The Senate

Standing Committee on Community Affairs

Gene Technology Amendment Bill 2007

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THE INQUIRY

1.1 The Gene Technology Amendment Bill 2007 (the Bill) was introduced into the Senate on 28 March 2007. On 29 March 2007, the Senate, on the recommendation of the Selection of Bills Committee (*Report No. 5 of 2007*), referred the Bill to the Senate Standing Committee on Community Affairs (the Committee) for report. The reason for the referral was to allow 'further consideration of the Bill and its implications for gene technology regulation, the environment and community safety'.[1]

1.2 The Committee received 15 submissions on the Bill; submissions are listed at Appendix 1. The Committee considered the Bill at a public hearing on 23 April 2007; details of the public hearing are contained in Appendix 2. The submissions and Hansard transcript of evidence can be accessed through the Committee website at http://www.aph.gov.au/senate_ca.

THE BILL

1.3 The purpose of the Bill is to amend the *Gene Technology Act 2000* (the Act) to improve its operation, without changing the underlying policy intent or overall legislative framework of the regulatory scheme.

BACKGROUND

1.4 The Act is the Commonwealth's legislative 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 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).

1.5 In 2005-06, an independent review of the Act and the Gene Technology Agreement 2001 (the Review) was undertaken. The Review concluded that the Act and the national regulatory scheme had worked well in the five years following their introduction. While no major changes were recommended, a number of minor changes were suggested, aimed at improving the operation of the regulatory scheme.

1.6 On 27 October 2006, the Gene Technology Ministerial Council (GTMC) agreed to proposals to implement the recommendations of the Review. The Bill implements those recommendations that require legislative change including:

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1 Senate Selection of Bills Committee, *Report No. 5 of 2007*, Appendix 3.

- introduction of 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);
- improving the mechanism for providing advice to the Gene Technology Regulator (the Regulator) and the GTMC on ethics and community consultations; this will be done by combining the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee into one advisory committee (Part 2 of Schedule 1);
- streamlining the process for the initial consideration of licences (Part 3 of Schedule 1);
- reducing the regulatory burden for low risk dealings by creating a new class of licence for limited and controlled releases of GMOs (Part 3 of Schedule 1);
- providing clarification on the circumstances in which licence variations can be made (Part 4 of Schedule 1);
- clarifying 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 persons who find themselves inadvertently dealing with an unlicensed GMO for the purpose of disposing of that organism (Part 6 of Schedule 1); and
- making technical amendments to improve the operation of the Act (Schedule 2).

1.7 The Minister has commented:

> The quality of this Bill is shown by the strong support it has received from the States and Territories and the approval of the Bill by the Gene Technology Ministerial Council. This is a great example of Australian governments working collectively to ensure that Australia has a world-class regulatory system that protects the health and safety of people and the environment as well as promoting research in this growing industry.[2]

FINANCIAL IMPACT

1.8 The proposed amendments to the Act have no financial impact.

ISSUES

1.9 The amendments proposed by the Bill reflect the recommendations arising from the independent Review of the Act and the intergovernmental Gene Technology Agreement 2001. Having thus resulted from a consultative and deliberative public process of review, the proposed changes were generally understood and supported by

2 Minister for Health and Ageing, *Second Reading Speech*, p. 2.

the submitters to the inquiry. However, the committee heard a number of objections to aspects of the Bill.

Part 1: Emergency dealing determinations

1.10 Part 1 of Schedule 1 to the Bill proposes the introduction of emergency dealing provisions to the Act. The explanatory memorandum to the Bill states that the purpose of these provisions is to 'increase the effectiveness of the gene technology regulatory system by increasing its responsiveness'.[3]

1.11 The proposed emergency provisions will 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 quickly. In this respect, the emergency dealing provisions are intended to further the objects of the Act to protect the health and safety of people and to protect the environment.[4]

1.12 A number of submitters to the inquiry expressed serious concerns about the proposed emergency dealing provisions. Greenpeace and Gene Ethics presented a number of arguments that were representative of opposition to these amendments.

1.13 First, the Committee heard a threshold argument that the emergency dealing provisions went beyond the objects of the Act. Although the EM claimed that the provisions went to the Act's objects of protecting human health and safety and the environment, witnesses argued that these goals were not unqualified. Ms Louise Sales of Greenpeace emphasised that the Act required that such protection be achieved 'by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs'.[5] Ms Sales argued:

> …part 5A of the bill as it currently stands is not intended to protect against risks posed by or as a result of gene technology but rather to bypass the regulatory process and to approve GMOs in cases where the minister is satisfied that there is an imminent threat.[6]

1.14 Second, Gene Ethics objected to what it felt were 'relatively unfettered' ministerial and Office of the Gene Technology Regulator powers under the emergency dealing determinations.[7] Mr Bob Phelps, Director, Gene Ethics, also expressed concern that the use of the term 'threat' in Part 5A was not sufficiently constrained.[8] Gene Ethics' submission argued:

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3 Explanatory Memorandum, Gene Technology Amendment Bill 2007, p. 2.

4 Explanatory Memorandum, Gene Technology Amendment Bill 2007, p. 3.

5 *Gene Technology Act 2000*, Section 3, p. 2.

6 *Committee Hansard*, 23.4.07, p. 1 (Greenpeace); see also *Committee Hansard*, 23.4.07, p. 12 (Gene Ethics).

7 *Submission 7*, p. 1 (Gene Ethics).

8 See *Committee Hansard*, 23.4.07, p. 12-13 (Gene Ethics).

> …'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.[9]

1.15 Third, Gene Ethics felt that the Minister's proposed discretion to make an emergency determination, coupled with the Minister's proposed wide and general discretion for those emergency determinations to apply to specified classes of dealing and GMOs, was broader than that envisaged or agreed to under the Review of the Act. Discussions on these provisions had relied on the particular example of a bird flu outbreak as justification for the use of emergency dealing powers; however, if the Bill were enacted, the Minister could potentially, for example, override State moratoria on cultivating genetically-modified crops.[10] Gene Ethics argued for a narrower potential for application of the powers:

> The Act should be clear that any real threat, of a specified scale, scope and severity to justify the use of the emergency powers…[and] the circumstances…[be] so exceptional as to justify an emergency response to avert widespread impacts on human health or the environment.[11]

1.16 Gene Ethics also objected to the apparent potential breadth of application of the emergency dealing provisions on the grounds that they could allow the release of GMOs without that material having undergone a full risk assessment. Greenpeace stated that all GMOs should undergo a full assessment and that 'this should never be compromised regardless of the severity of any given threat that they may address'.[12] The Gene Ethics submission argued:

> All Genetically Manipulated Organisms must be required to undergo a full risk assessment and this process should not be compromised unless the checks and balances on declaring an emergency are tamper-proofed. Full scientific risk assessments are necessary to the orderly and trouble-free introduction of any and all novel organisms into the Australian environment, including GMOs.[13]

1.17 Fourth, Gene Ethics were concerned that the operational and consultative arrangements envisaged by the Bill—whereby the Minister, in determining that a substantial emergency existed, would have to get the advice of one of three, plus any other, prescribed persons as well as the Gene Technology Regulator—were insufficient to ensure sound decision-making outcomes. The 'novelty and

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9 *Submission 7*, p. 2 (Gene Ethics); see also *Committee Hansard*, 23.4.07, p. 1 (Greenpeace).

10 *Submission 7*, p. 2 (Gene Ethics); see also *Submission 10*, p. 2 (Greenpeace).

11 *Submission 7*, p. 2 (Gene Ethics).

12 *Submission 10*, p. 2 (Greenpeace).

13 *Submission 7*, p. 2 (Gene Ethics).

unpredictability' of GMOs meant that, without a full safety assessment, such consultations were unlikely to deliver reliable advice to the Minister.[14]

1.18 The Department of Health and Ageing and the Gene Technology Regulator responded to these concerns. Ms Mary Murnane, Deputy Secretary, Department of Health and Ageing, commented that the type of emergency envisaged might involve a livestock disease or a human disease where the vaccine against it included a genetically modified organism. The powers under Part 5A would only be exercised 'where there was serious and imminent risk to Australia'.[15] Ms Murnane went on to explain the precautionary and commonsense basis of their intended use and inclusion in the Bill:

> They are last-resort powers. They would be used sparingly and they might never be used at all, but, if they were needed, they would be there to be invoked.[16]

1.19 Ms Murnane was equally clear in saying that there were 'very stringent safeguards' around the use of the emergency powers. She gave as an example of the checks and balances that would confine ministerial decision-making in respect of emergency determinations the need for a recommendation from the Chief Veterinary Officer or the Chief Medical Officer before the Regulator could consider an emergency licence. Also, the Regulator would have to be satisfied that the risks of the emergency release could be managed.[17]

1.20 Ms Murnane also placed the final form of the amendments firmly in the context of the consultation and consensus established by the Review and the negotiations on the implementation of the Review's recommendations. Ms Murnane provided an exhaustive description of the consultative process:

> There was extensive discussion on the emergency powers at a ministerial meeting of the advisory committee on gene technology in Adelaide in October last year…as a result of that meeting, we talked about how these powers would be administered. We agreed on the safeguards of the Chief Medical Officer and the Chief Veterinary Officer and agreed that there would be consultation to the degree that was possible, given the emergency, with all ministers.
>
> Following that, in early December or late November last year, there was a meeting of the Gene Technology Ministerial Council. Issues on the emergency powers were also raised by one jurisdiction. The parliamentary secretary, Mr Pyne, who had responsibility at that stage, answered that and, when the meeting ended, there was agreement on all the clauses of the act. Following that, we continued to refine the detail around the administration,

14 *Submission 7*, p. 2 (Gene Ethics).

15 *Committee Hansard*, 23.4.07, p. 27 (Department of Health and Ageing).

16 *Committee Hansard*, 23.4.07, p. 28 (Department of Health and Ageing).

17 *Committee Hansard*, 23.4.07, p. 29 (Department of Health and Ageing).

> particularly of emergency powers…We had a final teleconference with the jurisdictions about two months ago…[18]

1.21 The Committee was further advised that guidelines for the administration of the emergency dealing provisions had been developed within an 'extensive' process of consultation amongst the various jurisdictions. Ms Murnane described the evolution of the consensus around the content of the guidelines over approximately the last year:

> …there have been a number of discussions at the ministerial council level, at the standing committee level and at a working group level. As part of those discussions, which commenced in Adelaide last year around these issues—or probably a bit before that—we have worked up some guidelines in consultation with the states and territories that go to 'operationalising', if you like, how things will be managed in the case of an emergency.[19]

1.22 Ms Murnane informed the Committee that the substantive content of the guidelines was agreed to by the States as a condition of their acceptance of the proposed regime and, ultimately, the Bill. Consultations had been principled and rigorous, and had delivered an outcome that was acceptable to all parties:

> …there has been extensive consultation with the states and territories, and I think it is fair to say that there has been no rollover in terms of the discussion. It has been very vigorous and very carefully worked through to come to a position where the states were comfortable. I should add that getting comfort on this issue was one of the things that were critical to the states and territories and to their ministers signing off on the legislation.[20]

1.23 The guidelines, because they had not yet been considered and approved by ministers, were not available to the Committee. It is expected that ministers will consider them in early May.[21] The guidelines will have a direct impact on questions of Ministerial discretion in determining the existence of a threat and approving emergency dealings with GMOs which was a major concern for witnesses.[22]

1.24 In response to concerns that the powers under Part 5A could be used to override State moratoria, Ms Murnane informed the Committee that this was not the intended purpose of the proposed arrangements:

> This has to be an imminent and serious risk, so it cannot be something to leverage a preferred policy position on the part of anybody. That is simply not possible. We have to be facing something that is imminent and very serious and, what is more, there has to be a well-established view, supported by the Chief Veterinary Officer and/or the Chief Medical Officer,

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18 *Committee Hansard*, 23.4.07, p. 29 (Department of Health and Ageing).

19 *Committee Hansard*, 23.4.07, p. 30 (Department of Health and Ageing).

20 *Committee Hansard*, 23.4.07, p. 30 (Department of Health and Ageing).

21 *Committee Hansard*, 23.4.07, p. 30 (Department of Health and Ageing).

22 *Committee Hansard*, 23.4.07, p. 3 (Greenpeace).

> that what we are talking about importing is very likely to be a defence against this threat or that it is the best defence we are going to have and that if we do not use it there is going to be risk to either the population or to the economy. So it could only be used where there is a severe and imminent threat.[23]

Committee comment

1.25 The Committee notes that acceptance of the need for emergency dealing provisions has arisen from a consensus established by the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement*. Despite the use of particular examples to illustrate potential uses of the provisions, the Committee observes that the consensus was in fact based on recognition of the special potential for GMOs to provide tailored and/or unique solutions in a range of possible future scenarios.

1.26 The Committee observes that the Minister's discretion to deal with classes of GMOs and to utilise unassessed GMOs is appropriate given the emergency context of their envisaged application under the emergency dealing provisions. The suggested emergency provisions are similar in intent and effect to emergency provisions contained in other Acts, such as Part 3-2 of the *Therapeutic Goods Act 1989*.[24]

1.27 The Committee feels that the emergency character of situations requiring the use of the provisions, and the seriousness with which the relevant authorities view the potential for GMOs to damage or pollute, will ensure that such powers are used appropriately, and possibly only as a last resort. The Committee therefore finds that the proposed breadth of the ministerial discretion and potential application of the emergency dealing provisions are appropriate to their envisaged use and will be sufficiently open to advice, scrutiny and challenge.

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

1.28 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. The ethics and community committee will also provide advice on risk communication and community consultation around intentional-release licence applications.

1.29 The object of these proposed amendments is to increase efficiency by addressing the overlap between the roles of the ethics committee and the consultative

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23 *Committee Hansard*, 23.4.07, p. 29 (Department of Health and Ageing).

24 See *Committee Hansard*, 23.4.07, p. 28 (Department of Health and Ageing).

committee. The new committee would also allow relevant skills to be distributed across its membership so that it would be able to provide clear, balanced, appropriate and more-coordinated advice.[25]

1.30 Submissions from industry stakeholders commented favourably upon the proposed amalgamation of the ethics committee and the consultative committee. Comments in Bayer CropScience's submission exemplify the industry position on the formation of the new committee:

> Bayer CropScience supports the formation of the Ethics and Community Consultative Committee. The one committee to replace the previous two separate committees is viewed as a sensible proposal which would serve the same function as previously and accomplish this in a more efficient way. The one committee, in our opinion, is able to address the relevant issues as proposed in the description of functions.[26]

1.31 Similarly, the Victorian Farmers' Federation submitted that the combining of the two committees was a 'natural progression in providing greater links between risk communication and community consultation…[around] intentional release licence applications'.[27]

1.32 However, Monsanto, Bayer CropScience, Cotton Seed Distributors and CropLife argued that, while they supported the amalgamation of the two committees, the amendments would be improved by a provision preventing a person involved in public advocacy for or against GMO from being a member of the new committee. Mr David Penna, Monsanto, was concerned that persons prone to polarising ideological oppositions could prevent objective decision-making and cooperative relationships in such bodies:

> …we think that the participation of individuals and organisations that are actively campaigning for or against gene technology should not be eligible for inclusion on that committee, simply because their views tend to polarise the committee and the advice given to the regulator and, indeed, may appear to be predetermined…we consider that those campaigning for or against the technology hamper the effectiveness of those committees.[28]

1.33 The Monsanto submission explains that such a provision would be essential to ensuring the impartiality of the ethics and community committee:

> In our opinion, such persons are not necessarily representative of the community and may not present objective considerations or balanced views.[29]

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25 Explanatory Memorandum, Gene Technology Amendment Bill 2007, p. 10.

26 *Submission 4*, p. 1 (Bayer CropScience).

27 *Submission 15*, p. 1 (Victorian Farmers' Federation).

28 *Committee Hansard*, 23.4.07, p. 20 (Monsanto).

29 *Submission 3*, p. 1 (Monsanto).

1.34 At the hearing, the Committee sought to explore how such a limit to membership of the committee might work. In particular, there was some discussion about the practical difficulty of determining what would equate to a person being involved in public advocacy for or against GMO. After some discussion of what might amount to disqualifying behaviour, Mr Kay Khoo for Bayer CropScience conceded that the 'distinction can be difficult'.[30]

1.35 Greenpeace raised concerns that the proposed amalgamation was 'another attack on…[the] check and balance system provided in the original Act'.[31] The amalgamation, according to the Greenpeace submission:

> …effectively eliminates a twelve person committee intended to advise the Ministerial Council and the Regulator, further reducing the potential for public consultation regarding the government's policy on GMOs'.[32]

1.36 Greenpeace acknowledged that there had been concerns raised about the effectiveness of these committees and that a review was required. However, Greenpeace commented that:

> We think that the ineffectiveness of the committees is not an argument for scrapping them altogether. We think they need to be strengthened and made more effective.[33]

1.37 The Department responded that there had been concerns about the efficacy of the working of the two separate committees, from which the Review had concluded that a rationalised committee membership could both streamline and improve the committees' processes and outcomes. Ms Addison stated:

> …there was a sense that the consultation committee and the ethics committee had a degree of overlap in terms of consideration of the issues. The review saw benefit in bringing the two committees together so that the consultation still occurred and, clearly, that the ethical considerations still occurred, but within a streamlined consultation process which would enhance the operation of the act and assist the regulator.[34]

1.38 Dr Sue Meek, the Regulator, also noted that the committees were having difficulty distinguishing their roles. Dr Meek went on to comment:

> It is a situation where trying to get the views in the same room at the same time might actually enhance the quality of the advice rather than trying to in some ways artificially separate these two things. It is very hard to draw the

30 *Committee Hansard*, 23.4.2007, p. 25 (Bayer CropScience).

31 *Submission 10*, p. 2 (Greenpeace).

32 *Submission 10*, pp. 2-3 (Greenpeace).

33 *Committee Hansard*, 23.4.07, p. 6 (Greenpeace).

34 *Committee Hansard*, 23.4.07, p. 23 (Department of Health and Ageing).

> line between the concerns of the community and, if you like, the more formal ethical consideration.[35]

Committee comment

1.39 The Committee acknowledges that in the field of gene technology there is a tendency for proponents and opponents to hold strongly polarised views on the variety of relevant issues. As such, the Committee observes that the arguments contained in the submissions and outlined above reflect valid concerns about the prospective membership of the ethics and community committee.

1.40 However, the Committee has reservations that a provision preventing the appointment to the ethics and community committee of 'individuals/organisational representatives actively involved in campaigning for or against gene technology' could itself become the focus of protracted and possibly emotive conflict, where parties attempted to prosecute debates within, or influence the composition of, the committee.[36] This could see both delays and unwelcome cost attached to the process of making appointments to the ethics and community committee. Such a distinction could risk perverse outcomes in the exclusion of well-qualified individuals from the ethics and community committee. The Committee therefore does not support the proposal for a provision barring membership of the ethics and community committee to people with records of active public support for or against gene technology.

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

1.41 Part 3 of Schedule 1 to the Bill proposes two types of amendment. The first type would alter the order of events during the initial licence consultation process so that the Regulator would no longer be 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.

1.42 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. The Regulator would not, in considering and preparing an application for a limited and controlled release licence, need to seek advice from the States (including the Australian Capital Territory and the Northern

35 *Committee Hansard*, 23.4.07, p.32 (Office of the Gene Technology Regulator).

36 *Submission 3*, p. 1 (Monsanto).

Territory) the Gene Technology Advisory Committee, prescribed agencies, the environment minister and local councils.[37]

Limited and controlled release

1.43 According to the EM, the underlying rationale for these amendments is the recognition that release of a GMO for the purposes of obtaining experimental data will generally be limited in time, spatial scale and location, and employ containment measures to restrict dissemination. In contrast, a person wishing to intentionally release a GMO may wish to produce that GMO commercially, and so would usually 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 limited and controlled releases.[38]

1.44 The issue of the new limited and controlled release licenses was raised by a majority of submissions to the Committee, and was the topic of some discussion at the hearing.

1.45 The Grains Research and Development Council (GRDC) and Greenpeace identified potential problems in the approval processes for the proposed new limited and controlled release licenses. Both organisations were concerned with the removal of the requirement that the Regulator seek advice from the States and various bodies.[39]

1.46 Dr Meek advised the Committee that the operation of the provisions was being misunderstood, and that limited and controlled release applications were only to be exempt from the consultative process that was required at the application stage; limited and controlled release applications would still be subject to the required consultation around the preparation of the risk assessment and risk management plan. Dr Meek explained:

> At the present time, all applications for a release into the environment require two rounds of consultation. One is on the application…That grouping is consulted at that point in relation to the application, and then when a risk assessment and risk management plan is prepared by my office that same group of people is consulted, as is the public…The proposal in the context of the controlled release is that, rather than having two rounds of consultation—one on the application and one on the risk assessment and risk management plan—there will be one round of consultation when the risk assessment and risk management plan has been prepared.[40]

37 Explanatory Memorandum, Gene Technology Amendment Bill 2007, pp.12-13.

38 Explanatory Memorandum, Gene Technology Amendment Bill 2007, p.13.

39 *Submission* 9, p. 5 (Grains Research and Development Corporation); *Submission 10*, p. 2 (Greenpeace).

40 *Committee Hansard*, 23.4.07, p. 31 (Gene Technology Regulator).

1.47 Representatives of Monsanto, Bayer CropScience and CropLife approved of the proposal for the new class of limited and controlled release licenses. The Monsanto submission, for example, states:

> Monsanto strongly supports the creation of this category as it should improve process efficiency, and allow the Regulator's resources to be focused on assessing less controlled releases.[41]

1.48 However, Monsanto expressed concern that the application of the provision was to be limited by the purpose rather than the perceived risk of an intended dealing. Limited and controlled release licenses would be granted only 'to conduct experiments', which would exclude dealings such as 'seed increases on a small scale'.[42]

1.49 In response, Dr Meek explained to the Committee that the distinction between commercial and experimental dealings was a continuation of the operation of the previous Act. Thus the restriction of the limited and controlled release licenses to experimental dealings was both consistent and justifiable. The example of seed production used by some submitters was clearly an example of a commercial dealing, Dr Meek said.[43]

Committee comment

1.50 The hearing provided the opportunity for an improved understanding of the intended operation of the Bill with regard to consultation around limited and controlled release licences. Accordingly, the Committee supports the passing of the provisions of Part 3 without amendment.

Inadvertent dealings

1.51 Part 6 of 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.

1.52 The object of these amendments is to allow a person who has unintentionally come into possession of a GMO to dispose of the GMO without breaching the Act. Currently under the 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.[44]

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41 *Submission 3*, p. 2 (Monsanto).

42 *Submission 3*, p. 2 (Monsanto).

43 *Committee Hansard*, 23.4.07, p. 32 (Gene Technology Regulator).

44 Explanatory Memorandum, Gene Technology Amendment Bill 2007, p. 17.

1.53 All evidence received by the Committee on this issue, in both the submission and hearing evidence of the GRDC, supported these amendments as necessary and appropriate. GRDC stated:

> The amendments would provide a sensible solution to allow individuals who unintentionally come into possession of a GMO to dispose of the GMO without breaching the Act.[45]

Committee comment

1.54 The Committee supports the passing of the provisions of Part 6 without amendment.

CONCLUSION

1.55 The Committee observes that the Gene Technology Amendment Bill 2007 will institute a number of changes arising from the recommendations of the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement*. Despite concerns expressed about the operation and construction of the amended and new provisions, the Committee considers that the amended Act will reflect the spirit and substance of the Review recommendations, whilst retaining sufficient transparency and oversight to ensure confidence in the actions and decisions of the Regulator. The Bill therefore strikes an appropriate balance in managing the potential harms and benefits of developing gene technology.

Recommendation 1

1.56 The Committee reports to the Senate that it has considered the Gene Technology Amendment Bill 2007 and recommends that the Bill be passed.

Senator Gary Humphries
Chairman

May 2007

45 *Submission 9*, p. 2 (Grains Research and Development Corporation).

Dissenting Report

Gene Technology Amendment Bill 2007

Senator Rachel Siewert, Australian Greens

The Australian Greens do not support the introduction of emergency dealing provisions to the Act. We have serious concerns about the implications of such a provision.

This provision would essentially enable the fast-tracking of a probably untried Genetically Modified Organism (GMO) into the environment to solve an emergency unrelated to GMOs.

The proposal is to dispense with full assessment of the potential impact of release of a GMO, not merely expedite it.

We are deeply concerned that an organism may be released without any fail-safe device and will be beyond recall, possibly forever.

GMOs released into the environment without proper assessment and testing may have potentially dangerous consequences.

Even with full assessments, mistakes can happen. For example the *Klebsiella planticola* case, in which a GM microbe for producing ethanol on farms was approved by USDA, but when independently tested just prior to release was found to continue producing ethanol in soil where it would destroy susceptible plants (ie: most of them). It was stopped at the 11th hour.

There are a number of other international examples of the release of genetically engineered organisms resulting in harmful unintended consequences, despite some testing prior to their release. For instance in Brazil GE soya beans incorporating a nut gene produced severe allergic reactions in some people and had to be withdrawn. In the US the release of herbicide tolerant GE crops has led to an escalation of their weed problem, and there is a higher number of people manifesting allergies to GE corn and soya products.

Recently we had the situation where the ANU conducting research feeding genetically modified peas to mice. CSIRO modified the peas to contain a bean gene which was intended to produce resistance to pea weevils, resulting in a substantial change to the protein produced by the peas. The mice developed a hypersensitive skin response, and some experienced airway inflammation and mild lung damage. This could have had serious consequences if it had been released.

Mr Jeremy Tager's example to the committee hearing was very pertinent:

> **Jeremy TAGER**— "…And the notion of trying to deal with an emergency with a GMO that has not been tested has the potential to be an even worse cure. I think there is ample evidence and ample concern, even in the Gene Technology Act, that one of the reasons for having a regulatory regime is that the risks associated with GMOs are not well understood and need to be fully assessed.
>
> If I can throw in a personal note here, I remember that my father was working for the National Institute of Health in the 1950s when they rushed through a polio vaccine with the notion that this was an emergency that needed dealing with. They ended up killing more people than they saved with that particular vaccine. I think it is a highly risky activity to put that in the hands of a regulator, particularly a regulator that is, in our view, so politicised, and has tended to be very in favour of genetically engineered organisms, as has the current government."

The existing provisions for the testing of genetically engineered and genetically modified organisms prior to their release into our environment and community are there for a good reason. They reflect widespread community concerns about genetic engineering and embody community standards.

Triggers and levels of threat

The Greens are concerned about the triggers and level of threat necessary for declaring emergencies.

We are particularly concerned about the triggers for declaring emergencies. For instance Ms Murnane (Deputy Secretary, Department of Health and Ageing) said in evidence to the committee that some sort of economic threat may be considered a trigger for these provisions. The Greens do not accept that an economic threat would be significant enough to justify the release of Genetically Modified Organisms (probably experimental) which have not been properly tested and assessed, and which might pose an unknown and potentially unacceptable risk to human health or the environment.

> **Ms Murnane**—I will give you a precise one: we might have either a livestock disease in Australia or a human disease in Australia where the defence against that was a vaccine that included a genetically modified organism. To allow the rapid importation of that vaccine into Australia, there would need to be a pathway that was much faster than the pathway as laid down in the act for all normal circumstances. This would be regarded as a power that would only be exercised, as a clause that would only be exercised, where there was serious and imminent risk to Australia in the form of some sort of economic threat, say, to animals, or some form of human threat, say, in the nature of an epidemic—and we are not saying that this is going to happen imminently, but we need to

> be prepared should there be an influenza pandemic or another disease where we needed a rapid decision made to import a pharmaceutical, probably a vaccine, that contained a genetically modified organism.

The notion that these powers could be invoked for economic reasons is unacceptable, particularly when the release of an experimental organism could in itself pose an unknown economic or environmental health risk.

We also question how a situation might arise where there was a vaccine for a serious livestock disease that posed a major economic threat to Australian livestock that was already in use, for instance in the USA … and yet Australian livestock authorities were not sufficiently forewarned of this threat to get the assessment process underway before there was a major outbreak. We already have more than enough examples in Australia of hasty interventions where the 'cure' has proved a greater problem than the 'disease'. We do not want to see another repeat of the Cane Toad merely because corners were being cut to minimise economic impacts of a known threat to a particular industry.

The Greens believe that if this amendment proceeds it should be limited to medical emergencies.

The Bill does not specify the level of threat required to trigger the emergency dealings provisions as Gene Ethics said 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.
>
> The Act should be clear that any real threat, of a specified scale, scope and severity to justify the use of the emergency powers, is reviewed and confirmed by all jurisdictions and that the circumstances are so exceptional as to justify an emergency response to avert widespread impacts on human health or the environment.

Given that the Minister is being required to make a decision in response to a particular threat which also inherently contains an element of risk … it would seem negligent to be introducing a system in which the scale of the threat, the likelihood of adverse outcomes and the relative costs of acting or failing to act are not considered in light of the potential risks posed by an adverse outcome from the introduction of an unassessed GMO. This should be required in the legislation.

We understand from evidence to the committee hearing that the Ministerial Council is currently considering guidelines relating to the emergency provisions.

> **Ms Addison**—To add to the conclusion, as Ms Murnane and Dr Meek have said, there have been a number of discussions at the ministerial council level, at the standing committee level and at a working group level. As part of those discussions, which commenced in Adelaide last year around these issues—or probably a bit before that—we have worked up some guidelines in consultation with the states and territories that go to 'operationalising', if you like, how things will be managed in the case of an emergency. Those guidelines were signed off at the last steering committee and will be considered by ministers on 4 May. I cannot release them for you today because they still need ministerial consultation, but after 4 May, if the ministers agree with them, we would be happy to share them. I should add that there has been extensive consultation with the states and territories, and I think it is fair to say that there has been no rollover in terms of the discussion. It has been very vigorous and very carefully worked through to come to a position where the states were comfortable. I should add that getting comfort on this issue was one of the things that were critical to the states and territories and to their ministers signing off on the legislation.

This clearly suggests that there are residual concerns with this provision which it is hoped the guidelines will finally put to rest. Given the uncertainty that remains within the Act of what constitutes a sufficiently imminent threat and how possible response strategies might be assessed, it seems that the completion and approval of these guidelines would be a prudent and necessary first step before the introduction of the Bill. Further it would seem more appropriate that such guidelines are incorporated into the Bill.

Objects of the Act

Another witness suggested that the emergency provisions were not properly implementing the findings of the review of the Act, which they believed were that there was a need to put into place emergency provisions to be able to quickly respond to an emergency situation of imminent threat that was created by the release of a genetically engineered organism.

> **Senator SIEWERT**—If I understand your submission and the Gene Ethics submission, you do not believe that this is accurately reflecting the outcomes of the review of the Act. What we are being told is that this is actually implementing some of the reviews of the Act and that—

> **Mr Tager**—The way it reads is that the Office of the Gene Technology Regulator noted that they did not have emergency provisions. They use the example of, I believe, bird flu. I think that the notion of emergencies is absolutely correct but that these provisions have it the wrong way around. It should be dealing with emergencies associated with release of GMOs that are not approved and are potentially or actually dangerous—in other words, an imminent threat themselves. This is asking the Minister, via either the regulator or another adviser, to declare that a non-GMO threat exists, and this is where

> we think it is beyond the ambit of the Act and that the Office of the Gene Technology Regulator or other advisers to the Minister simply bypass the assessment provisions. It seems well beyond what was in the review document and what the regulator pointed out in her submission.

This raises the question as to whether the proposed changes in fact lie outside of the ambit of the Act. The Object's clause is very clear in this regard:

> **3 Object of Act**
>
> The object of this 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 GMOs.

It is very clear from this that the legislative intent of the Gene Technology Act 2000 is to identify and manage risks that are posed by gene technology. To the extent that the emergency declaration provisions clearly relate to risks that arise as a result of matters that are not associated with genetically engineered organisms, they appear to lie outside the intended ambit of the Act and assessment of the level of threat they pose lies outside of the ambit, the experience and expertise of the Office of the Gene Technology Regulator.

Surely if there's a medical emergency, the Therapeutic Goods Administration's emergency powers would be first invoked, and we would expect the TGA to have access to the necessary knowledge, skills and experience to be able to evaluate the threat to human health. The relevant experts and officials would look for solutions, which may or may not include GMOs. We would not necessarily expect this expertise to reside within the GTR, and developing or retaining it would be an expensive exercise.

Likewise with an animal disease - the APVMA's emergency powers would be invoked, relevant expertise called upon, and solutions would be sought, which may or may not include GMOs.

If we are to have emergency provisions to allow a rapid response to an imminent threat, then we should be making sure that the most appropriate body is assessing the threat and coordinating the response. In the case of a human vaccine responding to a serious outbreak of a major disease this might, for instance, result in the TGA declaring a medical emergency and requesting that the GTR make an emergency assessment of a genetically engineered vaccine.

To give the Health Minister and GTR the primary power to respond to an emergency with GMOs might shut down full consideration of all the options which may include safer and more conservative solutions.

In the case of a genetically engineered human vaccine that is responding to the threat of an outbreak of a particular disease, it would be necessary to vaccinate a much larger number of people who have the potential to contract the disease than those who might actually be exposed and contract the disease for the epidemiological containment response to be effective. Where the vaccine contains a genetically engineered organism which is untested and may have adverse affects on some or all recipients, this has the potential to impact on a much larger population than otherwise may have been affected. This is why there are currently such stringent assessment criteria applied to vaccines and why we should not consider by-passing them without a very stringent risk assessment process.

Recommendations

1. **That the Gene Technology Amendment Bill 2007 does not proceed**
2. **That if the Bill does proceed, provision should be made so that its use is limited to medical emergencies**
3. **That what constitutes a 'threat' needs to be defined within the Act**
4. **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.**
5. **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**
6. **That a full assessment needs to be undertaken before the release of a genetically engineered or genetically modified organism into the environment**

Senator Rachel Siewert
Australian Greens

APPENDIX 1

Submissions received by the Committee

1 Office of the Gene Technology Regulator (ACT)
2 CSIRO (ACT)
3 Monsanto Ltd (VIC)
4 Bayer CropScience (VIC)
5 Department of Health and Ageing (ACT)
6 Conservation Council of WA (WA)
7 Gene Ethics (VIC)
Supplementary submission received 24.4.07 and 26.4.07
8 Dow AgroSciences Australia Ltd (NSW)
9 Grains Research & Development Corporation (GRDC) (ACT)
10 Greenpeace Australia Pacific (NSW)
11 Cotton Seed Distributors Ltd (NSW)
12 CropLife Australia (ACT)
13 Australian Environment Foundation (AEF) (ACT)
14 Producers Forum (QLD)
15 Victorian Farmers' Federation (VIC)

APPENDIX 2

Public hearings

Monday, 23 April 2007
Parliament House, Canberra

Committee members in attendance

Senator Gary Humphries (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator Rachel Siewert

Witnesses

Greenpeace Australia Pacific

Ms Louise Sales, Community Organiser, Genetic Engineering
Mr Jeremy Tager, Campaigner, Genetic Engineering

Grains Research and Development Corporation

Mr Andreas Betzner, Manager Gene Discovery
Mr John Harvey, Executive Manager Varieties
Mr Zoltan Lukacs, Corporate Strategist Evaluation & Reporting

Gene Ethics

Mr Bob Phelps

Monsanto Ltd

Mr David Penna, Regulatory Affairs Lead, Australia and New Zealand

Bayer CropScience

Mr Kay Khoo, Manager, Regulatory, Public and Government Affairs

Department of Health and Ageing

Ms Linda Addison, First Assistant Secretary; Regulatory, Policy and Governance Division
Ms Mary Murnane, Deputy Secretary

Office of the Gene Technology Regulator

Dr Sue Meek, Gene Technology Regulator