Submission

to the

Gene Technology Ministerial Council Review of the Gene Technology Act 2000

on behalf of the GM-Free Australia Alliance, and 235 other organizations and individuals

by

gene ethics
working for a GM-free future

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Gene Ethics

Our Vision

Gene Ethics envisages a safer, more equitable and more sustainable GM-free society.

Our Mission

Gene Ethics is a non-profit educational and policy network of citizens and public interest groups. We want the precautionary principle, scientific evidence and the law rigorously applied to all proposed uses of genetic manipulation (GM) techniques and their living products. Gene Ethics generates and distributes accurate information and analysis on the ethical, environmental, social and economic impacts of GM. Our education programs critically assess GM for the public, policy-makers and interest groups.

Introduction

The Gene Technology Act 2000 (GT Act) is an important law and the public interest will be served by strengthening it. The Intergovernment Agreement on Gene Technology does not need substantial amendment.

We refute claims made by CropLife, for the international GM industry, that the GT Act and its regulations be weakened. The powers of state governments and the Commonwealth regulators that collaborate with OGTR should remain intact. We also oppose the CropLife proposal to move the burden of proof for safety and efficacy away from the GM industry where it belongs, so that many more genetically manipulated organisms (GMOs) could be listed on the GMO register, which essentially deregulates their use. The absence of adverse evidence is not scientific justification, especially when no independent monitoring or experimentation is done. Their empty claims for data submitted with applications to be more secret merely serve the self-interest of the corporate beneficiaries of GM products. Since GM regulation is cost free to industry, they can make no economic case for weakening assessment procedures. And Croplife's proposal to ignore and forgive GM contamination on the grounds that trade may suffer is outside the ambit of the Act and, again, merely self-serving.

The Act needs to be strengthened so that the public interest has primacy and is fully protected. In particular, the Act has not effectively met community aspirations for the precautionary principle to be rigorously applied to the assessment and licensing of dealings with all GMOs, This should include human gene therapies and other human related GM uses, now covered by the NHMRC's voluntary system of National Statements on human gene technology.

In 1999 and again in the 2005 review, Gene Ethics asked that the OGTR system be designed to serve the public interest but many of our representations went unheeded. Again we ask for the Act to be amended to deliver a more precautionary, enforceable, accountable and transparent system to meet the aspirations of a majority of Australians,

for the maintenance of Australia as a GM-free continent.

All uncontained dealings with GMOs should be banned until and unless they are shown to be necessary, beneficial, and in the national public interest. To do this they must meet stringent environmental, social and economic goals. There is still no consensus or compelling evidence that these goals can be achieved by releasing GM organisms into open environments.

The law should also mandate a genuinely scientific system of regulation, with clear benchmarks, standards and QA systems to ensure scientific rigour. The present system is said to be 'science-based' and 'case-by-case' so it has ad hoc requirements for the quality, scope and scale of data lodged with applications, and does not meet the criteria necessary to be called 'scientific'. The system must be made more rigorous, scientific, accountable and fully open to independent public and expert critique.

During 1999 and 2000, extensive and in depth public consultations were held to reach policy agreement for the GT Act. The governments of the day managed extensive processes of policy development and consultation. Gene Ethics recommends that the GT Act reviewers adopt similar processes now, to canvass the opinions of all interested parties, through public forums as well as private consultations. Only then can the reviewers fairly and fully gauge the breadth and depth of public concern about the operation and need for reform of the gene technology regulatory system.

The interested public missed out on their say in this review (as they did in 2005/06). It was not publicly advertised as Part 6 of the Intergovernment Agreement requires. The OGTR belatedly sent an email notice, apparently only to its subscribers. Just two weeks notice of the inquiry's deadline is manifestly inadequate, especially as governments and the GTMC had five years to prepare for the review, knowing that it is required.

To partly redress this unfairness to the public interest, Gene Ethics asks that the review process be an iterative one, in which there are further opportunities for the interested public to make comments throughout the process. Notifications in all news media are required.

Gene Ethics asks the review panel to incorporate our recommendations and requests into its findings and recommendations.

Comments on ToRs for this review

The Terms of Reference are those set out in the Gene Technology Agreement.

Improvement in its national consistency, efficiency and effectiveness and coordination of the regulatory system.

> The Intergovernment Agreement on Gene Technology established the national uniform system of gene technology regulation. It was never envisaged nor agreed that it might also require identical decisions by every jurisdiction.

The national uniform system of regulation was legislated by the Gene Technology Act 2000 (Commonwealth), passed with some amendmentsadded by the Parliament, including Section 4 (aa) on precaution. Each jurisdiction passed mirror legislation in 2001 but, even then, there were variations in what various parliaments agreed to legislate. Some state parliaments, for instance, adopted a 'gatekeeper' approach so they could decide whether or not to allow release of commercial GM crop varieties, to protect the interests of all their farmers. That was appropriate then and remains so now.

We reject the CropLife claim that the agreement or the law be changed to require absolutely identical decisions by every state, territory and the Commonwealth. Such a lock step arrangement would be against the public interest and would break the GT agreement.

The states and territories ceded some of their powers to the Commonwealth to establish the national uniform system but they did not forfeit their rights to exercise their own discretion in some areas, in their own interests. We recall, for instance, that not all governments agreed to every recommendation of the 2006 review of the GT Act but where agreement existed, changes were made and given effect. We urge the retention of this diversity of views and responsiveness to democratic processes.

The reserve powers held by state and territory governments to make policy principles pursuant to Section 21 of the GT Act enhance and enable the effective functioning of the national regulatory system and do not compromise its integrity. These powers should be retained. The one policy principle already promulgated gave the states and territories responsibility for protecting the markets of all their primary producers, by exercising their powers to establish GM and GM-free zones over all or part of their jurisdictions, for marketing reasons.

These powers were the basis for the state bans on growing commercial GM canola which had popular support. Though licences DIR 20 & 21 for commercial GM canola had been issued in 2003, all states imposed bans under their own laws, on marketing grounds, that prevented the crop being grown.

Yet in 2008, Victoria and NSW scuttled the consensus on GM-free bans that then existed. They unilaterally applied the exemption provisions in their Acts to licensed GM canola varieties so they could be grown within those states. This was without the agreement of other States and Territories and over the objections of some. WA also allowed GM canola to be grown in 2010 under an exemption to its state GT Act.

We abhor these decisions to allow GM canola. However, the 'gatekeeper' approach written into state GT Acts, which requires such decisions to be reviewed and referred back to their parliaments, is an appropriate exercise of state powers.

Other states and territories still retain their moratoria on growing GM canola, on solid marketing grounds, as a result of the policy principle. That is fair and appropriate and the state bans should continue. Experience has now discredited all the false promises that the WA, Vic and NSW governments used as justifications for lifting their bans – that farmers wanted 'choice' (though a majority opposed GM), that farmers would

benefit (though the cost of patented seed, proprietary chemicals and end point royalties were higher), and no market impacts (though there is a $50/tonne discount for GM canola now).

GM contamination of neighbouring farms has taken away the choice of some growers to remain GM-free. GM contamination of non-GM canola and organic crops also threatens the livelihoods of affected farmers. WA organic farmer Steve Marsh, for instance, has been decertified and sustained substantial losses and additional costs as a result of neighbouring GM canola being blown onto his farm. See: http://www.abc.net.au/rural/content/2011/s3129428.htm

Horsham (Victoria) district conventional grower Bob Mackley has also had his farm GM contaminated in floods so his options for growing non-GM canola are compromised. His management options have been limited and he will incur extra costs that his neighbour who grew GM canola, the state government and the GM seed owner, Monsanto,will not meet. See: http://www.abc.net.au/rural/content/2011/s3167650.htm

The extra costs of GM seed/chemical packages has not been recompensed either, as this season GM canola is discounted by up to $50/tonne in comparison to non-GM canola, by those grain traders willing to buy it. Grain traders Elders-Toepfer Grain and Glencore Grain are experiencing such strong shopper preference for non-GM in their markets here and abroad that they are not buying GM canola at all. Last season Co-operative Bulk Handlers (CBH) and Viterra also bought exclusively GM-free canola. CBH Manager Peter Eliott was widely reported as saying the non-GM canola premium, especially in Europe is durable, for up to 5 years. See: http://www.abc.net.au/rural/wa/content/2011/03/s3159549.htm

South Australian farmers are reaping the benefits of that state's GM-free crop status. For example, Kangaroo Island Pure Grains has long-term contracts with Japanese buyers for GM-free products (canola and honey) at premium prices. See for instance: http://www.safoodcentre.com.au/rss_feeds/outgoing_feed/news_items/general/kangaroo_island_pure_grain It is rational for the SA government to maintain the state's GM canola ban so its farmers can capture this added value, but CropLife seeks to hijack them into conformity with the GM canola approvals in three other states. This would senselessly rupture the agreement that the Commonwealth regulate to protect the environment and public health and that other parties to the agreement deal with market and social questions.

Emerging trends and international developments in biotechnology and its regulation.

The European Union's emphasis on:

- applying the precautionary principle in regulatory decision and policy making,
- strong independent peer-reviewed scientific biosafety research, and
- negotiated compromises between the 23 jurisdictions involved in EU governance,

makes it an appropriate model for the Australian regulatory and marketing environment.

European shoppers' market influence on the values and standards applied to production are already evident and Australia should align itself with these positive trends which are affecting our export markets. For instance, see: https://www.cbh.com.au/media-

centre/news/2011/april/cbh-grain-accreditation-provides-potential-premiums-to-canola-growers.aspx CBH Grain Head of Marketing, Tom Puddy, says: "CBH Grain's European customers are indicating that with current EU crop forecasts and the Renewable Energy Directive (RED) in place, Europe will be short of canola and rapeseed again during 2011-12 and will need to make up a sizable portion of the shortfall with Australian International Sustainability and Carbon Certification (ISCC) certified sustainable, non-GM canola." CBH Grain Protein and Oilseeds Marketing Manager, Peter Elliott, said that forecast strong demand from Europe had seen a large price spread emerge between GM and non-GM canola which was likely to continue for up to 5 years. GM canola contamination of non-GM supply chains could cost Australia dearly but some state governments continue to mouth the false mantra of 'choice' for GM growers.

Diametrically opposed to these market and regulatory trends, Croplife's proposals are to weaken the OGTR's regulatory environment and whip all our governments into lock step, in the interests of its foreign corporate members. Their submission would align Australia with our main competitors for global grain markets – the USA, Canada and GM corporations. These interests would benefit hugely if we adopted their proposals and lost our competitive advantage. We must not uncritically embrace GM production systems and follow the US by allowing GM companies to self-assess and self-regulate their own GMOs.

Regulatory changes that emulated the USA by weakening our GM regulatory regime would also be counter-productive here because the USA grows 50% of global GM crops, while Australian farmers grow perhaps 0.2%, a discrepancy that is very unlikely to change any time soon. Our very different farm and natural environments, diverse production and marketing systems, and contrasting regulatory space mitigate against Australian producers, food industry and public benefiting from GM crops, animals and micro-organisms designed for US conditions.

New GM products coming to market demand the law be strengthened, not weakened or made more flexible. US government and public values, standards and systems of governance are out of step with the Australian public interest, public sentiment, public health and environmental needs.

We strongly advocate the robust application of the precautionary principle and an increase in opportunities for public participation and independent expert advice to help to meet these challenges.

We also support the Hawke Review of the EPBC Act which notes that: "6.52 Considering the range of potential impacts and flow-on effects as a consequence of new innovations in agriculture, an alternative approach to risk assessment would be to conduct **broad strategic assessments**. The Act (EPBC) could support this strategic approach by including the ability to assess cumulative impacts in a manner appropriate for GMOs and other emerging technologies." See: http://www.environment.gov.au/epbc/review/index.html

We recommend that the broad strategic assessments proposed by the Hawke review, for inclusion in the EPBC Act, also be incorporated into the GT Act. The GT Act should require the OGTR to apply scientific systems methodologies and ecological principles to analysing the impacts of GM organisms on natural and modified environments before any licences are granted.

In stark contrast, Croplife advocates weakening our laws on behalf of foreign agrichemical and GM corporations. These agendas would not serve Australians' national, regional or local interests. There is no sound case for putting more GM organisms onto the GM Register as CropLife claims as there is very limited history of use (let alone safe use) with these novel GM organisms in Australia. The floodgates to new imported GM organisms should remain firmly shut, and our biosecurity, biosafety and product regulatory authorities should remain alert and on the job of approving only those that are proven safe.

Terminator Technology, officially known in United Nation's forums as Gene Use Restriction Technologies (GURTs), should be banned in Australia as they are by most Parties to the Convention on Biological Diversity. Yet the OGTR says it would accept and assess any application for a GMO containing GURTs. This is irresponsible and should not be permitted. The GT Act should be amended to require the OGTR to always operate in accordance with our international United Nations treaty obligations – in this case as a party to the Convention on Biological Diversity.

The GT Act should also require OGTR systems to be fully compliant with the Biosafety Protocol, the first Treaty negotiated under the Convention on Biological Diversity (CBD). The Commonwealth should further facilitate this by signing and ratifying the Protocol as 161 other countries have done. See: http://bch.cbd.int/protocol/#tab=1 US government and GM industry interests advanced by CropLife should not influence Australia's GM management policies, especially as the US is not even a Party to the Convention.

Unacceptable conflicts of interest exist for some state governments. The Government of Victoria, Office of The Premier of Victoria, and Queensland Government are full members http://www.bio.org/members/biomembers.asp?list=Australia of the Washington-based Biotechnology Industry Organisation (BIO) that promotes US GM interests abroad. The GTMC should encourage these governments to divest themselves of this vexed and compromising connection.

High risk organisms, such as GM fish, mosquitoes and trees, released in other parts of the world may pose special hazards that are not yet apparent. They are among those innovations that require biosecurity strategies and even more precautionary assessment than that now exercised by the OGTR over domesticated organisms. This is where the preauctionary strategy recommended by Hawke for the EPBC Act would be especially useful.

The emergency dealing provisions of the Act enabled expedited release of the horse flu vaccine, without public consultation. Other vaccines such as Gardasil, also create new demands on the regulatory that require fuller public participation and more precaution, not less. Gene Ethics proposes that the emergency dealing provisions of the GT Act be reviewed and amended so that more experts and the interested public can genuinely engage with the expedited processes of approval.

The Venter Institute has created the first synthetic micro-organism using synthetic biology techniques. These organisms have never existed before and are entirely human created, so they will pose major new challenges to regulators everywhere. More public

engagement in regulation and more precautionary systems are urgently required. Again, the proactive foresighting methodologies recommended in the EPBC review report should be used to prepare for the possibility that synthetic organisms may arrive in Australia.

Croplife proposals to weaken the Australian regulatory system are based on questionable interpretations of data. At page 10 of its submission, Croplife claims new GM crops will be available to "offer major benefits to human health and the environment," but their summary table refutes their claim, rather than supporting it. They cite a summary from page 39 of the European Union Joint Research Centre (2009) report, The Global Pipeline of New GM Crops. But these wildly optimist projections show that, even if achieved, over 80% of "GM crops commercialised globally" in 2015 would still be transformation events only in the four GM crops available in 2008 – soybean; maize, rapeseed (canola) and cotton. The data referenced in the Appendix to the EU report suggests that two agronomic traits already available - herbicide tolerance and Bt toxin - would continue to dominate. Other unspecified examples are crops and transformation events that remain purely speculative.

The industry report issued by the International Service for the Acquisition of Agrobiotechnology Applications (ISAAA) figures for the 2010 season supports the view that most GM traits will continue to be agronomic. The global GM pipeline contains few of the so-called second and third generation traits that CropLife promises. CropLife also cites Brookes and Barfoot whose work and performance have been widely critiqued and discredited. See, for example: http://www.powerbase.info/index.php/PG_Economics

Enforcement of compliance

Enforcement will remain weak while the OGTR issues unrestricted and unconditional commercial GMO release licences, as occurred with DIR 20 and 21 for herbicide tolerant GM canola. Some GMOs – micro-organisms, pollen and seed - are so difficult to contain or limit that if there were any licence conditions unauthorised releases and breaches would be inevitable and more frequent. Even where unauthorised research, releases and breaches have occurred, the OGTR takes the mildest of actions and has not imposed any fines, penalties or tougher compliance requirements. The breaches are generally excused as accidental, insignificant or benign. This must change. Without effective management and monitoring, compliance will remain patchy. The OGTR and the GTMC should review enforcement with a view to making improvements. The GT Act should mandate tougher monitoring by the OGTR, compliance on licensed dealings, and reporting of any breaches.

Changes in communication modes.

Social media tools and the National Broadband Network open up enormous new opportunities to enable robust and helpful public participation in OGTR operations and decisions. Public engagement with applications to the OGTR declined dramatically over the past decade, not because the public is indifferent but because the system has been unresponsive to community expectations and needs.

The OGTR's pre-digested summaries of applications are unhelpful as the absence of any objective assessment criteria set by the OGTR system, and a lack of access to

raw data, make it almost impossible for independent experts from outside the system to effectively critique proposals. **We propose that all data submitted in support of applications be posted on the OGTR website and accessible to everyone, so that independent evaluation and monitoring of methodologies, processes and experimental data would for the first time be possible.**

There would be few costs and many potential benefits from posting all applications and the data submitted with them. From May 1, 2011 FSANZ has begun to post applications and data on its site and we believe this new access and openness will be in everyone's best interests. The valuable advice that would come in from the interested public and independent experts world-wide should assist the OGTR to make better precautionary decisions in the public interest.

Greater transparency and accountability would be dramatically improved and we envisage much greater and more productive public engagement with OGTR processes. The lack of key information such as raw trial data means the interested public is now poorly informed and unable to meaningfully review or critique applications – eg: the OGTR declared seven years of agronomic data from Monsanto's GM canola trials (on about 250 hectares) and Aventis (now Bayer – on about 3,400 hectares) commercial in confidence at the companies' request. It is still secret, yet in 2003 the OGTR issued unrestricted, unconditional licences for unlimited commercial growing of herbicide tolerant GM canola throughout Australia. It was this secrecy not public indifference that turned people off engaging with the regulatory processes.

The functions and roles of the statutory advisory committees.

Broad independent expertise and advice should be embedded in OGTR risk assessment processes, especially on ecological and epidemiological issues which OGTR assessments now appear to ignore.. Despite a recommendation in the 2005 review that the Gene Technology Technical Advisory Committee (GTTAC) should include an ecologist, the present GTTAC membership does not include a professional ecologist to help assess the environmental impacts of GMO releases. It is unsatisfactory that

Greater parity between the committees advising the OGTR is also needed. While GTTAC can effectively influence decisions on whether or not a licence is granted, GTECCC is not consulted on technical matters, is poorly directed by the OGTR and GTMC, and their advice appears to be generally uninfluential. Both advisory committees should be further empowered to give wide-ranging advice to both the OGTR and the GTMC as the Act requires but does not happen. Advice from both committees should be accorded equal weight, be responded to, and be incorporated into OGTR and GTMC decisions and public communications;

Recommendations:

Gene Ethics recommends the GT Act and its regulations be amended as follows:

- **The Act to have the precautionary principle as a core tenet, defined as in other environmental laws such as the Environment Protection and Biodiversity Conservation (EPBC) Act, Ecologically Sustainable Development charters and the Convention on Biological Diversity, and the OGTR be required to apply it.** Section 4 (aa) of the existing GT Act is a weak, equivocal, imprecise and unenforceable provision, not the robust decision-making tool that is needed. It is tokenly applied as the 'precautionary approach'. Section 4 (aa) should be replaced with publicly agreed words such as: "Where scientific evidence is insufficient to support the safety of a GMO, measures to protect public health and safety and the environment will be adopted, in accordance with the precautionary principle." The precautionary principle has a long international history and is included in at least 45 environmental statutes, in Australian federal and state jurisdictions.

- **The Act to impose on licence applicants the burden of evidentiary proof for the environmental and public health safety and efficacy of their GMOs and dealings with them.** They must be required to produce robust scientific evidence to show why the proposed dealing should be licensed. Peer-reviewed scientific evidence would be needed to discharge this requirement. Instead, the present G T Act is framed to require the community and OGTR to show why a licence should not be granted, imposing an onerous and unreasonable burden where it does not belong;

- **The Act to require that the applicant's data be made available in raw, undigested form to all interested parties through the OGTR website.** Without this data, no independent evaluation and monitoring of experimental design, methodologies, processes and experimental data is possible. The digested documentation published by the OGTR is framed so that the risks and hazards of proposed dealings are often made to seem better understood, more predictable and more manageable than they really are. All the data submitted with applications should be downloadable from the OGTR website. Other regulators (e.g. FSANZ) are now posting such data online and this provides a compelling precedent. 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.

- **The Act to establish farmer and supply chain protection laws that impose strict liability on all dealings with GMOs licensed by the OGTR, so that liability for GM contamination and the resultant losses and costs rests fully on the licensees and the owners of GM patents.** These expenses should be recompensed from a pool of funds levied on the sale of GM seed. All release licences should require containment or control of GMOs so that any unlicensed presence of a GMO on public or private lands must be remediated and compensated by the licensee. Liability is now ill-defined and generally falls on everyone except the licence holders and patent owners. Common law remedies are inadequate to protect the interests of Australian farmers, food processors and shoppers, the vast majority of whom want to remain GM-free. Strict liability and automatic recompense for any losses and extra costs that result from GM

contamination should be funded from the levies;

- **The Act to create a rigorous scientific system for GMO assessments, to modify the present system which is said to be 'science-based' and 'case-by-case.** These tags are used to justify an unscientific and ad hoc approach to data collection and assessment methodologies. The OGTR accepts unscientific and ad hoc evidence as the basis for applications and most evidence submitted is corporate-generated or commissioned, is rarely peer-reviewed, is never replicated, is usually not experimental in design, is conducted for commercial not scientific purposes, and is so small-scale and short-term that the data and results are often meaningless. An ad hoc suite of data from often out-dated, contested, overseas, company-generated 'trials' or 'tests' (not experiments) should not be accepted

  OGTR assessments are not scientific and do not apply the agreed rules of scientific practice. Nor does the present approach conform with Recital B of the Intergovernment Agreement, which requires that "the Scheme should: (d) be based on a **scientific assessment** of risks undertaken by an independent regulator, …

  A systems approach to interactional analyses of GMO impacts on health and all environments is essential to scientific assessments. 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. Despite the recommendation of the 2005 review that an ecologist should be added to GTTAC membership, there appears to be no such expertise among the 20 present members.

  Broad independent expertise and advice should be embedded in OGTR risk assessment processes, especially on ecological and epidemiological issues which OGTR assessments now appear to ignore.

  Data generated from contemporary, controlled experiments, preferably conducted in Australia, should be the basis for sound regulatory assessments. The revised system needs objective assessment methodologies, with unambiguous benchmarks, standards, QA systems and environmental goals set beforehand in the GT Act and its regulations, These should be used to assess the relevance, robustness, objectivity and replicability of all evidence tendered in support of applications. The standards should also mandate the design, scope, scale and duration of relevant scientific experiments necessary for systematic collection of high quality data for precautionary assessment.

  Risk assessment methodologies, to robustly assess the good scientific data required, should also be set out in the Act and Regulations. These objective rules would not subject to variation at the preference of assessors or the GTR. They are the essential basis for the fair and objective assessment of the reliability, replicability and relevance of all evidence tendered in support of an application.

- **The GT Act to also adopt the sensible recommendations on GM and other new technologies proposed in section 6.2 of the Hawke review of the EPBC Act.** This would require the OGTR to make broad strategic assessments of the impacts of GM organisms on natural and modified environments. This would entail applying ecological concepts and scientific systems methodologies.

- **The GT Act to be amended to require the OGTR to always operate in accordance with our international United Nations treaty obligations.**

- **The Act to be reviewed and amended so that the emergency dealing provisions facilitate** more experts and the interested public to participate in the expedited processes of approval.

- **The Act to require equal assessment of both the potential benefits and risks of all proposed dealings with GMOs.** The OGTR now considers only a narrow range of poorly defined 'risks'. The scope and scale of the risks to be assessed should be reviewed and broadened. The OGTR does not assess any benefits but assumes that the benefits which may accrue to an applicant if a licence is granted are sufficient alone to justify granting the licence. This ignores the costs and benefits of GMOs to the general public. The Act ought to mandate a review of potential benefits, and if these do not outweigh the likely impacts and costs then the licence should not be granted;

- **The Act to require that a licence only be issued where an institution or person is mandated with the necessary responsibility, enforcement powers and liability to ensure that diligent management of the GMO occurs**, to prevent its impacts on public health and the environment**.** Where the OGTR acknowledges the risks of a GMO release but assesses the risks to be manageable, licences to deal with the GMO are generally silent on who is responsible for managing the risks. Without any designated management, failures inevitably result from the grant licences.

  The Act's present objects clause also wrongly assumes that all risks can be managed. The behaviour of living organisms in biological systems cannot be precisely predicted and not all impacts – such as GM seed or pollen dispersal and contamination – are predictable or manageable. Thus, the risks, hazards and costs of contamination and damage are nobody's clear responsibility. With GM canola, for instance, the licensees wrote voluntary guidelines and a Technology User Agreement, an unenforceable system of industry self-regulation. They do not monitor or enforce any aspect except matters of commercial interest such as preventing seed saving, tracking failed crops cut for hay, and the sale of land on which GM crops were grown – only in the interests of maximising returns to the technology owner. The government institutions in states where the crop has been grown have consistently refused to intervene.

- **The Act to provide for community rights of appeal from OGTR decisions.** As the law stands only applicants may appeal OGTR decisions. Community appeal rights should include administrative and merit reviews, and everyone should have standing to appeal OGTR decisions. There is no evidence that frivolous actions would follow from everyone having full appeal rights, equivalent to those enjoyed by applicants.

- **The Act to establish a one-stop-shop regulatory system, covering all uses of GM techniques to manipulate the genome of any living organism - human, animal, plant or micro-organism – GM processes and products.** The present gap fill model should be amended so that the OGTR is the lead agency. To the extent that this would involve 'harmonisation' of the Commonwealth's regulatory agencies, we support it.

- **The Act to define a much broader and more robust definition of 'environment'** to make it consistent with other environmental laws, particularly the Environment Protection and Biodiversity Conservation (EPBC) Act to which the OGTR must have regard when considering commercial GM licences. The recommendations of the Hawke review of the EPBC Act should be taken into account;

- **The Act to define 'GMO' to also include animals raised on GM feed and their products – meat, milk and eggs.** Prof Jack Heinemann's review (downloadable at: http://www.biosafety-info.net/article.php?aid=645) of the impacts of GM crop material on animals, supports the need for reviews by the OGTR. Monsanto has also lodged a patent application to cover animals enhanced by eating GM feed, making it entirely appropriate that such organisms and products should be regulated by the OGTR, in consultation with FSANZ. New evidence by Canadian gynaecologists Aris and Leblanc published in the peer-reviewed journal Reproductive Toxicology (google 'reproductive toxicology aris and leblanc' for the pdf) found Bt toxins in the blood of pregnant women and their foetuses, challenging our regulators' assumption that all DNA and protein is denatured during digestion. The authors draw no conclusions about the safety aspects of their findings but recommend more research.

- **The Act to require the OGTR to deal more strongly, decisively and publicly with licence infractions eg: non-compliance, contamination, unauthorised GMO releases, and accidents.** This should also include putting conditions on commercial GM licences so that contamination like that in the organic industry in WA would be remedied;

- **The objects clause of the Act to be amended to remove the assumption that GMOs will be released into the environment.** This pre-disposes the OGTR to licence every proposed dealing and it appears that an application has never been rejected, though some have been withdrawn;

- **The Act to require improved transparency and accountability by limiting the OGTR's discretion to permit commercial in confidence (C-in-C) approvals without public scrutiny or accountability.** We contest CropLife's claim that greater secrecy is needed as patented or peer-reviewed subject matter is already in the public domain and requires no secrecy. It appears that the OGTR approves most C-in-C applications, more or less automatically. Instead, the Act should require that any C-in-C approvals are fully justified by the applicants and that the OGTR publish and justify their decision to grant secrecy;

- **The Act to require the OGTR to publish a full statement of reasons for issuing a licence, for further public comment prior to any licence being issued;**

- **Sections 57 (2) and 58 of the Act to mandate stronger and clearer fitness criteria for the holders of licences to deal with GMOs.** When the OGTR assesses the suitability of an applicant to be licensed, all applicant conduct that may have been against the public interest (including criminal convictions) ought to be reviewed. The behaviour of close associates and parent companies must also be discussed, assessed and published with reasons. It is unsatisfactory that wherever the OGTR has

a discretionary power, it appears to be exercised in the interests of applicants and licensees rather than in the public interest;

- **The Act to require applications for release of a GMO into the environment or food chain to be backed by contemporary, scientific and independent data.** GM 'field trials' must be scientific and be required to produce objective data on the public health and environmental aspects of the GMO, to enable companies, regulators, industry and the interested public to fully and fairly assess the merits of a proposed dealing. Most trials are not experiments at all, primarily having agronomic performance and commercial goals. For example, Bayer's 10 hectare canola plots grown between 2003 and 2008 under exemptions from state GM crop bans were commercial operations to bulk up and export seed for sale in Canada. No data at all was produced from these 'trials' that would have qualified them to be regarded as experiments or to meet the standard criteria of scientific method and rigour – scope, scale, replicability, relevance and parsimony – yet they were licensed as 'field trials'.

- **The Act to not accept the data from agronomic or other 'trials' or 'tests', produced for commercial reasons, to be the primary evidence base for an application.** Such data is generated for agronomic and commercial use, not for safety assessment and does not have the requisite rigour to qualify as sound evidence.

- **The OGTR to be required to publish a full statement of reasons for intending to grant any DIR licence.** Further public comment should be invited prior to any licence being issued.

- **That members of the GTMC consider** whether Australia can manage GMOs safely without any designated research facilities or teams working exclusively on biosafety.

Discussion

The Precautionary Principle

The precautionary principle is mandated in environmental and public health laws around the world, and in the Convention on Biological Diversity. It makes a very positive contribution to ensuring that licence applicants are responsible for ensuring that their products entering the environment and our food supply are as safe as can be, with a high degree of confidence.

The OGTR appears to ignore the Precautionary Principle which should be fully enunciated and integrated into the GT Act, as it is in the EPBC Act. Section 4 (aa) of the GT Act is a mild imitation of precaution, ignored on the spurious assumption that GM organisms are generally no riskier to public health and safety and the environment than their conventional counterparts.

The 2005 Issues Paper (No. 1, P.12) says: "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 applying 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."

But the OGTR cannot base perception of a threat on 'credible scientific hypotheses' when so few genuinely scientific experiments have been required. The GM industry has actively prevented scientific data collection and peer-reviewed publication to identify causal pathways and accept or refute such hypotheses, as Nature Biotechnology, Vol 27, Number 10, October 2009 http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf and Scientific American (August 2009) report http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research)

The OGTR and GTTAC appear to operate on 'best guesses' and 'thought experiments' not grounded in relevant data. When new data is peer-reviewed and published, like that from Aris and Leblanc, our regulators (in this case FSANZ) merely post rebuttals on their website that contain no data or references and rely on debating points and unsubstantiated claims. The appropriate response would be to require licence applicants to produce impeccable scientific data that refuted the published findings. Instead, our regulators continue to ignore any evidence that tends to question or undermine their assumptions.

Accessible Data

There are no good reasons to keep secret the data from genuine scientific experiments on GM risks to health and the environment. All data supporting applications should always be scientific and public, to improve the transparency and accountability required by the Recitals. The OGTR system should publish applications and scientific research data in raw, undigested form on the internet. All interested parties would then have full access to all information.

Without access to this data, no really independent expert assessment and critique of proposals is possible. The OGTR's pre-digested documentation is framed so that the risks and hazards of proposed dealings are made to seem better understood, more predictable and more manageable than they are.

FSANZ began publishing the data sets it receives from May 1, 2011, and the GTMC should resolve that the OGTR be required to do the same.

One-Stop-Shop

All applications for the licensing of any dealing with a GMO, or registration of any product of a GMO, 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.

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 GM 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.

Suitability (Sections 57 (2) and 58

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. A preliminary assessment of an applicant's fitness to hold a licence, required by sections 57 and 58 of the Act, should be conducted when an application is first received. Thus, if the applicant were disqualified, the application would not proceed.

Stronger and clearer fitness criteria for applicants should be mandated in Sections 57 (2) and 58 of the Act. The OGTR should seek public submissions on an applicant's standing and conduct (including criminal convictions of the corporation and its officials). The behaviour of parent organisations should also be discussed, assessed and the reasons published. Australian offices of transnational companies are not separate from their parents as the OGTR has at times contended.

Strict Liability

The standard common law tests of negligence should not apply to living GM 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 California government recognized this and passed a law that limits the scope for GM companies to sue farmers who have patented seed on their farms without a licence.

The segregation of the pollen and seeds of some crops is impractical, especially GM canola, from non-GM canola and from its weedy relatives – wild radish and turnip - and some native relatives. For instance, the transfer of a GM 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.

State and Territory Powers

We fully support retention of the parties' powers to make policy principles, under Section 21 of the GT Act. The GTMC is first and foremost a forum for development of robust policies. **We also fully support retention of the policy principle already issued** under Section 21 (1) (aa) of the Act, by which State and Territory governments are empowered to recognise designated GM and GM-free areas within their jurisdictions for, among other things, the purpose of preserving the identity of GM and non-GM crops for marketing purposes. The consistent contamination of non-GM canola by GM, even before the commercial varieties were released, challenges the identity of those commodities and impacts trade and the

marketability of Australian canola, as we mention elsewhere. Without these powers, systems for preserving the identity of GM and non-GM canola varieties are manifestly inadequate, even with thresholds of allowable contamination of 0.5% in seed for planting and 0.9% in harvested grain. State or regional moratoria on commercial GM canola are still fully justified on marketing grounds and we strongly support them.

Definitions

The Act should define 'environment' so it is consistent with other environmental laws such as the Environment Protection and Biodiversity Conservation 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. The OGTR cannot assess the impacts on something undefined.

Conclusion

Gene Ethics submission has substantial community support and is in the public interest. We ask the reviewers to adopt our recommendations for the precautionary principle, scientific rigour and other positive features to be incorporated into the GT Act and the Intergovernment Agreement. These proposals would create a more open, responsive and accountable system for the regulation of genetic manipulation techniques and their living products.

We also ask the reviewers to reject Croplife's claims for a radical weakening of the Australian regulatory system which would serve their own private profits and interests. The national system of regulation requires more democratic checks and balances, not less. Any change to require absolute uniformity or lockstep decisions and actions by all jurisdictions would not be in the public interest and we oppose them.

Signatories

This submission is supported by the following organisations and individuals, and 201 other individuals from all Australian states whose names will not be published:

Gene Ethics – Bob Phelps – Carlton Vic; Friends of the Earth (Australia) – Georgia Miller Fitzroy Vic; Hon Lynn MacLaren MLC - Fremantle WA; Mt Leeuwin Springs Organic Farm - Mal & Sarah McGibbon; Kew Organics - Jack Verbeek - Kew Vic; Hotham Ridge Winery - Leonard Bruin & Wouter Denig; Spencers Brook Farm - Annie Kavanagh; Bee Happy Apiaries – Toodyay WA; Merri Bee Organic Farm - Bee Winfield - Nannup WA; Donnybrook Organic Chicken - Bell Organic Produce - Barry & Linda Bell – Donnybrook WA; Marleen Herbs of Tasmania - Ronald and Marleen van de Winckel - Barrington Tas; Organic Agriculture Association Inc – President, Stephen Cross; David Mattinson - Not Without My Llama Organics - Sawtell NSW; Chris Luhrs - Corporate Wellness Solutions - Clifton Hill Vic; Mothers are Demystifying Genetic Engineering (MADGE) - Frances Murrell – Fitzroy Vic; CirclesOfLearning – Judith Schulz – NSW; Super Natural Organics - Peter Doff and Wendy Robertson; Jonathan Pipke - 3CR Radio Food Fight Program – Collingwood Vic; Costa Georgiadis – SBS gardening presenter; Australians Want GM Free Food; Cr Samantha Dunn - Shire of Yarra Ranges - Lilydale Vic; Cr Lynne Saville - Willoughby City Council - Chatswood NSW; Halfmoon Biosciences - Lisa Nicholson; Margaret River Regional Environment Centre; Leeuwin Environment, WA; GM-free South Gippsland; Organic Federation of Australia (SA); Ethical Consumer Group Inc. - Nick Ray - Fitzroy North Vic; Four Leaf Milling P/L – Gavin Dunn - Tarlee SA; Greenpatch Organic Seeds - Taree NSW; Trees For Life; Beeswax Creations - Kalamunda WA; Power Super Foods - Paul & Lisa Jordan - Uki NSW; Columban Mission Institute, Centre for Peace Ecology and Justice - Anne Lanyon - Strathfield NSW

Appendix 1: Discussion Paper 2005

In the 2005 review of this Act, the review panel issued a discussion paper in which they posed a series of questions. Many of these questions remain relevant now so we again pose and respond to some of the questions as we did at that time. Our position on key policy settings remains substantially unhanged.

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

> Our comment: The OGTR and GTTAC 'considering' such risks is an inadequate response to on farm environmental threats. Scientific assessment of scientific data should be the OGTR's core business but in the absence of scientific data it does not fulfill its responsibilities. 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. The introduction of GM cotton varieties appears to be associated with the spread of fusarium wilt, a cotton pathogen that can also affect other plants. Experiments are needed to establish or refute the connection and the OGTR should regulate accordingly. Similarly, blackleg resistance in GM canola varieties needed OGTR assessment before issuing commercial licences. 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. The impact of GM canola spilled on rural roadsides, which are in many places the sole repositories of rare native plant species, was so discounted by OGTR without any data from controlled experiments. The invasion of key ecological niches by GM canola remains an environmental challenge needing scientific research and assessment.

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

> Our comment: The proponents of gene technology constantly make public claims that GM products have benefits. These often-baseless claims need to be reality checked. The OGTR, as well as state and territory governments, should assess them through public processes, just like those assessments of risk. For instance, we question industry claims that GM herbicide and insect tolerant varieties have greatly reduced chemical use on the Australian cotton crop as our attempts to secure supporting data were unsuccessful. And US evidence (Benbrook 2004) shows that only in the first three years of GM crop commercialization did overall chemical use decrease.

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

> Our comment: Change the Act to require the applicants to justify their claims for commercial confidentiality to the OGTR and the public. Now, the OGTR appears to automatically approve all C-in-C requests. 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 allows information to be secret without good justification. For instance, seven years of agronomic data from GM 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 GM canola throughout Australia. In this state of secrecy the Australian public was understandably incensed and this national resistance supported the states imposing bans for marketing reasons.

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

Successful C-in-C claims should be kept to a minimum. Individual items rather than whole pages or sections of documents may be allowed, including just the details of the actual constructs 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?

Our 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 GM 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 GM 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, applicants should get no better protection than they have now.

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

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

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

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

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

Our comment: Scientific research and the commercialisation of GM products are social and cultural activities which also require scrutiny by the regulatory processes. Bringing gene technology R&D results to market as living products is not a purely objective or scientific process beyond criticism.

The Act must require scientific experiments, not trials, as the basis for applications. Applicants must have ongoing responsibility for the commercial use of their living GM products and this is why we propose Protection Laws, including strict liability, so that those who bear extra costs or losses can be automatically recompensed from a fund established for the purpose.

For instance, GM contamination of conventional canola that led to thresholds of allowable contamination being set appears to have resulted from trials that were supposed to be contained. The Tasmanian government is still monitoring test sites contaminated with GM canola in 1998 and 99. 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.

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?

Our comment: Yes, definitely. Conformity with the data requirements of a genuinely scientific regulatory system set out in the Act, would mandate the submission of rigorous data with every application. A screening stage to ensure compliance would be 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.

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

Our 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 OGTR compliance strategies effective in protecting the health and safety of people and the environment?

Our 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 GM crop. The OGTR and other regulators do little scientific or evidence-based assessment of the health and safety impacts of GM 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)?

Our 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?

Our comment: Living GM 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-GM canola, related weeds and native relatives is impractical. For instance, the transfer of a GM 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?

Our 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?

Our 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 GM-free seed. Seed companies should be required to certify that any seed they sell is GM-free, except for licensed varieties of cotton.

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

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

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

Our comment: Rigorously apply the precautionary, polluter pays and public participation principles. These principles are necessary because GM 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 GM 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?

Our 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. As the OGTR is not a cost recovery regulator, the burden of regulation is inflated by applicants.

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?

Our 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.

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

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

Our 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 GM crops are false and have decided to invest in more worthwhile and pressing enterprises. Two traits in four crops after 30 years of work and at least $45 billion spent on R&D does not recommend GM crops to any investor.

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?

Our comment: We want the OGTR to be a one-stop-shop that would cover all GM 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 in future.

Gene Ethics has always supported a one-stop-shop system for the regulation of all GM 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 GMO, or registration of any product of a GMO, 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.

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 GM organisms by the USA, we do not support it.

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

We do not support harmonization of the GT Act with the requirements of overseas agencies. However, we do support the general approach of the European Union countries rather than the US system. The US system only requires the GM industry to apply for commercial GM releases where patent owners themselves make a judgment that their organism poses sufficient risks to justify a regulatory assessment. This approach is insufficiently precautionary and too laissez faire to suit Australia's situation.