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Gene Technology Amendment Bill 2007

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Glossary of Terms

GMO	genetically modified organism
GRDC	Grains Research and Development Corporation
GTA	Gene Technology Agreement
GTCCG	Gene Technology Community Consultative Group
GTEC	Gene Technology Ethics Committee
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
GTMC	Gene Technology Ministerial Council
OGTR	Office of the Gene Technology Regulator
Regulator	Gene Technology Regulator
RARMP	Risk assessment and risk management plan
Statutory Review	Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement
State	the States, the ACT and Northern Territory
VFF	Victorian Farmers Federation

Gene Technology Amendment Bill 2007

Date introduced: 28 March 2007

House: Senate

Portfolio: Health and Ageing

Commencement: Sections 1 to 3 commence on Royal Assent. Parts 1, 3, 4, 5, and 6 of Schedule 1 and Schedule 2 commence on 1 July 2007, or on the day after Royal Assent, whichever is the later.

Part 2 of Schedule 1 commences on a single day to be fixed by Proclamation, which must be before 1 January 2008, otherwise this Part commences on 1 January 2008.[1]

Purpose

The object of the *Gene Technology Act 2000* ('the Act') is to protect the health and safety of people, and to protect the environment by identifying any risks posed by, or as a result of, gene technology, and by managing those risks through the regulation of certain dealings with Genetically Modified Organism ('GMOs').[2]

The Gene Technology Amendment Bill 2007 ('the Bill') was introduced to the Senate on 28 March 2007 in response to the acceptance by the Gene Technology Ministerial Council ('GTMC') of the recommendations of the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement* ('the Statutory Review').[3] The GTMC is an intergovernmental body comprised of State, Territory and Commonwealth Ministers.

This Bill proposes to implement the Council recommendations requiring legislative change to the Act at the Commonwealth level, which will then require mirror State legislation by the end of 2007. The States would also have to agree to any amendments to this Bill.[4]

The measures include:

- the introduction of emergency powers, giving the Minister the ability to expedite the approval of a dealing with a GMO in an emergency as defined (**Part 1 of Schedule 1**)
- the replacement of the two current committees, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee, with one new Gene Technology Ethics and Community Consultative Committee ('GTECCC') which will provide advice to the Gene Technology Regulator ('the Regulator') and the GTMC on ethics and community consultations (**Part 2 of Schedule 1**)

- 'streamlining' the process for the initial consideration of licences and the 'reduction of the regulatory burden for low risk dealings'[5] (**Part 3 of Schedule 1**)
- clarification on the circumstances in which licence variations can be made (**Part 4 of Schedule 1**)
- clarification of the circumstances under which the Regulator can direct a person to comply with the Act (**Part 5 of Schedule 1**)
- providing the Regulator with the power to issue a licence to protect persons 'inadvertently' dealing with GMOs so as to enable appropriate disposal of such organisms (**Part 6 of Schedule 1**), and
- the making of technical amendments as proposed by the Office of the Gene Technology Regulator ('the OGTR') (**Schedule 2**).

Background

Brief timeline—background to the Gene Technology Act 2000

- 1953. Watson and Crick establish the structure of deoxyribonucleic acid (DNA).
- 1973. Scientists produced the first genetically modified organism, *Escherichia coli* (*E. coli*), implanted with a frog gene.[6]
- 1975. Genetic engineering guidelines were introduced in Australia in order to provide guidance for those involved in a new area of scientific endeavour. The Academy of Science Committee on Recombinant DNA Molecules was established.
- 1978. Genentech, the first company to use the technology, produced human insulin from a strain of E. coli.[7]
- 1980. The Commonwealth Government assumed responsibility for the monitoring of genetic engineering research from the Australian Academy of Sciences.
- 1981. The Recombinant DNA Monitoring Committee (RDMC) was overseeing a voluntary regime. Institutional Biosafety Committees were set up.
- 1986. The first five year review of the RDMC reached the conclusion that Commonwealth gene technology legislation was not necessary because States and Territories were responsible for the release of novel agents.[8]
- 1987. GMAC (The Genetic Manipulation Advisory Committee), a non-statutory body, was established, along with a Group of Officials on Biotechnology Regulations.
- 1997. October. Ministers Anderson, Hill and Moore announced the Commonwealth Government's position on genetic engineering regulation which included the establishment of a Gene Technology Office and a national regulation system.[9]
- 1999. December. The Draft Gene Technology Bill 2000 was released.

- 2000. November. Senate Committee on Community Affairs tables inquiry report: *A cautionary tale: Fish don't lay tomatoes A report on the Gene Technology Bill 2000*.
- 2000. The *Gene Technology Act 2000*[10] was passed along with the *Gene Technology (Consequential Amendments Act) 2000*[11] and the *Gene Technology (Licence Charges) Act 2000.*[12]
- 2001. Dr Sue Meek commenced as Australia's inaugural Gene Technology Regulator on 3 December. The OGTR established.
- 2001. The Act came into force on 21 June 2001.
- 2001. Labelling regulations for foods containing genetically modified ingredients came into force on 7 December 2001. (This is regulated by the *Australia New Zealand Food Standards Code* and the *Food Standards Australia New Zealand Act 1991)*.
- 2001. *Gene Technology Act Regulations 2001* are issued.[13]
- 2001. The Commonwealth, States and Territories signed the *Gene Technology Agreement.*[14]
- 2005. Ms Susan Timbs appointed on 24 May to chair a three person panel to undertake an independent review of the *Gene Technology Act 2000* and the Gene Technology Agreement 2001 as required under section 194 of the Act.
- 2006. In April, the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001* was released.
- 2006. In November, the *State, Territory and Australian Governments' response to the recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001* was released.
- 2006. In December, the *Gene Technology Amendment Regulations* 2006 (No. 1) (SL1 2006 No. 314) were tabled so as to 'remove obsolete provisions, clarify areas of confusion and provide greater flexibility in relation to information requirements for notifications and licence applications'.[15] It came into force on 31 March 2007.
- 2007. On 28 March, the Gene Technology Amendment Bill 2007 ('the Bill') was introduced[16] into Parliament.[17]
- 2007. On 2 April, the OGTR announced that after eleven years of commercial production and distribution in Australia, four carnations have become the first genetically modified organisms (GMOs) to be placed on the Australian 'GMO Register'.[18]
- The *Inquiry into Gene Technology Amendment Bill 2007* by the Senate Community Affairs Committee reported to Parliament on 1 May 2007.[19]

Basis of policy commitment

There are federalism and constitutional issues around the regulation of gene technology, as explained at length in the Bills Digest on the Gene Technology Bill 2000:

> The Bill is intended to operate as a national scheme, requiring complementary legislation at Commonwealth, State and Territory levels. The advantage of a national cooperative scheme is its ability to regulate comprehensively all dealings with GMOs. Although the Commonwealth's constitutional powers relevant to gene technology are extensive,(68) nevertheless, the federal Government does not have constitutional power to regulate every dealing with a GMO.[20]

All States except Queensland and the Northern Territory have imposed moratoria on various dealings with GMOs. The relevant State legislation is set out in table 9 of the Statutory Review report.[21] Jurisdictional bans on the commercialisation of GM canola are still in place, despite the varieties under consideration having been approved for commercial release by the OGTR.

The current Commonwealth government is generally supportive of commercial applications of GM technology.[22] National Party MP John Anderson has recently called for a 'rethink' on the State bans on GM crops on the basis that Australia is 'falling behind in the rapid world growth of more productive biotech crops such as drought-tolerant and pest-resistant strains' and may also face 'food versus fuel fights' over the diversion of crops to biofuels.[23]

Statutory Review

The Statutory Review of the Act was carried out by an independent panel before the fifth anniversary of the Act as required by section 194. Chaired by Susan Timbs, the Review prepared five issues papers, received over 300 submissions and held a series of public forums over an eleven month period in 2005-2006. In addition, the Review Panel sets out other activities in the Report:

> In addition to conducting public forums and stakeholder meetings, the Review visited contained laboratories and field trial sites. In undertaking the review and deciding recommendations, the Review considered material including the submissions received, the issues raised during consultations, the experience of the first four years of operation of the Act, emerging trends and international developments in gene technology and a range of reports and related literature.[24]

The Statutory Review report was released in April 2006. The Review found that the policy objectives of the Act remained valid and recommended the scope of the Act be maintained, but set out some minor changes, 'aimed at improving the operation of the Act at the margins'.[25]

The official response to the Review by the GTMC in November 2006 ('GTMC Response')[26] showed that there was substantial agreement about most recommendations by all State, Territory and Commonwealth Ministers on the Council.

The Ministerial Communiqué states:

> Ministerial Council members today endorsed a State, Territory and Australian Governments' Response to the recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001, noting Queensland's support is subject to Cabinet endorsement. The Review panel presented its report to the previous meeting of the GTMC. While the Review panel found that the objective of the Act – the protection of the health and safety of people and the environment – was being achieved, it highlighted the need for some changes to the regulatory scheme to improve its workability and effectiveness.
>
> In response to the Review, the Ministerial Council agreed to a range of recommendations. The key amendments proposed are intended to adjust application timeframes and reduce the administrative burden on low risk dealings in order to focus the resources of the Office of the Gene Technology Regulator on areas of greatest potential risk to people or the environment. The GTMC heard progress reports on the development of a nationally consistent co-existence framework for genetically modified and non-genetically modified crops, which is being considered by the Primary Industries Ministerial Council. The framework can be assessed for adoption by the States and Territories, which wish to do so, as each jurisdictions' moratorium ends or is reviewed. New arrangements for dealing with emergencies will also form part of the changes.[27]

The amendments contained in this Bill reflect the Ministerial Council's response to the Statutory Review and have been agreed by the States. However, there was not complete governmental accord by the Ministerial Council with the Statutory Review recommendations.

In some cases, where there was not consensus, legislative amendments were not required. For instance, Tasmania and Western Australia did not support recommendation 9.2, namely, that the Commonwealth and States work towards a national framework for co-existence for non-GM and GM crops to address market considerations. Both of these States have expressed a strong stance about preserving the commercial advantage of GM-free crops.

Recommendations 5.8 and 5.9 regarding statutory timeframes failed to gain the support of Queensland.[28]

Senate Community Affairs Committee Inquiry

On 29 March 2007 the Senate referred this Bill to the Community Affairs Committee for inquiry and report by 1 May 2007. The inquiry received fifteen submissions. A Canberra hearing was held on 23 April, with the transcript available here.

Submissions

The OGTR, CSIRO, the Australian Environment Foundation and Department of Health and Ageing support the Bill. The Department of Health submission contains a useful outline of the public consultation process leading up to the Bill.

The industry bodies Monsanto Ltd, Bayer CropScience and Dow AgroSciences Australia Ltd, and Croplife express concerns in similar language about committee composition and the use of the term 'experiments' in relation to 'limited control and release' applications. The Producers Forum (Qld) and Cotton Seed Distributors share this latter concern. The Victorian Farmers Federation ('VFF') also raised concerns about the 'current impasse of minor interest groups opposing any form of GM'[29] and urges due diligence about the appointment process for community representatives.

The Grains Research & Development Corporation ('GRDC') and the Conservation Council of WA express different concerns about 'limited control and release' applications. GRDC and the VFF strongly support the inadvertent dealings provisions in Part 6.

The Gene Ethics and Greenpeace submissions generally oppose the Bill, in particular the emergency dealings provisions. Gene Ethics question whether the Bill itself is a bona fide response to the Statutory Review.

The substantive criticisms of specific provisions of the Bill raised by these submissions are noted in the relevant 'Main Provisions' section of this Digest.

Final Report

The Committee tabled its report on 1 May with the sole recommendation that the Bill be passed without amendment. The Committee concluded that '[t]he Bill…strikes an appropriate balance in managing the potential harms and benefits of developing gene technology'.[30]

Dissenting report - Australian Greens

Senator Rachel Siewert made a dissenting report on behalf of the Australian Greens with the following recommendations:

> That the Gene Technology Amendment Bill 2007 does not proceed

> That if the Bill does proceed, provision should be made so that its use is limited to medical emergencies
>
> That what constitutes a 'threat' needs to be defined within the Act
>
> That the question of guidelines for the emergency powers should be presented to the Ministers at their May 4th Ministerial Council meeting, and the final agreed decision-making criteria should be incorporated into the Act.
>
> That the responsibility for assessing an imminent threat and managing the response to it should reside with the appropriate authority (such as the TGA for a human disease) who might then direct the GTR to make an expedited emergency assessment of a particular gene technology
>
> That a full assessment needs to be undertaken before the release of a genetically engineered or genetically modified organism into the environment.[31]

Financial implications

The Explanatory Memorandum states that the proposed amendments to the Act have no financial impact.

Main provisions

Schedule 1: Amendments to the 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 in order to 'increase the effectiveness of the gene technology regulatory system by increasing its responsiveness'.[32] The Explanatory Memorandum states:

> 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.[33]

Item 1 inserts a definition of *emergency dealing determination* into the definitions subsection 10(1) of the Act, referencing **proposed section 72B** set out below.

Items 2 to 8 update the existing offence provisions in the Act to deal with emergency dealings**. Item 3** substitutes **proposed subsection 32(1)** into the Act to provide that a person commits an offence if:

- he or she deals with a GMO, knowing that it is a GMO, and the dealing:
  - is done without a licence authorising the dealing,
  - is not specified in an emergency dealing determination,
  - is not a notifiable low risk dealing
  - is not exempted from the application of the legislation under the Regulations, and
  - is not 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.

This is a strict liability offence **(items 4 and 5, proposed paragraph 33(1)(ba))**.

Item 8 would insert two **proposed offence provisions, section 35A and 35B**.

Proposed subsection 35A(1) creates an offence for intentionally breaching the conditions of an emergency dealing determination with the penalty of 2 years imprisonment or 500 penalty units (**proposed paragraph 35A(2)(b)**), or for an aggravated offence 5 years imprisonment or 2,000 penalty units (**proposed paragraph 35A(2)(a)**). The penalty is increased 5 times for a corporation.

Proposed section 35B creates a strict liability offence for breaching the conditions of an emergency dealing determination, similar to existing section 35 of the Act. The penalty is 50 penalty units or 200 penalty units for an aggravated offence. Knowledge of the conditions is required.

The Scrutiny of Bills Committee requires a clear explanation in the Explanatory Memorandum when the Government creates a new strict liability offence.[34] In this case, the Explanatory Memorandum states:

> 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.[35]

Gene Ethics respond in their submission:

> This is truly outrageous. The community has consistently asked that the law apply strict liability to GMO licence-holders and GMO users where a GMO causes harm but this has been constantly and almost universally rejected by governments.[36]

Item 10 inserts a **new Part 5A** with the title 'Emergency dealing determinations' into the Act. **Proposed section 72A** creates a simplified outline for the Part.

Proposed 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'.[37]

Normally a legislative instrument is tabled in Parliament and is disallowable. The Explanatory Memorandum states that an instrument made under subsection 72B(1) will not be disallowable because it is in furtherance of an intergovernmental scheme, and would therefore fall under the exemption in subsection 44(1) of the *Legislative Instruments Act 2003* ('the LIA'). The States have to be consulted under paragraph 2(e).

However, an emergency which threatened national security, which is presumably when such a power would be used, may come within the executive power of the Commonwealth and might not require State approval if not for this Bill, unlike the normal cooperative federalism underpinning everyday gene technology regulation.

Proposed subsection 72B(2) sets out the conditions under which the Minister is permitted to make an emergency dealing determination. Before making an emergency dealing determination the Minister must:

- have received advice from the Commonwealth Chief Medical Officer; or the Commonwealth Chief Veterinary Officer; or 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' (**paragraph a**)
- be satisfied him or herself that there is an 'actual or imminent threat' as described above (**paragraph b**)
- be satisfied that the risks posed by the proposed dealings can be managed safely (**paragraph d**), and have received advice from the Regulator to that effect (**paragraph c**), and
- consulted the States (which includes the Territories).

Proposed subsection 72B(3) gives a non-exhaustive list of what might constitute an actual or imminent threat, including

- where there is a threat of plant, animal or human disease

- where there is a threat from a particular animal or plant (such as a pest or alien invasive species), or
- where there is a threat from industrial spillage.

The Explanatory Memorandum gives examples where the new provisions might be employed:

> 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.[38]

The example given in the Statutory Review is of a GM cholera vaccine.[39] However, there is no requirement in the provisions as drafted that the threat be 'serious and immediate'.

Both Gene Ethics and Greenpeace are concerned in their submissions that these provisions will be used to override State moratoria, and that the comparison with other emergency dealings provisions is a false comparison due to the irreversible nature of a GMO release. Greenpeace suggested at the Canberra hearing that a safer mechanism would be for the TGA to make a request to the OGTR to fast-track the release of any required vaccines that are confined to a laboratory rather than what is characterised by unfettered Ministerial determination of threat and risk that results in a GMO released into the environment.[40] Gene Ethics state in their submission:

> For example, 'threat' includes 'pests and diseases' but there is no requirement that the threat be of a particular imminence, severity or scale. The word 'threat' is not explicitly defined yet the Bill proposes that the Minister merely be satisfied that a 'threat' is imminent without requirements or procedures to prove that a 'threat' of the sort envisaged really exists.[41]

Proposed subsection 72B(4) provides that the Minister may make a determination in relation to all dealings with a GMO.

Proposed section 72C deals with dates that the determination takes effect, when they cease, and possible extensions (determinations cannot apply retrospectively).

Proposed section 72D allows a wide range of conditions to be imposed on an emergency dealing determination, including conditions at the complete discretion of the Minister.

Under **proposed section 72E** the Minister may vary the conditions of an emergency dealing determination by legislative instrument, including by imposing new conditions on a determination. Again this instrument would not be disallowable because the exemption in subsection 44(1) of the LIA applies. The Minister can also suspend or revoke the instrument after consultation with the States.

Greenpeace state in their submission in relation to these provisions:

> In addition, while extension provisions of the emergency dealing determinations are detailed at length, any mention of a remedy for a State – or any other entity other than the Minister – to revoke the emergency dealing determination is completely absent. Ironically, a majority of jurisdictions must agree to an extension of the emergency dealing determination, while the agreement of a majority of jurisdictions is not explicitly required to implement an emergency dealing determination (Part 5A, Div. 2, 72C(5)(e) - page 8 of the Amendment).[42]

Gene Ethics makes the following criticism of this proposed amendment to the Act:

> This is an invitation for experimental organisms (perhaps one or many), probably never released into the environment before, to be unleashed on the public and the environment without any assessment processes or public notice at all. This is totally unacceptable and we cannot believe that all the jurisdictions were so tamely stampeded into accepting and allowing this on the basis of a hypothetical worst case scenario – bird flu. If it or other viruses are really the threats we are told, then preparing in a measured and timely way makes sense – being stampeded into giving certain parties too much power is dangerous and against the public interest.

Item 15 updates the OGTR's obligations to provide quarterly reports to the Minister to include information about emergency dealing determinations (**proposed paragraphs 136A(2)(ba) and 136A(2)(bb)**). **Item 16** similarly updates the current record keeping requirements (**proposed subsection 138(3A)**).

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.

Items 19 to 23 generally cross-reference the new emergency dealing determinations into the rest of the Act.

There is no express provision covering compensation from any Commonwealth release of a GMO in an emergency. Such an action would be covered by existing common law actions. Releases by the Commonwealth pose specific compensation issues.[43]

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

Part 2 of Schedule 1 to the Bill would remove the legislative basis of the Gene Technology Ethics Committee (the Ethics Committee) and the Gene Technology Community Consultative Committee (the Consultative Committee). These two committees previously had twelve members each.

The provisions would create a new statutory committee to be known as the Gene Technology Ethics and Community Consultative Committee (GTECCC). It would carry out the functions of both the previous committees as well as take on the new tasks of providing advice on risk communication and community consultation in relation to intentional release licence applications. It will have twelve members.

The Explanatory Memorandum states:

> 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.[44]

The GTMC will review the performance of the new advisory committee after 18 months, but before it has been operating for two years.[45]

The Statutory Review Issues Paper No 2 on the 'Operation of the Act' summarises the commentary from the submissions about the existing committee system.

> The commentary about the statutory committees was divided. However, most of the commentary expressed varying degrees of dissatisfaction with the present committee arrangements.
>
> NGOs and individuals noted that the non-scientific advisory committees have a lack of influence and advocated that all of the committees be given equal standing.
>
> …The membership of the committees was a key theme in submissions from industry groups. While there was strong support for GTTAC, the argument was made that membership of GTEC and GTCCC should be based on expertise and should not be overly representative of those with an agenda based upon non-scientific rationale.[46]

Item 33 replaces subsection 100(7A) to provide that a member of the new combined Committee still sits on the Gene Technology Advisory Committee.

Item 34 would repeal Divisions 3 and 4 of Part 8 of the Act and insert a **new Division 3.**

Proposed section 106 establishes the Gene Technology Ethics and Community Consultative Committee, to be known as the Ethics and Community Committee.

Functions of new Committee

Proposed section 107 sets out the function of the Committee. It is to provide advice, on the request of the Regulator or the Ministerial Council, on matters on which the Ethics Committee (**proposed paragraphs 107(a), (b) and (c)**) and the Consultative Committee (**proposed paragraphs 107(d), (g), and (h)**) currently advises (existing sections 112 and 107). In addition, the Committee would have the new tasks of providing advice on community consultation matters relating to intentional release licence applications (**proposed paragraph 107(e)**); and providing advice on risk communication matters relating to dealings that involve the intentional release of a GMO into the environment (**proposed paragraph 107(f))**.

'Risk communication matters' are not defined in the Act or in this Bill. The Explanatory Memorandum states that risk communication 'involves an interactive dialogue between risk assessors, risk managers and stakeholders. It underpins the processes of risk assessment and risk management'.[47]

There is no detail given as to what the risk communication matters relating to dealings that involve the intentional release of a GMO into the environment might be. The Explanatory Memorandum states:

> 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.[48]

Gene Ethics states in their submission that '[b]oth committees have been largely hamstrung by the Act's requirement that they give advice at the OGTR and GTMC's request'[49] instead of on each licence application as the Technical Advisory Committee does.

Membership

Proposed section 108 relates to the membership of the Ethics and Community Committee. It is in the same terms as the existing sections 108 and 111 of the Act. Although the two committees have been merged, the new committee will have only twelve part-time members, one of whom has to be a member of the Technical Advisory Committee, and one of whom has to be a member of the Australian Health Ethics Committee (**proposed subsection 108(4)**).

Another major change is in **proposed subsection 108(3)** which lists the areas of experience members of the Ethics and Community Committee are required to have. The Minister must not appoint a person as a member of the Ethics and Community Committee unless satisfied that the person has skills or experience relevant to gene technology in one or more of the following areas:

- community consultation
- risk communication
- 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.

The new areas are skills or experience in community consultation and risk communication. Risk communication is an undefined term as noted above.

Remuneration, membership and procedures of the Ethics and Community Committee, the appointment of expert advisors and the regulation-making power are all drafted in the same terms as the equivalent provisions in existing Divisions 3 and 4 of the Act.

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

Timing of Office of the Gene Technology Regulator risk assessments

Part 3 of Schedule 1 seeks to alter the order of events during the initial licence consultation process. Currently the Regulator is required to consider whether an application poses a significant risk to the health and safety of people or the environment (existing section 49) before developing a risk assessment and risk management plan (RARMP) required by section 50 of the Act.

Item 36 would repeal section 49 of the Act. The Explanatory Memorandum states that this is to give the Regulator 'more time to consider whether dealings pose a significant risk'[50], and that the risk assessment before the RARMP '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'.

The risk assessment process contained in existing section 49 still occurs, but at a later stage of the application process. **Item 44** inserts **proposed paragraph (ba)** into subsection 52(2) of the Act. If the Regulator is satisfied that dealings with a GMO pose a significant risk after the RARMP process, then the Regulator should make a statement to that effect in the notice published under subsection 52(1) before the consultation process begins.

Item 45 would insert **proposed subparagraph 52(2)(d)(i)** which provides that the time period for submissions must be at least 50 days if the Regulator is satisfied that the dealings pose a significant risk, and **proposed subparagraph 52(2)(d)(ii)** which would provide for a 30 day time period for all other dealings.

This should therefore provide for a longer statutory 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.[51]

Part 3 would also introduce a new category of licence to distinguish between licences for a limited and controlled release, and licences for intentional release. The Explanatory Memorandum states that 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'.[52]

Limited and controlled release applications

Item 39 would insert **proposed section 50A** into the Act to create a new category of licence application, to be known as 'limited and controlled release' applications.

Item 38 would amend existing 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.[53]

The license application will be classed as a limited and controlled release if the Regulator is satisfied of the following:

- that the principal purpose of the licence sought is to enable *experiments* to be conducted
- 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
- that it is appropriate for section 50(3) of the Act not to apply to the licence **(proposed subsection 50A(1))**

Further clarification of the term 'controls', limits and 'experiments' are provided in proposed subsections 50A(2), (3) and (4). *Controls* can relate to the dissemination and persistence of the GMO, methods for the disposal of the GMO, data collection and 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 (existing section 24) or a technical and procedural guideline (existing section 27): p**roposed subsection 50A(2).**

The Regulator will therefore not be obliged under the Act to consider the issues set out in current subsection 49(2) which is being repealed, except in this framework of limits.

Proposed subsection 50A(3) provides further clarification of the term *limits* in subsection 50A(1). Limits can include limits on the scope, scale, location and duration of dealings with a GMO, as well as limits on the persons who are permitted to conduct dealings with the GMO.

Proposed subsection 50A(4) provides that in determining whether the principal purpose of the licence is to conduct *experiments*, the Regulator must have regard to whether the applicant proposes that any or all of the following be authorised for and done under the licence:

- testing hypotheses
- gaining scientific or technical knowledge
- gaining data for regulatory purposes or for product development or marketing, and
- any other matters that the Regulator considers to be relevant.

In their submissions to the Senate Community Affairs Committee, the industry groups uniformly called for removal of subsections 50A(1)(a) and 50A(4), and subsections 71(2A)(a) from the Bill arguing that the term 'experiment' should be replaced with 'dealings' (see further **item 48** below). As Monsanto argues:

> [W]e do have concerns regarding criteria listed in subsection 50A(1)(a) that requires such applications to have the principal purpose of enabling the licence holder "to conduct experiments". We consider in protecting the health and safety of people and the environment (which under section 3, is the object of the Gene Technology Act), the limits and controls on the proposed dealing are far more important than the purpose of the dealing.

> To illustrate this, during the consideration by the Regulator of Monsanto's application for commercial use of Roundup Ready Flex cotton (DIR 059/2005), our partner seed companies were able to produce limited quantities of seed under the limited and controlled release conditions of DIR 055/2004. This enabled the produced seed to be stored and subsequently made available for use by cotton growers when DIR059/2005 was issued. However these production activities do not fit within the criteria of experiments as defined under subsection 50A(4), and thus in the future would be not allowed under a limited and controlled release.
>
> Excluding such activities from this category only delays access to technology for growers, yet provided the release fits within the meanings of 'controls' and 'limits' , there is no difference in protection of the health and safety of people or the environment.
>
> Other examples of limited and controlled release that may not fit the definition of experiment are seed breeding activities, seed production for export, seed production for shipment to areas in Australia where commercial use of a GMO is allowed (noting that licences on commercial release could contain geographical restrictions due to differing environments in Australia), production of plant-made pharmaceuticals under limited and controlled conditions, and plantings of GMOs to demonstrate use of the technology to growers.[54]

Some of these concerns could be covered by the activity of 'gaining data for regulatory purposes or for product development or marketing' in **proposed subsection 50A(4).**

Gene Ethics states in their submission:

> Most so-called 'trials' are not experiments in any meaningful scientific sense as they primarily test agronomic performance and have no safety or environmental goals at all. Some seed bulking activities, where seed is harvested for export and sale, are even dishonestly labelled 'trials' and allowed under exemptions from state moratoria on commercial growing of GM canola.[55]

Part 4: Licence variations

Existing license system under the Act

The Act revolves around a system of prohibitions and approvals. Every dealing with a GMO currently needs to be licensed by the Regulator, unless the dealing is an exempt dealing, a notifiable low risk dealing ('NLRD') or on the Register of GMOs.[56]

Part 4 proposes amendments which would give the Regulator the power to permit licence variations in certain circumstances. The Explanatory Memorandum states:

> 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.[57]

Item 46 would substitute a **revised subsection 71(1)** and a **proposed subsection 71(1A)** into the Act. **Proposed subsection 71(1)** provides that the Regulator has the power to vary a licence either unilaterally, or after receiving an application from a licence-holder. **Proposed 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 48 deals with circumstances in which the Regulator is not permitted to vary a licence.

Proposed 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 as set out in proposed section 50A. The Explanatory Memorandum states: '[i]n 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'.[58]

See further criticisms by industry groups in relation to limit to 'experiments' rather than 'dealings' as discussed above under **item 38** above.

Proposed 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 50 would insert four new subsections into the Act.

- **proposed subsection 71(5)** provides that the Regulator must consult with any appropriate local council before varying a licence.
- **proposed subsection 71(6)** provides that the Regulations may impose additional limitations on the Regulator's power to vary the licence.
- **proposed subsection 71(7)** provides that the Regulations may set a time limit in which the Regulator must vary, or refuse to vary a licence.
- **proposed 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 inserts **proposed item 4A** into the existing table in section 179 of the Act. The Regulator's decision to refuse to vary a licence would become a reviewable decision, meaning that the licence holder could 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 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, especially if it is in the public interest. The Explanatory Memorandum states:

> 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.[59]

Item 54 inserts **proposed subsection 146(2A)** into the Act which sets out the matters that the Regulator must consider in deciding whether it is desirable in the public interest to make a direction, including:

- the type of the GMO dealing and whether it is a one-off or ongoing dealing, or emergency determination
- whether any measures 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.

Part 6: Inadvertent dealings

Part 6 would allow the Regulator to grant a temporary permit to a person who inadvertently deals 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 Explanatory Memorandum states:

> 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.[60]

Item 55 inserts a definition of 'inadvertent dealings application' into subsection 10(1) of the Act.

Item 56 inserts a **proposed section 40A** to provide for a new category of licence relating to inadvertent dealings.

Proposed subsection 40A(1) provides that a person does not need to apply for a licence in respect of inadvertent dealings with a GMO if they consent, although they can under **proposed subsection 40A(2).** The Explanatory Memorandum states:

> 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.[61]

Items 57 and 58 insert **proposed sections 46A and 49** into the Act. These sections provide 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;

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

The Explanatory Memorandum states:

> 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.[62]

Item 61 would insert **proposed subsection 60(3)** to provide that a licence issued for an inadvertent dealing cannot be valid for a period of longer than 12 months.

The Grains Research and Development Corporation commended Part 6 as a 'sensible solution'.[63]

Schedule 2: Technical Amendments

Items 1 and 2 amend the definition of 'deal with' in existing subsection 10(1) in relation to a GMO by including transport and disposal of a GMO as a dealing.

The other amendments in this Schedule can be understood easily by reference to the Explanatory Memorandum. The original recommendations by the Regulator are contained in Appendix 7 of the Statutory Review.

Concluding comments

This Bill represents the culmination of a long public consultation process and cooperative federalism contained in the Statutory Review process. Any amendments made during the passage of the Bill through the Commonwealth Parliament would have to go through a State approval process.

As the Statutory Review panel sets out in its final report, the issue of gene technology regulation is a polarised field, with strong differences of opinion between the Commonwealth and State governments, farmers and corporations, researchers and community groups. As such, the *Statutory Review* recommendations that form the basis of the amendments in this Bill did not address issues excluded from the *Gene Technology Act 2000* that have remained of ongoing concern to some academics and community groups. Understanding of these ongoing concerns assists in analysing the relative merits of the present Bill, as they primarily relate to differing characterisations or perceptions of risk involved in GM releases.

Emergency Release

One example of ongoing concern, particularly germane to the emergency release provisions in Schedule 1, Parts 1 and 3 of the Bill, is the question of liability for contamination. Suggestions were made in the Review that a compensation scheme akin to that in Denmark for farmers whose GM-free crops are contaminated by the unintended presence of GM plants would be of benefit to Australia. Such a scheme was considered and rejected by the *Review* on the basis that 'existing common law and consumer protection legislation was adequate'.[64]

As the Bills Digest for the *Gene Technology Bill 2000* states:

> There is no provision in the Bill for a statutory right of action or a compensation fund to compensate for a breach of the legislation, nor is there provision for liability or immunity of GM-free farmers…. Persons affected by GMO contamination will continue to have recourse to common law of trespass, public or private nuisance or negligence.[65]

Commentator Charles Lawson has suggested that one legislative solution could entail considering suitable insurance against loss or damage to the broader society, including individual third persons, as a result of releasing GMOs into the environment (including the likely remote and indirect adverse effects causing loss or damage).[66]

The *Statutory Review* concluded that mandatory product insurance for GMOs should not be required. 'The Review considered that the Regulator should retain the existing power under the Act to impose such an insurance condition on a particular release if she considered it warranted by specific circumstances.'[67]

Precautionary Principle

The concern about adequate compensation is linked to a more conceptual criticism made of the regime contained in the Act in that it fails to adequately embody environmental regulatory principles such as the precautionary approach,[68] and that the risk assessment methodology currently undertaken by the OGTR is inappropriate.[69] For example, the Australian Network of Environmental Defender's Offices state in their submission:

> The GTA 2000 is a half-way house; it is partly an Act about biotechnology and biosafety and partly about environmental protection. As a consequence, little guidance is provided to the regulator with Ecologically Sustainable Development (ESD) principles unevenly imbricated into the framework of the Act. This imbalance is compounded as the regulator is arguably more experienced in dealing in matters relating to biotechnology and biosafety than biodiversity.[70]

Environmental commentators see this approach as crucial to gene technology regulation because they characterise the release of a GMO as a 'genie out of the bottle' scenario. As environmental law expert Don Anton expresses it:

> The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. One released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be "recalled". A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.[71]

Limited and controlled release

The aim of the provisions in Part 2 of the Bill is to administratively distinguish between commercial releases and limited and controlled releases of genetically modified organisms (GMOs). This is designed to lower the regulatory burden on researchers testing novel GMOs but still maintain environmental and health and safety standards.

The question posed by this Bill is whether streamlining the licence consideration process and reducing the administrative burden for low risk dealings increases any risk to those standards. The GTMC proposes the changes in order to focus the resources of the OGTR 'on areas of greatest potential risk to people or the environment'.

This may be an area where balancing issues of risk is difficult. Don Anton, Director of the Australian Centre for Environmental Law (ACEL) at the Australian National University, has noted in a submission on the Gene Technology Bill 2000 that due to the nature of biotechnology, any moves towards efficiency in the approval process may 'seriously undermine the purpose of the risk analysis and identification regime' established by the Act.

> [T]he raison d'être of an assessment, including risk assessment, prior to the approval of regulated activity is not to streamline pathways. Indeed, it is just the opposite. As emphasised in *Prineas v Forestry Commission of New South Wales* the purpose of an assessment is "to ensure that government and semi- government bodies properly understand the environmental consequences of carrying out or not carrying out an activity". It is designed to slow things down; to require that we take a "hard look" before doing something that may have irreversible catastrophic consequences.
>
> …Skimping and cutting corners in these areas is an invitation to disaster. The potential dangers to human safety and the environment require robust monitoring, enforcement and compliance requirements, with little consideration to cost.[72]

Composition of the Committee

The composition of the Committee is a matter of concern to the commercial companies who made submissions to the Senate inquiry into this Bill. They have uniformly called for an amendment to the Bill which would ban the appointment of community advocates who are either strongly for or against gene technology.

The composition of the Committee will be linked to perceptions of its independence and robustness. It will impact on the Australian community's trust in the Regulator. Biotechnology Australia mapped the key ethical concerns held by Australians around biotechnology regulation in 1999 and 2001. Spokesperson Craig McCormick summarised the findings:

> Key area of concern that emerged at all phases of the research related to the control of biotechnology and gene technology in Australia and overseas. Most respondents felt

> that biotechnology was changing at such a rapid pace that developments could not possible be anticipated nor legislated against. And it was generally felt that Australian society and government were powerless, compared to the international financial and political power of the large multinational companies who were driving biotechnological innovations.
>
> There was a strong perception that there were no adequate controls over the processes, motivations and outcomes of the development and application of biotechnology and gene technology in Australia. This particularly applied to applications that raised complex and disturbing ethical questions about human life.[73]

To alter the number of committees by combining the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee into the Gene Technology Ethics and Community Consultative Committee may have consequences for public consultation and trust. For instance, while it is argued that the combined committee would enable pertinent expertise to be shared more readily, the proposed arrangement does mean that there will be fewer experts and community representatives in total than at present. Given the comments of the industry bodies, there might be a perception by some groups that these reforms are an attempt to remove a particular member of a current committee.

The Committee has gained the new roles of advising on 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.

As the Regulator Dr Susan Meeks states in her submission to the Community Affairs Committee, community trust in this area of regulation is an important value to maintain:

> While decision-making based on sound science is the fundamental basis of Australia's regulatory system, a factor shared with those of other countries, it is the extensive consultative processes and access to information about applications and licences that sets the Australian regulatory system apart.[74]

Endnotes

1. Explanatory Memorandum, p. 2.
2. For more information on gene technology and GMOs, see further Katrine Del Villar and Angus Martyn, Gene Technology Bill 2000, *Bills Digest* No. 11, 2000-01, 16 August 2000. See http://www.aph.gov.au/library/pubs/bd/2000-01/01BD011.htm
3. Statutory review of the Gene Technology Act 2000 and The Gene Technology Agreement. Canberra: Department of Health and Ageing, 2006. See: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gtreview-report.htm.

The submissions may be found at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gtreview-submisions-index.htm .

The Gene Technology Agreement may be found at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gene-genetechagreement.htm-copy2.

4. Senate Community Affairs Committee. Dept of Health and Ageing submission no. 5, p. 3. See: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_technology/submissions/sub05.pdf
5. Explanatory Memorandum, p. 1.
6. R. Cohen et al. Construction of Biologically Functional Bacterial Plasmids In Vitro. Proc. Natl. Acad. Sci. USA, vol. 70: 3240-3244, 1973.
7. Genentech: *Press Releases* - News Release September 6, 1978. The insulin synthesis is the first laboratory production DNA technology.
8. Recombinant DNA Monitoring Committee. Monitoring recombinant DNA technology: A five year review, Canberra: Department of Industry Science and Technology, 1986. p. 11.
9. John Anderson MP, Senator Robert Hill and John Moore MP. 'New regulatory system for gene technology', Department of Primary Industries and Energy, Press release 327/97, 30 October 1997. See: http://parlinfoweb.parl.net/parlinfo/view_document.aspx?id=853&table=PRESSREL .
10. See current legislation and regulations at: http://www.ogtr.gov.au/pubform/legislation.htm.
11. *Gene Technology (Consequential Amendments) Act 2000*. See: http://scaletext.law.gov.au/html/pasteact/3/3429/top.htm .
12. *The Gene Technology (Licence Charges) Act 2000*. See: http://scaletext.law.gov.au/html/pasteact/3/3430/top.htm .
13. Gene Technology Regulations 2001. See: http://scaleplus.law.gov.au/html/pastereg/3/1664/top.htm .
14. The Gene Technology Agreement 2001SR 106. See: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gene-genetechagreement.htm-copy2
15. Explanatory statement, p. 1.
16. Senator Abetz, Gene Technology Amendment Bill 2007 and Food Standards Australia New Zealand Amendment Bill 2007. Second reading speech, Hansard, 28 March 2007, p. 4. See: http://parlinfoweb.parl.net/parlinfo/view_document.aspx?ID=2416429&TABLE=HANSARDS.
17. A question and answer brochure about the Bill is available at the Gene Technology Ministerial Council web site: *Gene Technology Amendment Bill 2007. Questions and answers.* See:

http://www.health.gov.au/internet/wcms/publishing.nsf/Content/CB6FC13CE59601E7CA25707B0015C90E/$File/Q&A%20Gene%20Technology%20Amendment%20Bill.pdf .

18. OGTR *Media Release*, 'First Genetically Modified Plant On Australian 'GMO Register', 2 April 2007.
19. Senate Community Affairs Committee, Inquiry into Gene Technology Amendment Bill 2007. See: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_technology/index.htm .
20. Katrine Del Villar and Angus Martyn, 'Concluding Comments', Gene Technology Bill 2000, *Bills Digest No. 11* 2000-01, 16 August 2000. See http://www.aph.gov.au/library/pubs/bd/2000-01/01BD011.htm
21. Statutory Review, op cit, p. 40.
22. The Hon Peter McGauran, 'APEC Forum discusses agricultural biotechnology', *Media release*, 24 January 2007.
23. Mark Metherall, 'Grow GM crops or face strife: Anderson', *Sydney Morning Herald*, 28 February 2007, p. 5.
24. Statutory Review, op. cit, p. 3.
25. Dept oh Health, Gene Technology Amendment Bill 2007. Questions and answers. p. 1.
26. State, Territory and Australian Governments' response to the recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001, Canberra, 2006. See: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/CB6FC13CE59601E7CA25707B0015C90E/$File/Governments%20Response%2027%20Oct%2006%20Final.pdf .
27. The Gene Technology Ministerial Council, Communiqué, October 2006, See: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gene-communiques-gtm271006.htm .
28. Recommendation 5.8: states 'The Review recommends that the statutory timeframe for commercial DIR licences be extended to 255 working days (this is consistent with other relevant regulatory systems) to ensure that the Regulator has adequate time for assessment and public consultation'. Recommendation 5.9 states: The Review recommends that a 90 working day statutory time frame be applied to variations for licences and there be an explicit power to allow a licence-holder to apply for a variation.
29. VFF, Senate Community Affairs inquiry Submission No. 15, p. 1.
30. Senate Community Affairs Committee. Inquiry into Gene Technology Amendment Bill 2007. Final Report. 1 May 2007. See: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_technology/report/report.pdf .
31. Dissenting report, Senate Community Affairs Committee. Inquiry into Gene Technology Amendment Bill 2007. 1 May 2007, p. 20. See: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_technology/report/d01.htm
32. Explanatory Memorandum, p. 2.
33. ibid, p. 2.

34. See further, Senate Scrutiny of Bills Committee, Inquiry into absolute and strict liability offences in Commonwealth Legislation, report tabled 26 June 2002.
35. Explanatory Memorandum p. 4 (the text refers to item 6 but must mean item 8).
36. Gene Ethics, Senate Community Affairs inquiry Submission no. 7, p. 4.
37. Explanatory Memorandum p. 4.
38. Ibid, p. 5.
39. Statutory Review, op cit, p. 42.
40. Senate Hansard, 23 April 2007, p. CA1.
41. Gene Ethics, Senate Community Affairs inquiry Submission no. 7, p. 4.
42. Greenpeace, Senate Community Affairs inquiry Submission No. 10, p. 2.
43. Rosemary Polya, Genetically modified governance issues, Canberra: The Department of the Parliamentary Library, 2001, p. 6. (Research paper no. 17, 2000-2001). See: http://www.aph.gov.au/library/pubs/rp/2000-01/01RP17.pdf .
44. Explanatory Memorandum, p. 9.
45. State, Territory and Australian Governments' response to the recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001, Canberra, 2006, p. 7.
46. Statutory Review, Issues Paper No. 2, pp. 13–15.
47. Explanatory Memorandum, p. 10.
48. ibid, p. 10.
49. Gene Ethics, op cit, p. 5.
50. Explanatory Memorandum, p. 12.
51. ibid, p. 13.
52. ibid, p. 12.
53. ibid, p. 13.
54. Monsanto, Senate Community Affairs inquiry submission no 3, p. 2. See: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_technology/submissions/sub03.pdf
55. Gene Ethics, op. cit, p. 5.
56. OGTR website: www.ogtr.gov.au
57. Explanatory memorandum, p. 14.
58. Op cit.
59. Explanatory memorandum, p. 15.
60. ibid, p. 16.

61. ibid.

62. ibid, pp. 16–17.

63. GRDC, Senate Community Affairs inquiry submission no 9, p. 1.

64. Statutory Review, op cit, p. 40.

65. Katrine Del Villar and Angus Martyn, op. cit, p. 21.

66. Charles Lawson, Risk assessment in the regulation of gene technology under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 (Cth), *Environmental and Planning Journal*, vol. 19(3), 195–216, 2002, p. 214. See: http://parlinfoweb.parl.net/parlinfo/Repository1/Library/Jrnart/4QW660.pdf .

67. Statutory Review, p. 42.

68. Sharon Fox et al, 'Biotechnology risk assessment in Australia: a molecular perspective', *Environmental and Planning Law Journal*, 2006, pp: 236–248. See: http://parlinfoweb.parl.net/parlinfo/Repository1/Library/Jrnart/2Z7K61.pdf .

69. Charles Lawson, op. cit, p. 197.

70. Australian Network of Environmental Defender's Offices. *Review of the Gene Technology Act 2000*, 15th July 2005, See: http://www.edo.org.au/edonsw/site/policy/gtareview050928.php

71. Don Anton, Submission to the Senate Community Affairs References Committee in the matter of the Inquiry into the Gene Technology Bill 2000, 29 August 2001.

72. ibid.

73. Craig McCormick, 'Ethical underpinnings of changing community attitudes to biotechnology'. Paper presented to the International Institute for Public ethics Biennial Conference 2, 4-7 October 2002, Brisbane, p. 6.

74. OGTR, Senate Community Affairs inquiry Submission no 1, p. 2.

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