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in Brazil GE soya beans incorporating a nut gene produced severe allergic reactions in some people and had to be withdrawn.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.
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> 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.
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> 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**
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> 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