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Submission to the Senate Community Affairs Committee on the Gene Technology Amendment Bill 2007

Introduction

We have serious concerns about some aspects of the Gene Technology Amendment Bill 2007 and do not think it fairly or fully reflects the decisions of the Gene Technology Ministerial Council and the governments' responses to the recommendations of the Timbs review of the Act. Our particular objections are to the relatively unfettered Ministerial and OGTR powers under Part 5A – 'Emergency Dealing Determinations' - and deletions from the Gene Technology Act 2000 which would remove important consultations, advice and other procedures that generally create checks and balances. For instance, the Regulator would be enabled to bypass essential advice that is now required on field trials.

Submission

The communiqué from the Gene technology Ministerial Council following its consideration of the Timbs Review of the Act says:

"The Australian Government intends to introduce legislation in relation to this recommendation. The provisions would enable the Minister responsible for the Act to issue a special licence following advice from the Chief Medical Officer, the Chief Veterinary Officer and/or Chief Plant Protection Officer that there is an emergency; and **on advice from the Regulator and in consultation with the States.**"

The Bill does not fully reflect the GTMC's intention. The communique continues:

"The Minister must not issue the licence unless the Regulator is satisfied that any risks posed by the dealings proposed by the licence are able to be managed."

This sort of statement reflects the inherent problems of the Act and the proposed amendments. They do not contain any objective, scientific criteria or standards, established in advance, by which these issues can be judged. This ad hoc approach to decision-making characterizes all the OGTR's processes and determinations and it will be doubly dangerous under emergency conditions. Moreover:

"An emergency is when there is an actual or imminent threat to the health and safety of people or to the environment. The licence would be in relation to an activity for a GMO which is intended to address the threat; including activities to minimise or eradicate the problem organism, its vectors, or to convey immunity in humans and/or animals."

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.

The provisions of Part 5A – 'Emergency Dealing Determinations', Divisions 1-3 of the Amendment, ("Part 5A") give sweeping Ministerial discretion and there are few constraints. 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.

In addition, the dealings in respect of which the Minister may make an emergency dealing determination may be (a) all dealings with a GMO or with a specified class of GMOs; or (b) a specified class of dealings with a GMO or with a specified class of GMOs; or (c) one or more specified dealings with a GMO or with a specified class of GMOs (Part 5A, Div. 2, 72B(4)) (P. 7 of the Amendment). This Bill is in no way restricted to vaccines for bird flu that have been given as an example to justify giving the Minister such extraordinary powers.

Gene Ethics wants the law, agreed to by all Australian governments, to be absolutely clear that the Minister's powers could not be used, for instance, to override State GE crop moratoria. 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.

This provision, as now written, might be construed as allowing the Minister to override state crop moratoria. Part 5A, Div. 2, 72B(2)(e)) (see page 7 of Amendment only requires the States to be consulted rather than requiring them to approve any emergency proposal. We strongly object to this.

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.

It is proposed that the Minister, in determining that a substantial emergency existed, must get the advice of: (i) the Commonwealth Chief Medical Officer; or (ii) the Commonwealth Chief Veterinary Officer; or (iii) the Commonwealth Chief Plant Protection Officer; or (iv) a person prescribed by the regulations, as well as advice from the GTR. (Part 5A, Div. 2, 72B(2)(a) (see page 6 of the Amendment). But given the novelty and unpredictability of GMOs, these officials alone are unlikely to be able to offer reliable advice without a full safety assessment.

We object, the Bill gives no powers to States or other entities to end or modify an emergency dealing determination. The Minister has too much power and discretion. A majority of jurisdictions agreed to extend the powers to make emergency dealing determinations but the agreement of those jurisdictions is not required to invoke emergency dealing determinations (Part 5A, Div. 2, 72C(5)(e)) (see page 8 of Amendment). Thiis is not satisfactory.

Unfortunately it appears to have the agreement of the states which should, in the public interst, have more jealously guarded their important reserve powers. The GTMC communiqué says:

"The Review found that the Act provides the flexibility to change the definition of a GMO through declaring that an organism is, or is not, a GMO. The Review also found that this flexibility will enable the regulatory scheme to keep pace with emerging trends. However, the requirement for regulations to be approved by the GTMC could inhibit the expeditious making of regulations to bring an organism under the scope of the Act. The key element of this provision is that an emergency occurs where there is an actual or imminent threat to health and safety of people or the environment. Governments noted that, in accordance with standard practice set out in the section 27(g)(ii) of the Act, the Regulator would provide advice on the making of such a regulation. Guidelines will be prepared, for approval by the GTMC, to ensure that this provision operates in parallel with relevant regulatory schemes."

We also note that the Bill says should, "a person become aware of any unintended effects of the dealings specified in the emergency dealing determination," the GTR must be informed. She must advise the Minister, but the Minister has the discretion to act or not on such advice (Part 5A, Div. 3, 72D(2)(h)(iii)) (see page 9 of Amendment)." Instead, the Bill should mandate checks and balances on unbridled Ministerial discretion.

The Bill proposes the complete omission of Section 49 'Dealings that may pose significant risks to the health and safety of people or the environment'. This omission removes the requirement that the GTR tell the public that at least one of the proposed dealings may pose significant threat to the to the health and safety of people or the environment (Part 5, Div. 4, Sect. 49(1) of the Act) (see page 22 of the Amendment). This omission also removes requirements that the GTR take notice of the nature of the organism; the expected effect of the GMO; the potential spread or persistence of the GMO or its genetic material; and any likely impact on the health and safety of people (Part 5, Div. 4, Sect. 49(2) of the Act).

This permissible absence of advice raises major concerns of abuse of power with unilateral decision-making lacking any checks or balance.

We also object to the proposed revision of Part 5, Division 4, Subsection 50(3) of the Act, and the addition of Subsection 50A (see page 22 of the Amendment). This proposes that if the GTR is satisfied that the controls and limits on field trials (generally decided by the applicants or non-government bodies NOT the OGTR) are appropriate, then the GTR need not seek advice from (a) The State governments; (b) the Gene Technology Technical Advisory Committee; (c) relevant Commonwealth authorities and agencies; (d) the Environment Minister; or (e) local councils that the GTR considers appropriate (Part 5, Div. 4. Subsection 50(3) of the Act). These proposed amendments remove more checks and balances from the Act and are unacceptable.

Proposed Subsection 35A – 'Person must not breach conditions of emergency dealing determination' (see page 4 of the Amendment) implies that a person is guilty of a strict liability offence, where they intentionally take an action or omit to take an action in breach of any condition of a GMO license. 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.

Gene Ethics Comments on the State, Territory and Australian Governments' Response to the Recommendations of the Statutory Review of the Gene Technology Act 2000 and Gene Technology Agreement 2001

As already implied, Gene Ethics does not consider that the proposed Commonwealth Amendment Bill fairly or fully reflects the substance or sentiment of the GTMC's statement. The Commonwealth Government is seeking to facilitate further deployment of GM Organisms by stealth.

For instance, the communiqué refers to a two stage process with large consequences for the law in every jurisdiction: "The Australian Government intends to introduce the Gene Technology Legislation Amendment Bill into the Australian Parliament as soon as possible. States and Territories will use their best endeavours to introduce corresponding amending legislation into their Parliaments before 31 December 2007."

We therefore strongly propose that all State and Territory Governments be invited to critique the Commonwealth Bill as part of the present process.

All governments agreed with the Australian Government's intention to introduce legislation to implement Recommendation 4.4:

"that technical amendments (in Appandix 1) suggested by the Regulator should be made to improve the workability of the Act.".

On the whole Gene Ethics agrees that these changes will be useful. However, we also make the following comments and suggestions:

Section 185 – Confidential Commercial Information, should be more open. Our experience has been that the OGTR generally appears to uncritically accept applicant requests for CCI as a routine matter and publishes no compelling reasons as to why these requests are granted.

Section 57 Consideration of suitability to hold a licence, should also include a timely invitation to the public to submit relevant evidence about the fitness of applicants, in the Early Bird notifications. GeneEthics seeks a provision that the OGTR should also publish reasons for accepting or discounting evidence. Our experience has been that evidence submitted to show a lack of fitness to be licensed is seen as irrelevant to the performance of the local branches of global entities. We refute the rationale that the Australian offices of transnational corporations are autonomous entities.

We strongly support "Recommendation 5.1: The Review recommends that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment."

This should be mandated when GTTAC members are next appointed since Public Health, Safety and Environment are the core concerns of the Committee. Provision for independent outside experts to be consulted routinely, not just in exceptional cases, would also be wise.

While Gene Ethics also supports "**Recommendation 5.6:** The Review recommends that the DIR category be split to distinguish between field trial and commercial release licences", we are adamant that the controls on field trials not be weakened in any way.

As explained above, we are most dissatisfied that: " The provision would define an application as a field trial application where the Regulator is satisfied that the principal purpose is to carry out experiments and that the applicant has proposed controls to restrict dissemination, persistence and release of the GMO and its genetic material (that is, that the GMO is contained and controlled within the trial site)."

This gives the OGTR too much discretion which, with the checks and balances removed from the Act, are likely to be even more arbitrarily exercised.

We absolutely dispute the Bill's intention that, "The provision would also provide that the requirements to seek advice from the existing range of bodies (which include the States, the GTTAC, prescribed agencies, the Environment Minister and any local council that the Regulator considers appropriate) on the preparation of the RARMP apply only to commercial releases and not to field trial applications."

Removing these essential consultation processes ends most of the checks and balances that resulted from the extensive public consultation process initiated by Health Minister Wooldridge in 2000 and 2001. These public processes are essential to public confidence in the OGTR and the regulatory process.

In light of the proposed changes, the incorporation of GTCCC into GTEC is even more ominous but predictable. Both committees have been largely hamstrung by the Act's requirement that they give advice at the OGTR and GTMC's request.

The OGTR system was already established to facilitate the deployment of GMOs but now the Regulator and the Minister can do virtually as they like with impunity. The OGTR already operates on arbitrary criteria and would be enabled to be even more arbitrary if this proposal proceeds.

The following statements in the government communiqué are just confirmation of the agenda to fast track trials into the Australian environment with minimal interference:

"Governments consider that applications should not be assessed against **arbitrary criteria** to determine whether applications are for commercial releases or field trials. This would be determined by the Regulator based on the primary purpose of the application. In considering how to split the current DIR category, governments noted that that there should be broadly two types of releases. The purpose of one type of release is for commercial production of the GMO, the proponent thus wishing to use the GMO with as few restrictions as possible. These types of releases have been called 'commercial releases' and would need a wider range of environmental and ecological settings to be considered in any risk assessment. The purpose of the other type of release is not commercial but to gain experimental data needed for the commercial release, including any data needed for regulatory purposes. For example, the Regulator may impose research conditions on releases that are limited and controlled to address uncertainty that would otherwise prevent larger scale releases of the GMO. These releases are proposed to be called field trials (to be called 'limited and controlled releases' in the legislation) and require less comprehensive assessments because they are limited in terms of time, spatial scale and location and have containment measures to restrict dissemination."

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 labeled 'trials' and allowed under exemptions from state moratoria on commercial growing of GM canola.

Gene Ethics again raises the issue of the unregulated use of GM kits in High Schools and other institutions by untrained personnel in uncontained facilities. The communiqué says:

"Recommendation 6.1: "The Review recommends that there should be no legislative requirements on exempt dealings beyond listing in the Regulations. Research organisations stated to the Review that the current obligations in relation to exempt dealings represented an excessive administrative burden, given that this category of dealings poses negligible risks to people or the environment. The Review heard from GTTAC that exempt dealings do not need to be conducted in physical containment (PC) 1 facilities."

We would like to know if GTTAC has ever been asked to consider the kits and what its view is. The OGTR always maintains that GM kits, which can be ordered on the internet and imported without a licence, do not justify any regulation. They have offered no evidence in support of their view.

We ask the Senate Committee to note our concerns about these exempt dealings and to initiate a process with a view to their being covered by the Act.

Conclusion

The time frame for this Senate review was ridiculously short. So this submission serves only to scope out some of the inherent flaws in the Act and the Bill. We strongly recommend that the Senate Community Affairs Committee consider the implications of the Bill and its wholesale removal of the checks and balances on Ministerial and OGTR powers. Please favourably consider our submission and give us an opportunity to appear at the Committee's hearing.