposed subsection 50A(3) gives guidance on the meaning of the term 'limits' in subsection 50A(1). 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.

Subsection 50A(4): the proposed subsection 50A(4) 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(4)(b) makes clear that the Regulator may also consider any other matters that he or she considers to be relevant.

PART 4: Provisions relating to variation

Part 4 of Schedule 1 to the Bill proposes amendments which would give the Regulator the power to permit licence variations in certain circumstances. While it is apparent from the existing subsection 72(5) that licence-holders can request variations to their licences, this is not explicitly stated in the Act. The introduction of amendments to explicitly permit licence variations is intended to increase the clarity of the Act. Furthermore, the imposition of limits on the circumstances in which Regulator can vary a licence is intended to prevent a variation being used to unreasonably extend the coverage of a licence.

Item 46 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.

Item 47 would make a consequential amendment to subsection 71(2) of the Act.

Item 48 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.

Item 49 would make a consequential amendment to subsection 71(4) of the Act.

Item 50 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.

Item 51 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.

PART 5: Regulator's power to direct

Part 5 of Schedule 1 to the Bill proposes amendments which would increase the circumstances under which the Regulator may direct a licence-holder, or a person covered by a licence, to comply with the Act or Regulations.

The object of these proposed amendments is to reduce ambiguity in the Act, by clarifying that the Regulator may direct a licence-holder to comply, even if there is no immediate risk to the health and safety of people or the environment.

The effect of the proposed amendments will be to increase the Regulator's compliance tools and ensure that all breaches of licences can be dealt with under the Act. This recognises that it is important to maintain the integrity of licences, even if there is no immediate risk to the health and safety of people or the environment.

Item 52 would add the phrase "or for certain other reasons" to the end of paragraph 145(b) 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.

Item 53 would insert new subparagraphs 146(1)(b)(ii) and 146(2)(b)(ii) into the Act. These subparagraphs provide 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.

Item 54 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.

PART 6: Inadvertent dealings

Part 6 to the Bill proposes amendments to allow the Regulator to grant a temporary permit to a person who finds himself or herself inadvertently dealing with an unlicensed GMO. The licence will be issued to the person for the purposes of disposing of the GMO in a manner which protects the health and safety of people and the environment.

The object of these proposed amendments is to allow a person who has unintentionally come into possession of a GMO to dispose of the GMO without breaching the Act. Under the current Act, the Regulator can rely on the offence provisions or injunctions to deal with unapproved dealings with a GMO. However, these tools are not suited to a case where a person wishes to act cooperatively and dispose of the GMO in accordance with the Regulator's requirements to protect the health and safety of people or the environment.

Item 55 would insert a definition of ***inadvertent dealings application*** into subsection 10(1) of the Act.

Item 56 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.

Items 57 and 58 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 in Divisions 3 or 4.

Item 59 would add a note to section 56 of the Act. The note makes clear that paragraphs 56(2)(a),(b) and (c), which relate to risk assessment and risk management plans, do not apply to inadvertent dealings applications.

Item 60 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.

Item 61 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.

SCHEDULE 2: TECHNICAL AMENDMENTS

Items 1 and 2 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.

Item 3 would amend subsection 10(1) of the Act with the intention of clarifying the meaning of Institutional Biosafety Committee by defining it as an organisation established in accordance with guidelines issued by the Regulator under section 98 of the Act.

Item 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.

Item 5 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.

Item 6 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.

Item 7 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.

Item 8 would add a new subsection 72(7) 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.

Item 9 amends subsection 78(3) 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.

Item 10 adds subsection 89(7), 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.

Item 11 would provide for the insertion of:

- 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 the certification to be subject to the same conditions which applied before the transfer.

Item 12 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.

Item 13 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.

Item 14 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.

Item 15 would 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.

Item 16 would add a new subsection 97(7) 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.

Item 17 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.

Item 18 would insert Item 3A 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 70 to refuse to transfer a licence.

Item 19 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.

Item 20 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.

Item 21 would insert into section 182 of the Act the wording ‘reviewable decision to reject the application’, thereby removing any doubt that a deemed rejection of an application on account of elapse of time is reviewable under the Act.

Item 22 would add a new subsection 185(3B) 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.