Review of the *Gene Technology Act* 2000; June 2011

Introduction - Deregulation is Not Appropriate at this Time

1. This review of the *Gene Technology Act* 2000 is likely conducted on the premise that the *Gene Technology Act* 2000 and the regulations made under it have worked well and, along with the Office of the Gene Technology Regulator, have now pretty much served their purpose; being primarily to provide for a controlled progression to a general acceptance of this exciting and potentially lucrative, but also scary, still new technology. That follows from an apparent view from stakeholders that no major catastrophes have occurred and the ending of moratoria on genetically modified (GM) crops indicate an acceptance of the technology in the wider community.

2. However, in my view, there remain major public interest issues and significant public health and environmental concerns despite declining radical anti-GM activities. Why are environmentalists not expressing concerns about the horizontal gene transfer of Monsanto genes to native corn species in Mexico?

3. I do not accept either that the Act has worked well or as it should have or was intended to, or that it is the appropriate time now for significant deregulation of the gene technology industry. I had a role at the instigation of this legislation in 2000 but on a number of occasions since then have had concerns about the use of the legislation and the functioning of the OGTR.

New and Dangerous Microorganisms Keep Emerging

4. Only this week the media reported a serious outbreak of an "unidentified" pathogenic *E. coli* in Europe. Whilst toxin producing, enteropathic *E. coli* exist in nature, in 2011 the question must be asked whether or not this is a new strain resultant from recombinant DNA technology; either accidental or deliberate or by transfer mechanisms such as horizontal gene transfer. It is the virulence and antibiotic resistance of this new strain that is particularly concerning. *E. coli* is routinely used in genetic modification techniques.

5. Then today's media reported a new "super bug" found in cow's milk in Europe. Antibiotic resistance occurring by horizontal gene transfer from genetically modified organisms is a real threat, in my view. I have previously expressed concerns about the risks of horizontal gene transfer from recombinant GMOs.

6. The litany of recent public health failures and inadequacies is disturbing not least because they indicate that a serious pathogenic GMO escape, release or bioterrorism event could not be handled by the authorities in 2011. Notable failures include: poor responses to influenza so called "pandemics"; resurging childhood diseases; hospital antibiotic resistance "super bugs"; poor quality influenza vaccines; serious quarantine breaches; inability to efficiently contain serious disease outbreaks such as cholera in Haiti or HIV in Africa; and so on.

The Office of the Gene Technology Regulator Has Not Fulfilled its Intended Role

7. A second issue stems from the recent floods. The OGTR now grants licences for controlled releases of GM plants into the environment easily. I believe that many strains are not properly characterized; for gene stability for example. I have raised these concerns for a number of licence applications where the risk of horizontal gene transfer of the genes involved was, in my view, of concern. Most disturbing was one from Monsanto for release of many uncharacterized strains of cotton at numerous locations throughout the country. I conjecture that many GM plants ready to set seed were flushed down our inland and other water systems by the recent floods; despite the standard licence condition that sites be certain distances from waterways. So much for controlled release.

8. More to the point where are the OGTR media releases acknowledging the problem and advising how they are monitoring the situation.

Public Consultation is a Fiction under the *Gene Technology Act* 2000

9. A third issue is the fiction of public consultation and consultation generally. It has been left to me to raise the failures of statutory authorities to properly consider public submissions that may contain hidden but useful expertise, made as part of the specific legislative public consultation processes. At one point the Ombudsman acknowledged that such legislative provision set a very "low bar"; that is that terms such as "consider" or "take account of" mean virtually nothing. Add to that the high probability that directed consultations are made to stakeholders with possible commercial and vested interests in promoting the technology, and then the consultation process is seriously flawed.

10. The culture amongst public servants that they can determine who they consult or whose views are relevant and who should be ignored needs to stop. I have seen it in a number of Authorities and statutory bodies. Opinionated public servants are unhelpful where different stakeholders have strongly held opposing views.

> *Section 10 of the Act needs to include a definition of "'stakeholder' includes members of the public with provable expertise in areas of gene technology and other relevant areas of study".*
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> *A new section 51(3)(c) should require that public submissions by stakeholders, whether or not requested by the OGTR, must be properly considered, and, where expertise is present, be considered by persons of comparable expertise.*
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> *A new section 52(4) should state "the regulator should properly consider submissions by stakeholders at a level of expertise appropriate to the expertise of that stakeholder".*
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> *The phrase "have regard to" in s 56(2) should be defined to mean "must consider at an appropriate and comparable level of expertise, and respond to all submissions by stakeholders".*

11. Two examples illustrate my point. The first is the release of e-mail addresses in the possession of the OGTR, of opponents, to Monsanto and others with commercial interests in

deregulating gene technology.

12. The second is the process for appointing members of committees. Clearly the Minister (or Ministerial Council) has final say but the process of selecting names and recommendations to the Minister are open to abuse and manipulation. On at least one occasion I put my own name forward and was apparently simply ignored. No reasonable person acting honestly could look at my *curriculum vitae* and ignore it in this context unless they were attempting to stack the committees in particular ways. I propose that applicants long listed (that is suitably qualified with experience) for a role on these committees provide a summary of their resume for public release and comment prior to short listing.

> *Sections 100 and 108 should require that applicants for committee positions provide a resume summary for release to the public and comment by stakeholders prior to short listing.*

"Confidential Commercial Information" Provisions are Abused

13. The "confidential commercial information" exemption from disclosure of key scientific data needed for assessment and scrutiny of licence applications must be modified to allow access to construct and preliminary stability and gene number and gene location data, for examples, to those interested in commenting on a proposed release. This type of data is supposedly required in the application and, given the uncertainty about committee or ethics committee members' views or expertise; it must be available to all stakeholders. That could be done by mandating a summary of such data, in limited specific terms, to be signed off by the committee which has seen the entire application, to be placed on the public record. Blanket "commercial in confidence" claims are open to abuse and are abused and should be eliminated. If it has reached the release stage it should be sufficiently characterized to warrant patent protection.

> *A new section 184(3) should state "an applicant must by written submission provide reasonable grounds to justify its claim that the specific information is 'confidential commercial information'".*

The Office of the Gene Technology Regulator Risks being Accused of Preferential Treatment

14. A fourth issue is the relationship of OGTR with particular stakeholders. This is always an issue where commercial interests are involved. I have mentioned Monsanto generally and DIR081/2008 in particular. I have seen no other licence application to release anything like 500 strains, 63 recombinant constructs and 25 shires (sites) under the one licence. Parliament never intended any such thing; a few at most. Why should the taxpayer miss out on licence fees because a large company has not selected properly from its own research or properly it’s GMOs? By any analysis this appears unwarranted, preferential treatment.

The Office of the Gene Technology Regulator Sets Australia's International Standing on Gene Technology

15. A fifth issue is the international standing of the OGTR. I doubt that DIR081/2008 would

have received approval in any other country or US states with comparable authorities and regimes. Australia runs the risk of being linked to India and other advancing countries that use gene technology with minimal control or regulation. Care must be taken that the OGTR acts at arm's length from multinational organizations like Monsanto, and other entities, that have been suggested in the media as acting against opponents with legitimate views. The OGTR should keep itself informed about litigation and other activities showing the big biotech companies acting against opponents.

> *A new section 27(jj) should be included to state that the regulator "must monitor activities in other countries, especially litigation, between biotech companies and others".*

16. I raise also DIR097/2009 which was for a vaccine trial using a recombinant parainfluenza virus. The applicant was a US company. Why pick Australia for the trial? A number of countries allowing the trial had low regulatory regimes. It was for an unnecessary, problematic vaccine raising significant safety issues. Why would the OGTR allow it?

17. Particularly disturbing was the view of the OGTR that it does not have to consider safety issues which were dealt with by the Therapeutic Goods Administration, ANZFA or other similar statutory bodies with public health responsibilities. Clearly that view was wrong under the clear objects of the Act and needs to be corrected in the Act. Section 3 of the Act states that the object is to "... protect the health and safety of people ...". It does not provide for the OGTR to opt out or limit its health considerations as it wishes; whatever the reason. If there are GMOs involved then the OGTR must consider all health issues relating to their use.

> *Section 3 should be modified to express that the regulator must consider all public health issues arising from use of gene technology.*

18. Again there were commercial considerations and benefits for the hospitals and doctors involved.

19. I am not anti-vaccine and note in passing the licence granted to trial a vaccine against Japanese encephalitis. Here you have a serious disease, endemic to developing countries; a good application and, in my view, a valuable use of the technology. Consequently I did not oppose it despite concerns over the dangerous virus being modified.

<u>Decisions of the Regulator Must be Reviewable</u>

20. Provision for review of decisions is not adequate. ADJR has a place but if licence applicants have access to the Administrative Appeals Tribunal then why should other stakeholders or concerned members of the public, given the public interest in the topic, not also be given access? Alternatively a tribunal or board composed of committee members or other experts could fulfill that role at first instance.

> *Section 179 should be amended to provide that "reviewable decision" and "eligible person" includes:*
> *1B to grant a licence; by a stakeholder;*

15. To declare information to be confidential commercial information; by a stakeholder.

Section 10 of the Act needs to include a definition of "'stakeholder' includes members of the public with provable expertise in areas of gene technology and other relevant areas of study".

Transfer of Regulatory Powers to Institutional Ethics Committees is Problematic

21. This review and that of the Gene Technology Regulations 2001 suggests an attempt at deregulation. Greater use of institutional ethics committees for certain research applications is proposed. Those committees do not necessarily have the necessary expertise and access to such expertise should be provided for; to members of OGTR committees or a panel of experts. Also it should be a requirement that discussions by institutional ethics committees about gene technology proposals be properly minuted and be made available for the public record.

The Act should mandate that institutional ethics committees nominate a person of suitable expertise in recombinant gene technology, independent from the research, to assess the science.

Scientists working with Gene Technology Should be of Good Character

22. Possibly in addition to institution registration and certification requirements, a registration system of licensing should be introduced for scientists working in the gene technology area. A "good character" requirement exists for doctors, lawyers, teachers and other professionals but any person can be a scientist; no matter how dangerous the materials they work with. There are no shortage of examples of dishonest or disreputable scientists; and the list gets longer the more money there is involved.

The Act should require a registration system for scientists working in gene technology including a "good character" test.

Sections 32, 33, 40(5A) and 58 should include a "good character" test.

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