GENE TECHNOLOGY ACT REVIEW
Gene Ethics responses to the Issues Papers 14/11/05

Issue Paper #1

- If the regulatory scheme were to include consideration of socio-economic and cultural impacts,
  - How would economic, social and cultural considerations be measured?
  - Who would be responsible for the analysis of economic, social and cultural considerations?

COMMENT: The scheme already includes consideration of socio-economic impacts by state and territory governments, using the policy principle created under Section 21 of the Gene Technology Act. This is sanctioned by section B(c) of the Gene Technology Agreement Recitals. It is working well and is appropriate.

- Markets can change rapidly. How could the regulatory system accommodate these changes?

COMMENT: Everything, including gene technology can change rapidly. States and territories are responsive to socioeconomic change so this is not an issue for the regulatory system.

- What evidence is there that the Regulator does not consider risks to the farming environment in her assessment?

COMMENT: The OGTR and GTTAC may 'consider' such risks but that is inadequate. Scientific assessment of scientific data is essential. For instance, the OGTR has not considered the full impacts of herbicide tolerant and Bt crops on soil micro-flora, nor the resistance of those varieties to pathogens. Preliminary evidence suggests the introduction of GE cotton varieties may be associated with the spread of fusarium, a cotton pathogen. Experiments are needed to establish or refute the connection and the OGTR should then regulate accordingly. Similarly, blackleg resistance in GE canola varieties also needed OGTR assessment. The possibility of canola outcrossing to weedy relatives such as wild mustard or turnip was assumed by the OGTR to be 'negligible' on the basis of little controlled local experimentation. Yet even at low levels, official UK farm scale trials have found outcrossing to have a major potential environmental impact. IHER's point, that rural roadsides are in many places the sole repositories of rare native species was also discounted by OGTR without any data from controlled experiments. The invasion of key ecological niches by GE canola is an environmental issue needing scientific research and assessment.

- How in practice could the regulatory system take account of the benefits of GMOs?

COMMENT: The proponents of gene technology are constantly making public claims about the benefits of the products of their technology. These often baseless claims need to be reality checked. The OGTR, as well as state and territory governments, should assess them. For example, industry claims that GE herbicide tolerant crops reduce chemical use but US evidence (Benbrook 2004) shows that since the first three years of commercialisation, there have been seven years where overall chemical use, especially of herbicides, dramatically increased.

- Is the current method of risk analysis undertaken by the Regulator sufficient to satisfy the precautionary principle, which is triggered when there are threats of serious or irreversible environmental damage? If not, why not?

COMMENT: No. The OGTR appears to consistently ignore Section 4 (aa) of the Act which should be fully integrated into the GT Act, as it is in the EPBC Act. The OGTR system cannot

be precautionary because it is not scientific. The OGTR operates 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, whose decisions must be consistent with policy principles issued by a Council of Ministers concerning social, cultural, ethical and other non-scientific matters (which principles must not derogate from the health and safety of people or the environment);"

To comply, the Gene Technology Act and its regulations should mandate the design, scope and scale of relevant scientific experiments by setting down unambiguous benchmarks, standards, Quality Assurance systems and protocols 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.

A systems approach to interactional analyses of GEO impacts on health and all environments is essential to properly scientific assessments. So the assessment process should draw on the expertise of ecologists, risk modellers and other systems experts in the OGTR, on GTTAC and accessible to outside experts. Broad independent expertise and advice should be embedded in OGTR risk assessment processes, especially on ecological and epidemiological issues which OGTR assessments now ignore.

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

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

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 proposed above should be necessary to discharge this requirement. 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. This aspect of the Act requires urgent reform.

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.

Issue Paper #2

- Is the Regulator's use of print media, a client register and the internet the most cost-effective way to communicate with the Australian community?

COMMENT: See the papers produced by the GTCCC and its subcommittees. 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.

- Are there more effective models of communication in other regulatory systems?

COMMENT: Not in Australia.

- Is it possible to explain gene technology or any complex technology in simple, meaningful ways?

COMMENT: Gene technology and the issues that surround its commercial uses can be understood by any interested person. Government and industry falsely believe that they can convince the public to accept gene technology with more public relations, information and explanations. Only full public participation in a scientific, objective and fair system would build the public confidence and trust needed for OGTR consultations to work well.

- How do we strike the right balance between the public's right to know and the applicant's right to data protection?

COMMENT: Change the Act to make the applicants justify their claims for commercial confidentiality to the public, instead of OGTR automatically approving them. 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.

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

Keep C-in-C claims to a minimum. Individual items rather than whole pages or sections of documents may be allowed. Keep secret just the details of the actual construct unless these have already been disclosed in patents or testing protocols. If information is in the public domain anywhere else (eg: FSANZ or the USDA), then the information should also be disclosed by OGTR.

The OGTR's licencing decisions under the present Act are not objective or scientific, and are not in the public interest.

- Would it be practical (and enforceable) to release data on condition it is not used for profit by other parties?

COMMENT: Yes. Item B(f) of the Gene Technology Agreement Recitals says "the Scheme should be characterised by decision-making that is transparent, and that incorporates extensive stakeholder

and community involvement." Without information being shared, these goals cannot be achieved. Applicants cannot expect their GE dealings to be licensed unless full scientific data is available to everyone. Their licence is a contract with the community, so if the public is kept in the dark or misled there can be no valid agreement.

People harmed or contaminated by GE organisms can only seek compensation through the common law and the courts. Applicants would have the same means of redress if their data were misused and that is adequate. Until other affected people are protected against the applicant's technology by strict liability provisions in the law, applicant's should get no better protection than they have now.

- Is there a useful distinction between information on the genetic modification itself (which involves intellectual property) and information on its impacts on people or the environment?

COMMENT: Patented information is already protected and public. All other information should be in the public domain and should be accessible without a visit to Canberra and costly photocopying. To make a full assessment, everyone is entitled to full and fair access to all information.

- Is the definition of 'eligible person' for internal review and AAT review still appropriate?

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

- Are there particular characteristics of decisions by the Regulator which should require access to the AAT by persons not directly affected?

COMMENT: Yes. Living GE organisms are mobile in the environment, able to multiply and are usually beyond recall once released. This makes release a matter of public interest which must have precedence over private commercial gain.

- Given the current scope of the Act, are the three separate expert advisory committees the most appropriate way to consider the range of scientific, ethical and social issues?

COMMENT: They are part of the solution. More importantly, full public participation must be facilitated and encouraged.

The biased composition of GTTAC, including a lack of independence from commercial and ideological interests, compounds the lack of scientific objectivity in the whole regulatory system. The lack of ecological and public health professionals on GTTAC is a major flaw.

GTEC and GTCCC are hamstrung by a lack of direction from the OGTR and Gene Technology Ministerial Council. GTCCC also asked for more avenues for direct engagement with the public, which would have substantially enhanced its processes and results, but this was resisted.

- What would be gained by automatically referring all licence applications to the ethics and community consultation committees?

COMMENT: It would better inform these committees as functioning groups of diverse opinion, representative of the wider society, about the scope and scale of GE innovation. It would provide two additional forums for discussion of applications and the non-technical issues they raise.

- Could the Regulator take account of advice on applications received from all three committees without changing the scope of the Act to take account of social and cultural issues?

COMMENT: Scientific research and the commercialisation of GE products are social and cultural activities which also require scrutiny by the regulatory processes. It is a total fiction and pretence to assert that bringing gene technology R&D results to market is an objective and scientific process beyond criticism.

Are there particular circumstances when it may be appropriate for all three committees to consider licence applications?

COMMENT: Yes. GE pharma crops and animals, fish, and live unattenuated viruses would be some examples. They pose practical, ethical and public policy questions that would make wider forums for discussion and resolution essential.

- What could be done to reduce the statutory timeframes for DNIRs? DIRs?
- Do the consultation provisions in the approvals process take a disproportionate amount of time? Can steps be taken to shorten the timeframes involved without comprising the transparency of the process? What steps?

COMMENT: Times are generally appropriate as they are. However, the timeframe for all DIRs should lengthened to, say, 250 days to allow more time for genuine public participation and engagement in the process, which takes time and resources to organise successfully. Processes of face-to-face consultation at local level on all DIRs are needed, preferably through local councils. Additional time is needed to enable these processes to occur.

- Should the legislation be amended to differentiate between categories of DIRs (i.e. field trials and commercial releases)?

COMMENT: Yes. The Act must require experiments not trials as the basis for applications and applicants have ongoing responsibility for the commercial use of their living GE products. For instance, the present GE contamination of conventional canola appears to have resulted from trials. Mismanagement and unauthorized releases from trials in Australia have been numerous and they have always been forgiven by the OGTR. This does not give due weight to their potential impacts.

- On what basis would it be reasonable for the statutory timeframe for assessments associated with commercial releases to be extended?

COMMENT: 250 days would be more appropriate. Commercial releases are probably forever and usually unconditional so more rigorous processes of consultation at all levels are needed. Local and state government should be assisted to facilitate the full participation of people in the communities likely to be most affected. Additional time is needed to enable these processes to occur.

- Should an application screening stage be created to allow for checking that all information required has been provided before an application is accepted and the statutory timeframe commences?

COMMENT: Yes. Conformity of the application with the Act, especially with our recommended requirements of the scientific relevance and rigour of all data, would make this screening stage necessary.

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.

- With variations to licences, could silence (after a specified number of days) constitute consent on the Regulator's part? Or should a statutory timeframe apply?

COMMENT: No. We strongly reject any proposal that allowed nil response to be taken as a 'yes'. Timeframes and licences issued should be the only basis for variations. Otherwise, ambiguities over actual fulfillment of requirements and transmission of advice would abound.

- What could IBCs do to expedite accreditation and certification processes?

COMMENT:

- What is the most effective way of consulting with local government?

COMMENT: Public processes of participation and engagement with local communities is 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 ahs 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.

- Are the penalty provisions appropriate to ensure compliance?
- Do the penalties reflect the differing severity of offences?

COMMENT: Some penalties may be disproportionate. In our view, some of the un-authorised releases, accidents and contamination that have been reported by the OGTR deserved to be penalized but not one ever has been punished. A mixture of incentives and punishments is needed to encourage compliance and they should be more often used to show the OGTR is not just a paper tiger.

- Are the current OGTR compliance strategies effective in protecting the health and safety of people and the environment?

COMMENT: No. The environment is adversely affected by herbicide tolerance crop technology that will lead to the spread of plant pathogens, increased use of herbicides, more herbicide tolerant weeds and crop volunteers in disturbed environments, and the contamination of the gene pools of native relatives of the GE crop. The OGTR and other regulators do little scientific or evidence-based assessment of the health and safety impacts of GE organisms and the industry-generated concept of substantial equivalence is invoked to support assumptions, not facts, about health and safety.

- Should the Act be more prescriptive about what enforcement method should be used or should operational detail be contained in the non-compliance protocols (as it is currently)?

COMMENT: Precaution and prevention of contamination and harm should be mandated by the Act. Licences issued by the OGTR should have clear and enforceable conditions attached to them. Few licences now carry clear and unambiguous conditions, so the basis for enforcement is unclear and the OGTR has let all reported cases of unauthorised release and contamination go unpunished, and in most cases also unremedied.

- What characteristics of GMOs require the application of strict liability rather than the standard common law tests of negligence?

COMMENT: Living GE organisms are mobile in the environment, able to multiply and are usually beyond recall once released. 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.

- Is it reasonable to hold the proponent of a GMO responsible for crop contamination when the contamination was caused by the actions of a third party such as another farmer?

COMMENT: Yes. GMOs are inherently genetically unstable, mobile, self-replicating and enduring in open environments. It is therefore the responsibility of the creator of the organism, as well as its user, to take responsibility for negative impacts.

- How should cases of crop contamination be handled if they involve a GMO that can be identified but has never been licensed for use in Australia? Or which has been licensed but not released due to State moratoria?

COMMENT: The OGTR assessed and approved Topas 19/2 despite Bayer's stated intention never to commercialise the crop in Australia because it is not blackleg resistant. As no dealing with Topas 19/2 (and several other varieties) was contemplated, the application was outside the OGTR's powers to grant under the GT Act. Nonetheless, when Topas 19/2 contamination was discovered the OGTR and Bayer said it was an approved variety. As no licence was ever issued to grow Topas 19/2, the claim that it was approved was baseless and seriously misled the public as to its status.

All contaminated crops should be destroyed as soon as contamination is discovered, preferably before the crop set seed where that is possible. Contaminated seed or harvested grain should also be destroyed as soon as the contamination is discovered.

Prevention of further contamination should be undertaken by all regulators and actors in at-risk supply chains. AQIS should allow only the importation of certified GE-free seed. Seed companies should be required to certify that any seed they sell is GE-free, except for licensed varieties of cotton.

- If a GM crop has undergone a safety assessment and been approved for commercial release by the Regulator, is there a need for the regulatory system to impose a threshold for the GMO in conventional seed or grain or should the marketplace decide on a suitable tolerance level?

COMMENT: Zero detectable should be the threshold of GE contamination in non-GE grains and oilseeds. Any higher thresholds or tolerances are unacceptable.

- Should the regulatory system contemplate thresholds for GMOs that have not been assessed and

approved but may be present unintentionally?

COMMENT: No. In the Topas 19/2 case it is barely credible that the contamination of conventional canola was unintentional, nor that it was undetected for more than five years.

- Are thresholds for GMOs the appropriate solution to the problem of co-existence between GM and non-GM crops?

COMMENT: No. They would be the road to GE contamination on a grand and irreversible scale. They impose the liability and extra costs of preventing contamination onto GE-free conventional and organic growers, when these imposts should be the sole responsibility of the technology owners and their licensed users.

Issue Paper #3

- How do we judge the right balance between regulatory burden and risk?

COMMENT: Rigorously apply the precautionary, polluter pays and public participation principles. These principles are necessary because GE organisms are randomly created, inherently unstable, able to proliferate, mobile in open environments and unpredictable in their behaviour so there is no scientific consensus on the accurate assessment or robust prediction of risk.

This question is partial. The relevant Recital B(e), requires that "the Scheme should: ensure that the regulatory burden is commensurate with the risks" but it also requires that the regulatory burden is "consistent with achieving the objectives referred to in Recital A;". Recital A says "there is a need for a co-operative national legislative scheme 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 genetically modified organisms;" Recital A is the over-arching objective and B is about the means. So, the right balance is the one that achieves the over-arching objective, in concert with the other means listed in B.

Regulation is not a burden. It is a process for creating a contract between the applicants and the community which is only legitimate and appropriate where the applicant is permitted to deal with GE organisms or their products on terms agreed to by a broad consensus of the interested public.

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.

- Should we measure regulatory burden as it is perceived by the organisations regulated or seek some objective measure?

COMMENT: The participating public and democratic processes must be the arbiter of appropriate

regulation and regulatory burden. Those organisations being regulated are certainly not entitled to determine alone the rigour of regulation.

- If a regulatory measure is described in a very prescriptive way, the regulatory burden of the measure is apparent. However, when the regulations are outcomes focussed and there is considerable discretion for organisations to meet their regulatory obligations in any number of ways which may result in very different costs, how can we judge the regulatory burden of the measure?

COMMENT: Exercising precaution and preventing harm of any kind ought to be key objectives. Again, all interested parties must agree to any measures adopted to meet these obligations. Self-assessment and regulation is not appropriate. The failures of the voluntary GMAC regime are even now, belatedly, becoming more apparent.

- Do you have any specific comments or suggestions on the possibilities of:
  - Streamlining process and paperwork requirements
  - Quantitative targets for burden reduction
  - Legislative simplification and codification
  - Privatisation of certification function
  - Introducing further statutory time limits and "silence is consent" provisions?

COMMENT: We consider the existing statutory time limits to be generally appropriate and we absolutely reject any proposal for "silence is consent" provisions. Along with their exclusive rights to merits appeals under the present Act, "silence is consent" provisions would gravely disadvantage the interested public and the OGTR.

Issue Paper #4

- Are all the aims listed in the Recitals of equal importance?

COMMENT: This question is irrelevant and we reject its implied intent - to downgrade some of the aims and give priority to others. Such rankings would serve no useful purpose and a broad consensus among the interested parties could not be reached.

The Act also needs an objects clause which does not assume that GEOs will be released, since this disposes the OGTR to licence all applications submitted to them, which they appear to have done to date.

- Are all the aims still relevant?

COMMENT: Yes.

Is the issuing of policy principles related to State legislation consistent with the stated intent of an efficient, effective and nationally consistent regulatory system for GMOs that employs transparent
decision-making and extensive consultative processes?

COMMENT: Yes. State and Territory powers to make policy principles are entirely consistent with the constitutional division of powers between those jurisdictions and the Commonwealth. We would like to see the Gene Technology Ministerial Council act on the recommendations of the GTCCC and GTEC, and promulgate more policy principles – for instance, on a requirement for ethical, social, cultural and economic assessments of applications; for processes to ensure fuller

public participation in the regulatory system; for the precautionary and polluter pays principles to apply; and for strict liability on technology owners and users.

- What triggers make it acceptable for governments to intervene in the market?

COMMENT: 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.

- What evidence exists to support the view that research investment has reduced as a consequence of the moratoria?

COMMENT: This evidence is not in the public domain so we cannot comment. Any such claims should be dismissed unless they are fully supported by published documentary evidence. If evidence exists, then it would beg the question of whether investors had at lest understood that the extravagant claims made about the potential of GE crops are false and have decided to invest in more worthwhile and pressing enterprises. Two traits in four crops after 25 years of work and tens of billions of dollars spent on R&D does not recommend GE crops to any investor.

- What evidence exists that allowing approved GM crops to be grown will have a serious market impact?

COMMENT: For instance, we refer the Panel to: RIRDC Publication No 05/016 RIRDC Project No UA-57A

Among its summary findings are the following points:

… Indeed the European Union has a moratorium – in place since October 1998 – on the approval of GM products for domestic production or importation.

As a result, the US share of the EU's maize imports has fallen to virtually zero (from around twothirds in the mid-1990s), as has Canada's share of EU canola imports (from 54 per cent in the mid- 1990s). The GM-adopting countries have lost market share to GM-free suppliers (particularly Brazil for maize and soybean and Australia and Central Europe in the case of canola).

Food-exporting countries such as Australia need to weigh the potential economic benefits from biotechnology development against any net negative environmental risks associated with producing GM crops, any additional costs of segregation and identity preservation through the supply chain, any discounting and/or loss of market access abroad for conventional counterparts to those specific crops which may contain GMOs, and any discounting and/or loss of market access abroad for other farm products because of what GM adoption does for Australia's generic reputation as a 'clean, green, safe food' producer." …

Australia's crop production and exports are reduced more, not less, as a result of the EU moratorium.

On the other hand, if there were no EU moratorium and Australia adopted GM technologies, its crop production would expand instead of contracting. While domestic consumption of crop and

livestock products also would increase because of lower domestic prices, those estimated increases are not enough to prevent crop export earnings from rising instead of falling. Hence net economic welfare for Australia would be US$28 million per year higher as a result of GM adoption, less any negative value domestic consumers place on not knowing if they may be consuming GM products.

With the EU moratorium, the net economic welfare benefit to Australian producers and consumers of GM adoption in this case is estimated to be US$15 million per year. While that is $13 million less than if there is no EU moratorium, it still represents a net gain from joining the adopters of GM varieties of these four crops even if the EU moratorium remains in place. However, the average Australian farm household income would decrease with GM adoption – even with rice and wheat included – if the EU moratorium remains.

- Is there any evidence that the moratoria are leading to a situation whereby Australian technology related to GMOs, paid for in part by the Australian taxpayer, is likely to be used first by other countries?

COMMENT: None that we know of. However, Australian governments are spending well over $100 million pa on gene technology projects on food and farming. We are very concerned at the lack of explanation or accountability for numerous failed taxpayer-funded GM projects that have wasted scarce R&D resources needed for more pressing projects. For instance, CSIRO Plant Industry personnel worked for over a decade on the trivial project of creating non-browning fruits and vegetables. This was reportedly shelved when switching off the "non-browning" gene was found to make the potato plants more susceptible to pathogens. A field pea project, to produce a toxin from an inserted bean gene, was also cancelled. The peas were at long last fed to cattle, which lost condition as a result of being unable to properly digest the product. The CRC on feral animal biocontrol has also cancelled various projects for the production of live species-specific viruses.

The actual costs and the opportunity costs of failed GM projects are not published. It is time for a full accounting of the few successes and many failures of expensive and futile GM R&D projects. The Australian community has a right to be engaged in the setting of future publicly-funded R&D priorities.

- What have been the implications of the moratoria on farmers wanting to plant prohibited crops?

COMMENT: They have been saved from their own foolishness. There is only one crop at issue – canola. No other GM crops are likely to be proposed for commercialisation in Australia in the next five years, so giving up Australia's clean, green marketing advantage now, for the small rewards mentioned in the RIRDC report, would be foolish indeed. The latest ABARE modeling report that suggests losses of $3 billion over the next decade has no credibility. For instance, it assumes that GM wheat will soon be available but Monsanto stopped its GM wheat research in May 2004, following near universal rejection by North American farming organizations.

- The regulatory agencies mentioned above all manage different risks.
  - To what extent is it feasible for regulatory agencies to harmonise their requirements?
  - Can the regulatory system be nationally consistent without full harmonisation?
  - Should regulatory agencies seek to harmonise requirements with overseas authorities?

COMMENT: 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.

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

Issue Paper #5

- Are there other emerging technologies that ought to be covered by the regulatory system?

COMMENT: The present system appears robust enough to cope with most likely eventualities within the foreseeable future.

The following comment from the issues paper makes much more modest claims than the wild promises of science and industry. The author wisely says 'may' and proposes no time frames.

"As a general summary, current research (both within Australia and abroad) into GMOs that may lead to commercial products in the future falls into three categories:

- GMOs with input traits (eg herbicide tolerance, insect resistance, disease resistance, salt tolerance)
- GMOs with output traits (eg nutritional properties)
- GMOs that can be used as factories to produce pharmaceuticals or industrial oils.

Also on the horizon are related technologies such as RNAi technology which can be used to silence genes." Oh, yes. Where is the Flavr Savr now?

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.

GeneEthics Submissions:

1. The Network opposes the ABB Grain Ltd proposal that:

"The market access and commercial release components of the regulation could be managed by a committee of key industry members capturing the primary elements the entire supply chain." (Issues Paper 1, P.8)

Like other industry schemes, this excludes all other parties affected. Our experience with the Gene Technology Grains Committee convinces us that they would not exercise such powers responsibly. State and Territory Governments must retain these powers.

2. The Network questions the OGTR's comment that:

"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' which are not good enough.

3. We disagree with Dow Agrosciences Australia Limited, who say:

"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)

Our request that the applicants bear the evidence-based burden of proof is reasonable. To place the onus onto the OGTR or the public, to show why a GMO should not be released, is unfair.

4. GM backer Jeff Bidstrup unwittingly advocates cost/benefit analyses when he says:

"The OGTR already applies rigorous precaution to these products, and this maligned principle should only be considered in its practical intended form. We all apply the precautionary principle in our everyday life, balancing risks against rewards or adversities." (Issues Paper No. 1, P.13)

This is what the OGTR should do, to test the veracity of applicant claims.

5. The Network rejects Syngenta's plea for greater secrecy:

"It would be highly desirable to give data protection to some other information

submitted to the OGTR that is not claimed as CCI. This information may be released for public scrutiny but may not be used by third parties to their own gain. Data protection under such circumstances maintains the OGTR's need to be publicly transparent, however, by giving data protection to a broader spectrum of information, the OGTR will provide a more even playing field for companies, preventing their data being used by third parties with out their consent." (Issues Paper No. 2, P.10)

6. 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."

7. Monsanto should dramatically improve the quality and quantity of real scientific data supporting its applications, to lend a measure of credibility to its claim that:

"This creates inefficiencies as it involves the preparation of at least two, and possibly three or more applications (and a corresponding number of Risk Assessment and Risk Management Plans (RARMPs)). The changes to each application and RARMP are incremental, therefore repeating the whole process each time does not seem necessary. Furthermore, there is no distinction . . . [in] the time limit prescribed by the Regulations for assessment [of either type of DIR application]."

8. 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)

9. Bayer CropScience concedes the unpredictability of biological systems on

P21:

“Section 35 of the Act imposes strict liability on breaches of licence conditions. We believe this is inappropriate. Licences often deal with biological systems. There will arise instances where breaches may occur through no fault of the licence holder and be trivial.”

10. But then it tries to move responsibility for its actions onto others with the claim that:

“Strict liability should only be applied to activities that are inherently extremely hazardous to human health or the environment. Any expansion of strict liability provisions within the Act to agricultural biotechnology could only serve to discourage investment and development in this technology, which is, rather than being extremely dangerous, on the contrary, potentially beneficial.” (Issues Paper No. 2, P.25)

11. 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)

12. The Australian Oilseeds Federation’s arrogance was monumental, when it unilaterally decided:

“The Australian Seed Federation (ASF) has approved a standard for canola seed, which allows up to 0.5% of an approved event in canola sowing seed. All members of the ASF have indicated they will comply with this standard as part of its national Code of Practice for Seed Labeling and Marketing. The AOF has approved a threshold for non-GM for approved events of 0.9% GM in canola grain.” (Issues Paper No. 2, P.28)

13. GeneEthics refutes the self-interested assertions of the GE industry, that the G T Act is not working as intended. It is genuinely seamless and national.

The moratoria are evidence that the Gene Technology Act 2000 and the Intergovernmental Agreement on Gene Technology are not operating “in a seamless manner” between Commonwealth and State regulatory schemes.
Australian Academy of Science (Issues Paper No. 4 P.9)

A patchwork system of State/Territory legislation has developed across Australia not only limiting access to safe technology but demonstrating a national scheme has not been delivered. State/Territory prohibition legislation does nothing to answer the outstanding questions or offer a process for moving forward. This is damaging Australia’s reputation internationally in terms of reasonable regulation and is limiting investment not only in agri-business but also in other sectors.
Avcare (Issues Paper No. 4 P.9)

14. We agree with Syngenta that:

Coordination and clear delineation of responsibilities between federal regulatory agencies should be improved. (Issues Paper No. 4 P.11)

This problem of responsibility will be resolved by making the OGTR a lead agency and one-stop-shop for all GE licence and registrations.

15. We disagree with the Grains Council of Australia that:

The most effective way for the regulations to become more flexible, is to make them less onerous and prescriptive and to incorporate greater freedom for industry and the market to make appropriate technology adoption determinations. (Issues Paper No. 5 P.9)

The regulator's role should continue as before.