GENE TECHNOLOGY ACT REVIEW
Bob Phelps presentation 15/11/05

A Genuinely Scientific System

OGTR assessments are not scientific but operate under a so-called 'science-based' and 'case-by-case' system. These tags are used to justify an unscientific and ad hoc approach to data collection and assessment methodologies that does not conform with Recital B, which requires that "the Scheme should: (d) be based on a scientific assessment of risks undertaken by an independent regulator, … ;"

The Gene Technology Act and its regulations should mandate the design, scope and scale of relevant scientific experiments by setting down beforehand all the unambiguous benchmarks, standards, Quality Assurance systems and protocols necessary for the systematic collection of high quality data for assessment.

Risk/benefit assessment methodologies, based on good scientific data, should also be set out in the Act and Regulations. These rules are basic to the fair and objective assessment of the reliability, replicability and relevance of evidence tendered in support of applications.

Data from contemporary, controlled experiments conducted in Australia should be the basis of assessments. Instead, the OGTR (also FSANZ, APVMA, AQIS, etc) generally rely on the assessment of an ad hoc suite of data from out-dated and questionable overseas company-generated 'trials' or 'tests' (not experiments) to license dealings.

All interested parties should have full access to all the data and information about the scientific experiments, to enable the independent evaluation and monitoring of experimental design, methodologies, processes and experimental data.

Accessibility of Data

A key flaw in the system is that it does not make the applicant's data available in raw, undigested form. Without this data, no independent outside assessment of applications is possible. The digested documentation published by the OGTR is framed so that the risks and hazards of proposed dealings are made to seem better understood, more predictable and more manageable than they really are. The necessity to travel to Canberra to photocopy the files is impractical and expensive, and is an unreasonable barrier to full community participation in the OGTR system.

There are no good reasons to keep data secret when it comes from genuine scientific experiments on the risks to health and the environment. Data from agronomic or other 'trials' that is primarily commercial should not even qualify as the evidence basis for a successful application under the Act.

Data supporting applications should always be scientific and public, to improve the transparency and accountability required by the Recitals. It is very unsatisfactory that OGTR passively allows information to be secret. For instance, seven years of agronomic data from GE canola trials conducted by Monsanto (on about 250 hectares) and Aventis (now Bayer – on about 3,400 hectares) was declared commercial in confidence by the OGTR at the companies' request, and is still secret. Relying on this secret data, in 2003 the OGTR issued to both companies unrestricted, unconditional licences for the unlimited commercial growing of herbicide tolerant GE canola throughout Australia.

To be transparent, the OGTR should be required to always publish a full statement of reasons for granting a DIR licence, for further public comment prior to any licence being issued.

The Onus of Proof

The burden of evidence-based proof for the environmental and public health safety and efficacy of the GMO should rest entirely on the applicant for a licence to deal with the GMO. Peer reviewed scientific evidence which conforms to the requirements of a genuinely scientific system should be necessary in order to discharge this requirement.

By denying the interested public access to all the information, the present system unreasonably places the onus on the interested public and regulators to produce evidence that shows conclusively why a licence should NOT be granted. The Act requires urgent reform.

The Precautionary Principle

The OGTR appears to consistently ignore Section 4 (aa) of the Act – the precautionary principle - which should be fully integrated into the GT Act, as it is in the Environment Protection and Biodiversity Conservation Act.

"The Act indicates that the Regulator is required to take protective measures as a prudent and sound response in the face of a lack of full scientific certainty. The approach adopted by the Regulator in addressing s4 (aa) is outlined in the *Risk Analysis Framework* (RAF) document. Perceived threats should be based on credible scientific hypotheses and have a plausible causal pathway; the seriousness of the threat should be taken into account and measures to prevent damage should not be limited to bans." (Issues Paper No. 1, P.12)

We cannot see how the OGTR can proceed on the basis of 'credible scientific hypotheses' when no experiments are required to provisionally accept or refute such hypotheses. The OGTR and GTTAC appear instead to operate on 'best guesses'.

We refute Dow's claim that "The precautionary principle has been interpreted in some regimes in such a way as to prevent dealings with GMOs until there is full scientific certainty of no harm. This interpretation becomes intractable in implementation." (Issues Paper No. 1, P.13)

Appeal Rights

Only applicants have merits appeal rights. Everyone should have standing to appeal OGTR decisions. There is no evidence that frivolous actions would follow from everyone also having full appeal rights, equivalent to those enjoyed by applicants.

Suitability (Sections 57 (2) and 58

A preliminary assessment of the applicant's fitness to hold the licence, required by sections 57 and 58 of the Act, should also be conducted at this stage. If the applicant were disqualified, then the application would not proceed further.

Stronger and clearer fitness criteria should be mandated in Sections 57 (2) and 58 of the Act. The OGTR should seek submissions on all applicant conduct which may be against the public interest (including criminal convictions). The behaviour of associated parent organisations should also be discussed, assessed and the reasons published. We are very disappointed that

wherever the OGTR has a discretionary power, it appears generally to be exercised in the interests of applicants and licensees rather than in the public interest.

Strict Liability

The standard common law tests of negligence should not apply to living GE organisms as they are mobile in the environment, able to multiply and are usually beyond recall once released. It is therefore the responsibility of the creator of the organism, as well as its user, to take responsibility for negative impacts.

The segregation of the pollen and seeds of some crops, such as GE canola, from non-GE canola, related weeds and native relatives is impractical. For instance, the transfer of a GE herbicide tolerance trait to relatives of canola would likely create additional weed management problems. This makes release a matter of public interest which must have precedence over private commercial gain.

The Australian Food and Grocery Council also seeks to avoid responsibility:

"The AFGC rejects the proposal that the Act should include liability and insurance provisions as this would place an unnecessarily high level of responsibility on owners of gene technology to protect and restrict the use of such technologies and further add to costs. Furthermore, there is the potential that were this to be imposed that insurance costs would significantly rise and adversely affect community and local activities." *(*Issues Paper No. 2, P.26)

Cost Recovery

We support full cost recovery. The cost of a strong regulatory system should be fully paid for by the applicants, at arms length from the regulators, by payments into consolidated revenue. These costs are just another part of doing science or conducting business. They would be built into corporate or science budgets. The risks of gene technology and its products must also be internalised. The law should ensure that any negative short or long term impacts arising from the issuing of a licence are not a burden on the community generally - through taxes, depleted or degraded resources, long term (especially untraceable) negative health or environmental consequences, or through the opportunity cost when more important R&D is ignored.

Participation

Public processes of participation and engagement with local communities are the strength of local government. Councils are under-resourced and the frequency of release proposals in some shires makes it difficult for them to respond. As well as 'consulting' councils, the OGTR has a responsibility to fully inform and resource these engagements. The GTCCC members recommended to the OGTR that opportunities be created for the GTR and GTCCC to pro-actively engage in meetings with councils and their constituents over release proposals but this was never taken up by the OGTR. This is a legitimate and important role for the GTCCC members who saw themselves as broadly representative of the community and its diverse views.

OGTR Committees

Bayer CropScience is sexist and unfair when it questions the credentials and selection processes for OGTR committee membership:

"… we view the membership of [the ethics and community consultative] committees as a concern.

The membership should incorporate only those people with some expertise and are "reasonable" in their views held. After all the standard of "the reasonable man" is enshrined within our law courts. Therefore, we do not think it is appropriate to include on these committees persons who hold entrenched views and do not have the necessary recognised qualifications."

Local Government

Local government has a key role in facilitating OGTR exposure to the concerns of local communities and liaising with OGTR. But the OGTR was not pro-active and the process was under-resourced. With support, councils could get better informed about GM issues. We therefore disagree with GM industry advocates Agrifood Awareness Australia and SGA Solutions that:

"While AFAA supports wide consultation, we believe that to date this has not worked efficiently, primarily because the majority of councils have no expertise in gene technology – particularly in the science and an understanding of the regulatory process. As a result this consultation has generated a large amount of uncertainty in the community particularly in "consultation" is therefore highly ineffective and needs to be significantly enhanced or removed."

"However, one aspect of the consultation process which lacked credibility was in relation to the role of the councils in providing submissions to the application process … Going forward, either the councils take a more proactive educated approach to their role or their role is replaced by that of farmer based organisations (e.g. VFF, SAFF, NSWFF, PGA, WAFF) who represent the majority of environment within which the products are trialled. *(*Issues Paper No. 2, P.19)

State and Territory Powers

We fully support retention of the policy principle issued under Section 21 (1) (aa) of the Gene Technology Act, by which State and Territory governments are empowered to recognise designated areas for the purpose of preserving the identity of GM and non-GM crops for marketing purposes. The present contamination of non-GM canola with GM challenges the identity of those commodities and shows that the systems for preserving that identity are inadequate. Thus, the state moratoria on commercial GE canola are fully justified and GeneEthics' constituents support them.

One-Stop-Shop

GeneEthics has always supported a one-stop-shop system for the regulation of all GE organisms, processes and their products. The present gap fill model has not worked. To the extent that this involves 'harmonisation' of the Commonwealth's regulatory agencies, we support it.

All applications for the licensing of any dealing with a GEO, or registration of any product of a GEO, should come first to the OGTR and the OGTR should be the lead agency. Any assessments of specific aspects by other regulators (such as FSANZ, APVMA or TGA) should be commissioned by the OGTR and should then be issued for public comment as part of the OGTR's RARMP process. (See: Figure 1)

The applicants and the interested public cannot reasonably be expected to deal with a multiplicity of (often conflicting) Commonwealth regulators and regulatory systems over the licensing and registration of individual organisms or products.

To the extent that 'harmonisation' would take away the rights and prerogatives of the States and Territories under Section 21 of the Gene Technology Act, or adopt the lower standards applied to GE organisms by the USA, we oppose it.

We want the OGTR to be a one-stop-shop that would cover all organisms – plants, animals, microbes and humans. Some aspects of nanotechnology and its interface with living systems may also need to be covered by the Gene Technology Act.

Definitions

The Act should define 'environment' so it is consistent with other environmental laws such as the EPBC Act, Ecological Sustainability and the Convention on Biological Diversity. 'Health' should also be broadly defined. The Act is deficient in not having such a definition. We cannot see how the regulator can assess the impacts on something undefined.

Biosafety Protocol

The Commonwealth should sign and ratify the Biosafety Protocol immediately and the OGTR's systems should be made fully compliant with that treaty.

Terminator Technology

The Australian Government should desist from advocating the end of the de facto global ban on Gene Use Restriction Technologies (GURTS), better known as Terminator Technology. As a full member of the Convention on Biological Diversity, the government should refrain from acting on behalf of the US government and its transnational corporations which are not a party to the treaty.