MINORITY REPORT

GENE TECHNOLOGY BILL 2000

BY GOVERNMENT SENATORS

The Government believes that the *Gene Technology Bill 2000* adequately meets its objectives in designing a key piece of legislation that aims to protect both the public health and safety of Australians and the environment from the risks associated with gene technology. The Bill also has strong support from the States and Territories.

Vast consultation across the board, from organisations, to individuals to government has occurred in structuring the Bill as it stands. This high degree of consultation is unprecedented and any alteration now has the very real potential to jeopardise its implementation.

Government Senators would make the following observations about some of the recommendations that have the potential for such uncertainty.

Chapter 3

Risk assessment provisions currently in the Bill give sufficient weight to the consideration of the impact of the release of GMOs into the environment especially given Australia's unique flora and fauna and mindful of maintaining Australia's biodiversity. Measures to achieve this outcome include the establishment of a statutory officer (the Gene Technology Regulator), the prohibition of people from dealing with GMOs except in certain circumstances, the establishment of a scheme to assess human health and environmental risks in various dealings with GMOs, provision for monitoring and enforcement of the legislation, and the establishment of three key advisory committees each dealing with different aspects of gene technology.

Commercial in confidence provisions in the Bill are designed in order not to compromise the objectives of the Bill or dilute the transparency of the regulatory regime. If a licence applicant desires that certain information be protected, the GTR must assess each case individually and make a decision. If the GTR decides the release of information may be detrimental to an applicant, he or she may decide that the public good outweighs the interests of the applicant.

Independent review of the Act in three years is not practical for, as with any new scheme time is required to implement it fully. The Government is not amenable to any review before five years. After this time it is expected that review can more competently be performed after the legislation has been given sufficient time to be bedded down.

Chapter 4

The Committee recommendation concerning financial interest provisions overlooks provisions that already exist in the Bill. Strong conflict of interest provisions ensure that the Regulator is required to disclose to the Minister all interests, pecuniary or otherwise, that may conflict with the performance of his or her functions.

Precluding an individual who has worked for a regulated entity from holding the office of the Gene Technology Regulator for a two-year period is problematical. By virtue of the fact that this field is limited, this recommendation is totally impractical. As long as an individual declares his or her interests, an application must be assessed on a merit only basis.

The Government Senators are not opposed to the Bill being amended to require quarterly reporting, however provisions for reporting relevant breaches of licence conditions are already present requirements in the Bill.

The Government Senators however, are *entirely opposed* to the notion of the establishment of the Regulator as a Statutory Authority consisting of three people who will take the ultimate responsibility for decision making. This proposition is economically unviable, given the size of the GTR (50 people). Establishing the office as a Statutory Authority would cost at least an additional $500,000 a year. It would also be impossible to quantify the gain in establishing a Statutory Authority, given the high level of independence already achieved within the Bill.

Consideration of the feasibility of introducing a 'one-stop shop' model having regard to the operational effectiveness of the proposed 'gap-filler' arrangements is already something the Government is attempting to do. It is desirable that the arrangements as they stand encourage the 'one stop shop' concept however, continuing to be mindful that different authorities look after different areas of responsibility.

The Bill does creates a 'one-stop shop' for biosafety assessment of all GMOs and GM products by establishing a centralised national regulator who carries out risk assessment of all GMOs and GM products. This allows for the GTR to act as a centralised area of expertise that will make advice on GM products to other regulators. It also minimises duplication by employing strategies to improve the interface between regulators.

Significantly, this method will be able to be implemented in a shorter timeframe than a complex single agency to regulate all GMOs and GM products, which would take a great deal longer to establish and would fail to meet community and industry demand for a fully operational GTR by 2001.

In May 2000, the Federal Government established the Regulatory Reform Taskforce within the Department of Health and Aged Care in response to calls from consumers and industry for better coordination of public health regulators. The Taskforce is examining the current administrative arrangements for this regulation at Commonwealth level and will identify ways to improve it.

The Committee acknowledges that the proposed structure provides the option that ensures all aspects of the production, manufacture and sale of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. The system in the Bill guarantees the Regulator either directly regulates or provides advice to specific regulators on all GMOs and GM products.

The Government Senators believe that the assessment of environmental risks can be better met through the Gene Technology Bill rather than the *Environment Protection and Biodiversity Conservation Act 1999.* The objectives of the Bill are to meet environmental safety concerns in conjunction with human health and safety provisions. The GTR has been placed under the Health portfolio in this context. The issue of GTR flexibility is also a major point and risk assessments should be performed on a case by case basis whereby the Regulator must be afforded the flexibility to assess each case individually.

Listing of broad categories of risk once again addresses the notion of flexibility for each application on a case by case basis. The absence of prescriptive categories of risk was intentional because of the fact that there are so many varying types of GMOs that the Regulator will be required to assess. There are however, some broad categories of risk prescribed in the regulations, which the Regulator may take into account.

The Committee believes that the Regulator, when setting licence conditions may satisfy him or herself that applicants have made provisions with insurers for suitable coverage to protect them against the risks associated with the dealings.

Mandatory review or renewal of licences granted by the Regulator is provided for in the Bill and there is capacity for review at any juncture or time.

The Committee agrees that the ultimate responsibility lies with the applicant to provide adequate scientific support for its case to the Regulator. The Regulator is then obliged to make a decision based on independent assessment and evaluation of data provided by the applicant and then further through the public and committee processes. The Regulator will ensure, as much as is possible, that contamination of non-genetically modified produce or land cannot occur.

The Bill provides a number of requirements afforded to the Regulator to monitor compliance with the legislation. Provisions include the imposition of conditions, monitoring of compliance with these provisions, obligations to report, investigative powers addressing alleged breaches, enforcement powers and penalties.

Recommendations concerning licence holders to guarantee compliance is not necessary given companies will also monitor progress with dealings. The Regulator will also have the power to impose conditions to limit contamination and vary a licence, including imposing additional conditions or confiscating or altering existing conditions.

Furthermore, the Regulator is provided by the legislation with the following ways in which to monitor compliance with conditions. The GTR may require regular auditing

to be undertaken by a licence holder and reporting to be made to the Regulator. Routine audits may also be undertaken, as might 'on-the-spot' inspections or audits of dealings with GMOs.

The legislation allows for the Regulator to appoint inspectors for the purposes of investigating alleged breaches. In the event of non-compliance, the legislation describes a range of investigative powers that may be used by inspectors for determining whether a breach has indeed occurred.

Inspection powers are similar to those granted to the Australian Federal Police, Customs agents and inspectors appointed under the Therapeutic Goods Act and are substantial, and consistent with Commonwealth criminal law policy.

The 1999 Draft Bill has been amended to respond to requirement for monetary penalties in the instance of breaches of licence conditions, to reflect concerns that arose in previous consultation.

Provisions for penalties are clear and the Government believes suitably fitting. Offence provisions and penalties are consistent with criminal law policy and are significant in comparison to other regulatory schemes. It is clear that the Government has adequately introduced strict liability offences to the Bill. In the case of a breach of condition that causes significant damage to the health and safety of people or the environment, there are two alternative monetary penalties that may be pursued.

While the Government Senators recognise that there is a degree of anxiety about the issue of cost recovery, the policy is one hundred percent cost recovery. A KPMG Inquiry has determined that the annual cost for the first couple of years will be approximately $7.8 million. The Productivity Commission is in the process of looking at this issue and a draft report is due in March 2001.

Chapter 5

There is a requirement in the legislation that cross membership of the three advisory committees exist however, the Government Senators are not in favour of increasing the role of either the Community Consultative Group or the Ethics Committee.

The Committee believes that the Gene Technology Technical Advisory Committee should essentially be comprised of members who are capable of providing to the Ministerial Council and the Regulator scientific information and advice.

The function of the Gene Technology Community Consultative Group is to provide advice on matters of 'general concern' and will be consulted only in relation to general principles or guidelines, not in relation to specific decisions.

An increased role for either or both of these Committees would be entirely detrimental to the science-based decision making process. It would also be contrary to every other country's risk assessment policy and furthermore creates absolute uncertainty in the

process. Other foreseeable problems include unacceptable delays, increased costs for the OGTR and the possibility of leakage of in-confidence information.

Consultation by the Ministerial Council of the three Committees when issuing policy guidelines is both impractical and unworkable. The Ministerial Council is essentially political. This measure would also contribute to implementing another laborious procedure. The Bill as it is, is exceptionally consultative and need not be more so.

As a result of other mechanisms in the Bill, there is adequate opportunity for community input on individual applications. This high level of community involvement in decision making is unprecedented in most existing regimes.

It is not necessary to incur additional costs and resources to duplicate the process by allowing the Gene Technology Community Consultative Group to examine individual applications.

While the Bill does not directly provide for third party appeal, mechanisms exist for appeal. There are adequate opportunities for third parties to express discontent throughout the open process of assessment. It was also considered appropriate by the Government in conjunction with the States and Territories, that the right to review by the AAT to those directly affected by a decision would be limited. This was because of a number of issues including the concerns of the time and cost resources that would have to be donated to review after an already lengthy consultation process.

In addition, by limiting review to those immediately affected, the prospect of vexatious appeals is significantly reduced or eliminated and is consistent with Commonwealth policy. This is also consistent with similar legislation and hence the Government Senators believe is more than appropriate given the lengthy consultative process.

Also, by allowing the States appeal to the AAT, individuals are able to appeal to the State to make a representation on their behalf to contest the merits of a decision made by the Regulator.

Chapter 6

Provisions in the Bill requiring the Regulator to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions has already been taken into account, in part through the States and Territories role in the Ministerial Council. It is imperative that the integrity of a strong national regulatory system be maintained – it cannot afford to be fragmented.

Government Senators believe it is acceptable to allow the results of breaches to be made publicly available. However, issues such as the cost and manpower required to audit and publicly report *all* dealings are impractical. Not only would this be expensive and time consuming, it would not allow for the flexibility to spend more time on high-risk GMO dealings.

Conclusion

This legislation is being introduced to coordinate a national regulatory system that is transparent, open and heeds stringent regulatory processes. The emergence of growing debate about gene technology and its consequences has highlighted the urgent need for a piece of legislation such as the *Gene Technology Bill 2000* and its implementation is well timed.

The community at large has been extensively consulted, as have the States and Territories.

The Government Senators strongly believe that measures in the Bill ensure that all aspects have been fully addressed in the objectives set out. We also believe that an independent and rigorous system needs to be implemented in as timely a fashion as possible. Any alteration to the Bill at this point is likely to severely jeopardise this occurring.

We recommend that the Bill proceed as soon as possible in unamended form.

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