

September 29, 2017

Comments on issues: Gene Technology Regulatory Scheme Review 2017

Gene Ethics Vision

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

Gene Ethics Mission

Gene Ethics is a non-profit educational and policy network of citizens and public interest groups (now over 7,000). **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.¹

Introduction

Thank you for the opportunity to comment on the Review of the Gene Technology Scheme 2017, as we have on two past occasions in 2005 and 2011. Some issues raised in those previous reviews were not resolved to our satisfaction so we raise them again. Our 2011 comments are also attached.

We strongly favour Option 2 (with additions) of the OGTR's proposals for regulation of all new GM techniques and their products. We reject the deregulatory Option 4 that the GM industry favours, as it would enable most of the new GM techniques and their living products to be deregulated immediately. They could be researched, developed and released without public knowledge, which is unacceptable.

Deregulating the new GM techniques and their products, by exemption in the GT Regulations, would disadvantage a number of sectors. These include the community, export industries, the organic and GM free sectors and all those who welcome comprehensive, scientific and precautionary regulation of their processes and products. Regulations provide a social licence to operate. The licence cannot be issued without due process.

Regulation also signals a willingness to comply with the community's reasonable expectations that all products coming to market and into our environments are benign and efficacious. Industry's quest to invalidate or neutralise GM regulation will be rightly seen as attempting to hide new GM and undermine farmer and shopper support for GM-free futures. For several decades the GM industry has argued that acceptance will come with better information and knowledge. The opposite has occurred and so now the industry seeks to introduce the next generation of GM by stealth.

The success or failure of the GM regulatory scheme will finally depend on the presence or absence of genuine public participation, trust and confidence. That is in question, with the OGTR ignoring valid public interest stakeholder concerns. OGTR processes need to be strengthened and made more accountable. GM techniques and their living products should only be deployed if those who control and manage the biotech industries and science abide by the terms of their social licences, and if these licences include strong and adequate regulation, fully enforced.

Some aspects of the Gene Technology Scheme need reform while many remain adequate and fit for purpose, to achieve the Scheme's objectives. We seek to reform and improve the Scheme without sacrificing the checks and balances that all Governments originally agreed to, when the framework was negotiated and came into force in 2001.

¹ About Gene Ethics – working for a GM-free future. <http://www.geneethics.org/about>

We support improving the functionality, robustness and vigilance of the GT Scheme, so it continues to fulfil its core purposes. We also want it to meet all new and emerging social and technical challenges, and to be sufficiently agile and robust to deal capably and securely with uncertainties as new circumstances arise in the future.

Recommendations

1. Maintain the current broad definitions of GM, GMO and dealings to ensure that all new GM techniques are brought within the regulatory ambit of the GT Act 2000
2. Remove the new GM exemption decisions from the Technical Review of the GT Regulations and incorporate the process into this more open Review of the GT Scheme 2017
3. Retain the Gene Technology (Recognition of Designated Areas) Principle 2003
4. Broaden the nature of assessments for intentional releases to include social, ethical, cultural and economic matters, as mandated in the Inter-Government Agreement
5. Make provision in the Scheme for State Governments to propose social, cultural, ethical and other non-scientific principle to the other Parties
6. Amend the GT Act and the Agreement so that the OGTR has ultimate responsibility for all aspects of Gene Technology notification, assessment, licensing, monitoring and compliance, even where the agency is not supervising routine implementation of the Scheme.
7. For all the regulatory agencies engaged in the Scheme, harmonise all domestic definitions of GM, GMOs and dealings, using the current GT Act definitions
8. Review the long term health and safety effects of GMOs from seed to spoon
9. Base licensing and other decisions on independent and peer reviewed science, not unpublished industry-funded data
10. Ensure that any gaps in data, important to robust health and safety assessments, are filled with new independent data as part of the decision-making process
11. Mandate the design, scope and scale of relevant scientific experiments and data
12. Ensure these requirements include benchmarks, standards, Quality Assurance systems and protocols necessary for the systematic collection of high quality, independent data for assessment. Data from contemporary, controlled, experiments conducted in Australia should be the preferred basis of assessments
13. Conduct best practice cost benefit analysis in assessing the full impacts of potential release of GM crops
14. Define 'Environment' in the Act consistent with definitions in current Federal environment legislation
15. Define 'Health' in the Act to accord with the notions of health maintenance, prevention of disease, and other health impacts
16. Consider the broader impacts of the general release of GMOs including, for instance, the:
 - extent and implications of herbicide resistance in weeds, following introduction of GM crops and the herbicides used with them;
 - scale of human exposure to herbicides and herbicide residues for which use levels and maximum residue levels have greatly increased since GM crops were licensed;
 - likely human impacts from exposure to chemicals that the World Health Organisation has assessed to be probable human carcinogens;
 - environmental impacts on non-target species, including soil microorganisms, of large increases in applications of herbicides and pesticides, including Bt toxins
17. Amend the GT Act, to impose strict liability for GM contamination on proponents
18. Legislate a Farmer Protection Fund, resourced from a levy on GM seed sales, to automatically and immediately compensate landholders who suffer economic loss or other harm from GM contamination with any GM plant, animal, insect or microorganism
19. Amend the GT Act to strengthen and operationalise the Precautionary Principle
20. Ensure that applicants bear the onus of demonstrating that their product is safe
21. Require that industry data is not the primary or exclusive information that the OGTR and other regulators rely on when making assessments
22. Incorporate clear trigger points into the GT Regulations, so that new scientific and other evidence that calls into question existing licences, approvals or conditions of use prompts a review, with the possibility of terminating the licence
23. Amend the GT Act, so the public has the same rights to seek review of regulatory decisions as industry and licence holders now have

24. All interested parties, including the general public, should have full electronic access to all the raw data and information supporting each application
25. All information should be available or provided electronically
26. The OGTR should be required to always publish a complete statement of reasons for granting a DIR licence, for further public comment prior to any licence being issued
27. The OGTR should automatically publish annual, incident, and other Reports submitted to satisfy the conditions of licences for the release of GMOs
28. Without proper framing and implementation of conflict of interest rules, strict and mandatory recusal provisions may be necessary
29. Additionally, the OGTR should review how regulatory and policy decisions may be affected by undeclared or ignored conflicts of interest among experts and lay members on OGTR committees, or consultants
30. The food and feed products of all new GM techniques must be labelled so farmers and shoppers are informed
31. The Scheme should formally recognise the legitimacy of public concern over, and opposition to, GM techniques and their living products
32. Australia to sign, ratify and implement the Cartagena Biosafety Protocol to the Convention on Biological Diversity
33. Stronger and clearer criteria for the fitness of applicants to hold GM licences should be mandated in Sections 57(2) and 58 of the Act, with global reach in the case of transnational entities
34. Investigate legislative methods of ensuring that biohacking and other currently unregulated GM activities are captured by the GT Act and Regulations
35. Applicants should meet the costs of the OGTR's regulatory system. However, any such fees for service must be made at arm's length from the regulators so the regulator's independence cannot be compromised
36. The risks, hazards and opportunity costs of GM techniques and their living products must be internalised and assessed within the regulatory system
37. Ensure that the OGTR does not play a role as both regulator and promoter of GM techniques and their products
38. Do not impose a GM contamination threshold on the organic industry

The Review's Terms of Reference

The review sets out to:

Investigate the:

- Gene Technology Act 2001 and other gene technology legislation;
- Gene Technology Agreement, by State, Territory and Commonwealth Governments, 2001;
- interface with other regulatory schemes – APVMA; FSANZ; TGA; etc.

To ensure the Scheme:

- protects the health and safety of people and the environment;
- has legislative arrangements that meet the needs of the Scheme, now and into the future;
- is improved and strengthened, to be more effective;
- is appropriately agile, to take account of fast evolving scientific and commercial contexts;
- accommodates continued technological development;
- is sustainable, with funding levels and mechanisms aligned with the level and depth of regulatory activity needed to support the Scheme;
- supports innovation.

Taking account of published comments to the:

- OGTR's Technical Review of the Gene Technology Regulations 2001, "though outcomes of the Technical Review cannot alter the policy settings of the Scheme";
- Inquiry into Agricultural Innovation by the House of Reps Standing Committee on Agriculture and Industry, 2016;
- Productivity Commission's report on the Regulation of Australian Agriculture, 2016.

Gene Ethics' comments on the Terms of Reference and issues for review

This review of the Gene Technology Scheme should be informed by comments critical of the current regime. Its deficiencies, costs and benefits require evaluation, including its: legal basis; structure, processes and scope; ideological underpinnings and assumptions; the rigour and validity of assessments; monitoring regime, to ensure the detection of unauthorised activities that should be regulated, particularly biohacking; the state of the biological and related sciences; the legitimate public sentiment and concerns over GM and biotechnology; the interactions of various bodies and their rules governing GM in Australia; and, how overseas jurisdictions regulate current and emerging gene technologies and their living products, including the strengths and weaknesses of other models for notification, assessment, licensing, monitoring and compliance.

We note, for instance, that the government of our close neighbour and major trading partner, New Zealand, in 2014 decided to regulate all new GM techniques for engineering genes. This followed the Sustainability Council of New Zealand² winning a High Court judgement³ that the NZ Environment Protection Authority could not alone expand the list of breeding techniques exempt from being regulated as GM under the Hazardous Substances and New Organisms Regulations 1998. The NZ EPA had unilaterally decided that two new Genetic Manipulation techniques should be deregulated but the High Court quashed the decision, The court agreed with the Council that only Parliament or Cabinet could make such a determination.⁴

The Hazardous Substances and New Organisms Act 1996 (HSNO Act) regulates research into and release of all living things that do not already exist in New Zealand, including GMOs. Before any new organism (including GMOs) are imported, developed, field tested or released into the environment, applicants must get the approval of the Environmental Risk Management Authority (ERMA), set up specifically for this purpose. ERMA considers each application on a case-by-case basis, as each organism poses different potential risks and/or benefits.⁵

Australia's National Gene Technology Scheme does not consider the benefits of GM organisms or their products, presuming that applicants would not apply unless there were benefits, for them at least. This is insufficient justification for approving a proposal or issuing a licence. Robust laws and regulations are required, that respect community values and the principles they embody.

On May 6, 2004, Gene Ethics told the OGTR's Risk Assessment Framework Review, that:

“The Framework ignores the existence or scale of benefits arising from an application but no risk is worth taking unless there are clear benefits. The mere existence of an application does not constitute evidence that there are benefits. The applicant's perception that they will profit is insufficient justification for issuing a licence. This framework should mandate that clear social, environmental, economic or other benefits exist and can be quantified, to offset the inevitable costs and impacts of all new technologies and their products assessed with this Framework.”

This issue remains unresolved, along with several others raised in the 2005 and 2011 Scheme Reviews, We ask you to revisit them, along with new and emerging issues, like the new GM techniques (CRISPR, Talen, ZFN, RNAi, etc.) and their living products. The Review must resist pressure to exempt new GM techniques from public, proactive and precautionary regulation.

The Gene Technology Act 2001

The GT Act has withstood many tests of time, was slightly amended after two earlier reviews, and does not require fundamental revision now. However, unqualified operators experimenting with the new GM techniques in informal settings, outside the jurisdiction of the existing Scheme, require the law to be substantially strengthened. These and some other aspects of the Scheme's implementation are unsatisfactory and also require amendment.

² Sustainability Council of NZ. Government's Move Keeps New GMOs Regulated <http://www.sustainabilitynz.org/governments-move-keeps-new-gmos-regulated/>

³ Key Background to the NZ High Court Ruling http://www.sustainabilitynz.org/wp-content/uploads/2014/05/Backgrounder_ZFN-1HighCourtDecision.pdf

⁴ NZ High Court Prevents Developers From Bypassing GM Laws. <http://www.sustainabilitynz.org/high-court-prevents-developers-from-bypassing-gm-laws/>

⁵ Genetic modification in New Zealand. <http://www.mfe.govt.nz/publications/hazards/gm-nz-approach-jun04/genetic-modification-new-zealand>

Gene Technology Agreement between all Governments 2001

We support a scientific system of assessments and regulations of all GM dealings. Recital B of the Gene Technology Agreement requires the Scheme to:

“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);”

However, only one principle has been agreed to and enacted. It is the Gene Technology (Recognition of Designated Areas) Principle 2003 which says:

“Recognition of areas designated under State law

An area is recognised as an area that is designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes, if the area is so designated under a State law.”⁶

This principle has widespread support and was implemented by all governments when licences for the unconditional release of herbicide GM canola were issued in 2003, even in jurisdictions such as NSW and WA where some exemptions to a general moratorium are now permitted.

Governments that are party to the Agreement have not made any other policy principles, neglecting important matters for which they have responsibility. Provision should be made in the Scheme, for State Governments to propose social, cultural, ethical and other non-scientific principles for the consideration of all the parties to the Scheme, and adoption as policy principles under the Agreement.

Co-operation

OGTR must conduct safety and environment assessments before any GM crop, animal, microbe, tree, fish, insect, etc., is released. Such a licence should be a necessary but, not alone, a sufficient condition for such releases.

State and territory government powers must be retained and extended so they and their parliaments can also consider social, cultural, ethical and other non-scientific matters, including public values and sentiment, before any licensed GMO is released.

Retain the powers of State and Territory Governments to declare GM and GM-free Zones for marketing reasons, over all or a part of their jurisdictions, on all GMOs. Reconfirm the policy principle that gives them these powers, made under Section 21 of the GT Act 2001 (Cwth).

If a product of GM techniques – crops, animals, microbes, trees, fish, insects, etc. - are to be approved and deployed, the OGTR’s licence should be a necessary, but not a sufficient condition to allow unrestricted national release approval. State and territory powers to consider economic, social, ethical and strongly held public values must be exercised, before any OGTR licensed GMO release occurs within their jurisdictions.

Interface with other regulatory schemes

Harmonising the operations of the Commonwealth’s regulatory agencies is a worthwhile goal, provided it improves the performance of them all. The gap fill model has not worked, as the OGTR has been required to do more than merely fill the regulatory gaps left by other regulators.

We propose that the GT Act and the Agreement be amended so the OGTR has ultimate responsibility for all aspects of Gene Technology notification, assessment, licensing, monitoring and compliance, even where the agency is not supervising routine implementation of the Scheme.

⁶ Gene Technology (Recognition of Designated Areas) Principle 2003 <https://www.legislation.gov.au/Details/F2007B00679>

We support a one-stop-shop for applicants and the public, with the OGTR as lead agency for the regulation of all GM dealings, with both GM techniques and GM organisms – plants, animals, microbes and humans.

To coherently and effectively regulate Genetic Manipulation dealings, all the regulatory and other agencies that administer the Scheme or have legal responsibility for some aspects of genetic manipulation techniques or their products should adopt and apply the agreed definitions of GM, GMO, dealing, etc., as defined in the Gene Technology Act. Unless these common definitions inform the actions of each instrumentality, overall decisions will not be consistent or coherent. No regulatory Scheme can be fair, objective or rational if different entities apply diverse definitions, while each playing their separate parts in the assessment, regulation and licensing of GM techniques and their living products.

All applications to license any dealing with a GMO, or register any product of a GMO, should first require an application to the OGTR, as the lead agency. The OGTR would then commission the assessment of specific aspects of the dealing from other regulators (FSANZ, APVMA, TGA, etc.). These assessments and recommendations would then be issued for public comment as part of the OGTR's RARMP process.

Streamlining the system for applicants with a one-stop shop may relieve some regulatory burden. And the interested public could deal with one agency rather than a multiplicity of (often conflicting) Commonwealth regulators, which display varying degrees of candour, openness and transparency.

Protect the health and safety of people and the environment

As this is the Scheme's fundamental purpose, this goal must not be compromised.

The Science

The quality and accountability of the science used in safety assessments needs to be both broadened and strengthened.

The health and safety of people also needs to be more broadly defined. The Scheme as a whole should consider the maintenance of health and safety through reviewing the potential longer term and cumulative impacts of GMOs from seed to spoon.

The OGTR operates under a so-called 'science-based' and 'case-by-case' regime. The OGTR (and FSANZ, APVMA, Biosecurity, etc) license DIR dealings after assessing an ad hoc suite of self-generated, unpublished material, not peer-reviewed, often out-dated, and from usually overseas applicant-generated, 'trials' or 'tests', not scientific experiments.

The Scheme should be amended so the OGTR eschews the 'regulatory science' methods that, for instance, the APVMA⁷ uses which do not conform to the long-established standards and practices of scientific inquiry.

Under this regime, gaps in scientific information, data and knowledge are filled with best guesses not additional data.⁸ The OGTR should require applicants to fill such data vacuums with independent experimental data, generated to the OGTR's strict requirements.

To be rigorously scientific and precautionary, the Gene Technology Act and its Regulations should mandate the design, scope and scale of relevant scientific experiments and data. These rules are basic to the fair and objective assessment of the reliability, replicability and relevance of evidence tendered in support of applications.

Such requirements should be set in advance, with benchmarks, standards, Quality Assurance systems and protocols necessary for the systematic collection of high quality data for assessment. Data from contemporary, controlled, experiments conducted in Australia should

⁷ Australian Pesticide and Veterinary Medicines Authority (2015). APVMA Regulatory Science Strategy. <https://apvma.gov.au/sites/default/files/publication/19221-draft-regulatory-science-strategy-november-2015.pdf>

⁸ Ibid, p. 3

be the preferred basis of assessments.

We also see in action the effects of a fatally flawed misconception of safety in Food Standards Australia NZ's approvals of GM foods. It flouts the standards that real scientific inquiry sets, applies the industry-generated oxymoronic concept of 'substantial equivalence'⁹ to the industry data submitted in support of applications, and never rejects any GM proposal put to it.

The dramatic increase in the use of the 'probable human carcinogen' glyphosate¹⁰ is a clear result of the use of GM technology so the OGTR must assess the full ramifications and impacts of that use.

This includes human and environmental impacts as well as the impacts associated with the rapidly increasing problems of weed resistance.¹¹

The rejection of the WHO's reclassification by the APVMA¹² is deeply concerning. Rejecting the findings of the preeminent public health organisation globally without conducting a full review and based in good part on the findings of other regulators and the use of industry-funded data does not conform to the scientific standards that regulatory agencies should implement.

Costs and benefits, risks and hazards

The Inter-Government Agreement, the GT Act and the GT Regulations all ignore the purported benefits of GM techniques and their products. These legal instruments should be amended to require the OGTR to do best practice risk/benefit analyses, using agreed methodologies based on sound and independent scientific data. This would positively extend the scope of material that the OGTR is empowered to consider. At the same time it is critical that the OGTR has no role in promoting or facilitating the industry or GM techniques of products.

To approve GM using unscientific risk assessments, without ever acknowledging or assessing either the actual hazards or potential benefits of such proposals, ignores the public interest and community expectations.

Some fundamental issues are also contested amongst scientists, ethicists, and other experts that should be part of any evaluation. Simply accepting the applicants pitch for approval is remiss.

Legislation to meet the needs of the Scheme, now and into the future

This question is poorly framed. Does 'the needs of the Scheme' really mean achieving the goals of the Scheme? Or does the Scheme have other hidden needs to serve?

The broad definitions of Gene Technology, GM, GMOs and dealings in the Gene Technology Act (GTA) should remain unchanged. Visionary legislators deliberately made their scope very broad in the expectation that new GM techniques would be discovered or invented and commercialised at some time in the future. As it happens, CRISPR, Talen, ZFN, RNAi, and other new GM techniques did not exist in 2001 and have been invented since. Almost certainly, others remain to be invented or discovered in the future and, these too, should fall within the definitions in the Act.

This review should assess the extent to which the broad policy reflected in the GT Act's definitions would enable the Regulatory Scheme to continue to capture the uses of **all** future new GM techniques and their novel products. This requires a robust system of notification, assessment, licensing, monitoring and compliance.

⁹ Food Standards Australia New Zealand (2007). Safety Assessment of Genetically Modified Foods: Guidance Document, https://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20FINAL%20Sept%2007L%20_2_.pdf, p. 2

¹⁰ See, e.g., Benbrook, C. (2012). Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years. *Environmental Sciences Europe* 24:24. <https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24>. FSANZ (2017). Chemicals in food – MRLs

¹¹ Glyphosate Sustainability Working Group (ND). Glyphosate Resistant Weeds in Australia. <http://glyphosateresistance.org.au/RegisterSummary.pdf>

¹² IARC (2015). Monograph 112 – Glyphosate. www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf APVMA (2016). Regulatory position: consideration of the evidence for a formal reconsideration of glyphosate. <http://apvma.gov.au/sites/default/files/publication/20701-glyphosate-regulatory-position-report-final.pdf>

The Regulator cannot unequivocally assess the impacts on things undefined. Notable omissions from definitions in the Act are 'environment' and 'health'. 'Environment' should be defined so it is consistent with other environmental laws such as the EPBC Act,¹³ Ecological Sustainability, and the Convention on Biological Diversity. 'Health' should also be broadly defined to accord with the notions of prevention of disease and other health impacts.

New GM techniques and their products have no history of safe use and are as imprecise as the older cut-and-paste recombinant GM techniques. Scientists agree that all GM techniques can have off-target impacts that may cause unforeseen mutations in humans, plants, animals and microbes.¹⁴ All should be regulated under the National Scheme so that the OGTR is required to be notified, that every new technique and its living products are then assessed, approved or licensed, and monitored to ensure their safety for human health and the environment.

The discussion paper confidently asserts, in relation to new GM techniques, that:

“Gene technology provides a way of introducing precise changes to genetic material, which can include genes, parts of genes, groups of genes, etc. This allows researchers to transfer the properties ‘instructed’ by a single gene from one organism to another. Using these techniques, researchers can modify organisms by directly inserting or removing one or more genes so that an organism gains, loses or changes a specific characteristic or set of characteristics.”

This matches the optimistic but disputed and unconfirmed claims made for all new GM techniques now used in laboratories, the living products of which are proposed for general release into our environments. This appears to reflect the architects of the Scheme passively and uncritically accepting the narratives that GM proponents want to tell about these new inventions and their products, in order to deploy them as quickly and cheaply as possible, without meaningful surveillance, or public knowledge.

Improve and strengthen the Scheme to be more effective

Broaden the scope of assessments

Consider the broader impacts of the general release of GMOs, including the:

- extent and implications of herbicide resistance in weeds, following introduction of GM crops and the herbicides used with them;
- scale of human exposure to herbicides and herbicide residues for which maximum residue levels have greatly increased since GM crops were licensed;¹⁵
- likely human impacts from exposure to chemicals that the World Health Organisation has assessed to be probable human carcinogens;
- environmental impacts on non-target species, including soil microorganisms, of large increases in applications of herbicides and pesticides, including Bt toxins;

Strict liability on GM proponents

Amend the GT Act, to impose strict liability on proponents for GM contamination. Currently, there are no protections for farmers who are either required to be GM free or have chosen to be GM free in order to take advantage of the premiums on GM free produce.

Amendments should also facilitate a Farmer Protection Fund, resourced from a levy on GM seed sales, to automatically compensate landholders who suffer economic loss or other harm from GM contamination with any GM plant, animal, insect or microorganism.

¹³ See, e.g., Environment Protection and Biodiversity Conservation Act 1999, s. 526

¹⁴ Fagan, J., Antoniou, M., Robinson, C. (2014). GMO Myths and Truths. Earth Open Source, <http://earthopensource.org/wp-content/uploads/2014/11/GMO-Myths-and-Truths-edition2.pdf>

¹⁵ The Detox Project reports that tests conducted in 2015 in the United States found glyphosate in the urine of 95% of the American public, indicating high and regular exposure to glyphosate. <https://detoxproject.org/1321-2/>

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 licensed user, to take full responsibility for GM contamination.

The segregation of the pollen and seeds of some crops, such as GM 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.

Precaution

Apply the Precautionary Principle (PP) to all GM applications, especially to scientific uncertainty or data gaps. The OGTR appears to consistently ignore Section 4 (aa) of the Act – the precautionary principle. The principle should be fully integrated into the GT Act, as it is in the Environment Protection and Biodiversity Conservation Act 1999.¹⁶

Strengthen and operationalise the PP by amending the GT Act, in line with the Wingspread Statement on the Precautionary Principle, developed at the Wingspread Conference 1998.¹⁷

“... it is necessary to implement the Precautionary Principle: When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.”¹⁸

The Act says the Regulator is required to take protective measures as a prudent and sound response where a lack of full scientific certainty exists. The approach the Regulator adopted 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.

But the OGTR cannot proceed on the basis of ‘credible scientific hypotheses’ when no experimental data is required or supplied. Instead, the OGTR and GTTAC appear to use ‘regulatory science’ which makes ‘best guesses’ rather than requiring new scientific data to fill knowledge gaps.

Onus of Proof on GM proponents

There is no scientific consensus that any GM techniques and their products are safe.¹⁹ The burden of proof that they are not harmful falls on those that propose them for release.

The burden of evidence-based proof for the environmental and public health safety and efficacy of the GMO should rest entirely on the applicant for a licence to deal with the GMO. Peer reviewed scientific evidence which conforms to the requirements of a genuinely scientific system should be necessary in order to discharge this requirement.²⁰

By denying the interested public access to all the information, the present system unreasonably

¹⁶ EPBC Act S391 http://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/epabca1999588/s391.html

¹⁷ Wingspread Conference on the Precautionary Principle. <http://sehn.org/wingspread-conference-on-the-precautionary-principle/>

¹⁸ Wingspread Statement https://en.wikisource.org/wiki/Wingspread_Statement_on_the_Precautionary_Principle

¹⁹ European Network of Scientists for Social and Environmental Responsibility (2015). No Scientific Consensus on GMO Safety, <https://ensser.org/?s=no+consensus>

²⁰ Handbook of the Convention on Biological Diversity by the Secretariat to the CBD. Decisions P.577

https://books.google.com.au/books?id=E_zsAqAAQBAJ&pg=PA577&lpg=PA577&dq=The+burden+of+proof+that+a+proposed+introduction+is+unlikely+to+cause+such+harm+should+be+with+the+proposer+of+the+introduction&source=bl&ots=oOC8qRXJOf&sig=ocGtUJevANoTem1VBvjk_gOLiag&hl=en&sa=X&ved=0ahUKEwiv3lOJn8nWAhWKxrwKHei5A5QQ6AEIKDAA#v=onepage&q=proofThe%20burden%20of%20proof%20that%20a%20proposed%20introduction%20is%20unlikely%20to%20cause%20such%20harm%20should%20be%20with%20the%20proposer%20of%20the%20introduction&f=false

places the onus on the public and regulators to produce evidence that shows conclusively why a licence should NOT be granted. This provision requires urgent reform to ensure that the onus of proof of safety and efficacy falls squarely on applicants.

Credible data and evidence

Amend the GTA and/or GT regulations to require that independent, published and peer-reviewed evidence are the primary data on which GM safety and efficacy assessments are made.

Ensure that industry data is not the primary or exclusive information that the OGTR and other regulators rely on when making assessments.²¹

New data to trigger reviews

Significant new evidence always should always prompt a review of licenses and approvals already issued. Amendment to the GT Act or regulations should be made instituting a mechanism for review.

Incorporate clear trigger points into the GT regulations, so that new scientific and other evidence that calls into question existing approvals or conditions of use prompts a review of the licence or conditions.

Accountability

Appeal rights for all

Amend the GT Act so the public has the same rights to seek review of regulatory decisions, as industry and licence holders now have, through the AAT, the courts, parliaments and any other mechanisms of review.

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

Transparency - Accessible Data

All interested parties, including the general public, should have full electronic access to all data and information supporting each application, to facilitate independent evaluation and monitoring of experimental design, methodologies, processes and data. But the Scheme does not now make an applicant's data available in raw, undigested form.

Data supporting applications should always be scientific and public, to improve the transparency and accountability required by the Agreement Recitals. Without the raw data, comprehensive and independent outside expert and public interest assessments of applications is impossible.

The predigested RARMPs and documentation that the OGTR publishes are not fully informative and are framed to make the risks and hazards of proposed dealings seem better understood, more predictable and more manageable than they really are.

All information should be provided electronically to end the necessity of travel to Canberra to peruse and copy the files. This is impractical, expensive, and an unreasonable barrier to full community participation in the OGTR system.

There are no good reasons to keep data secret when derived from reports of scientific experiments on the risks to health, safety and the environment and when commercial protections already exist through IP laws.

Data from agronomic or other 'trials', is primarily commercial so should not qualify as the evidence basis for an application under the Act, as it often does.

²¹ There is now a significant body of peer-reviewed literature that shows industry-funded science is not reliable. See, e.g., Washburn, J (2007). Science's Worst Enemy: Corporate funding. Discover Magazine <http://discovermagazine.com/2007/oct/sciences-worst-enemy-private-funding>

The OGTR passively allows information to be secret upon an applicant's request. For instance, the OGTR declared commercial in confidence seven years of agronomic data from Monsanto's GM canola trials, on about 250 hectares and Aventis (now Bayer), on about 3,400 hectares. Yet relying on this secret data, in 2003 the OGTR issued to both companies unrestricted, unconditional licences for the unlimited commercial growing of Roundup herbicide tolerant GM canola throughout Australia.

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

The OGTR should automatically publish Annual Reports submitted to satisfy the conditions of licences for the release of GMOs. Now they are only released under FoI, which is time-consuming and wastes scarce resources.

The LGFGT should issue regular news of the Scheme, in addition to the occasional communiqués from its meetings.

Conflicts of interest

Granting exemptions in the GT Regulations to brand new innovations may also mean accepting advice from the GTTAC or consultants which is tainted by conflicts of interest. Scientific or corporate interests can benefit from regulatory advice that may be more or less deliberately or inadvertently coloured in favour of innovations. Such interests may benefit from e.g. increased research grants, patents, or a path to market for engineered organisms, if the techniques they use and their living products were prematurely deregulated. The current OGTR rules regarding conflicts of interest are not being properly implemented and members with conflicts are participating in the development of 'expert' recommendations that inform decisions taken by the Regulator.

In the absence of proper implementation, strict and mandatory recusal provisions may be necessary.

Additionally, the OGT should review how regulatory and policy decisions may be affected by undeclared or ignored conflicts of interest among experts and lay members on GTTAC, GTECCC and other bodies providing advice to OGTR, FSANZ, etc.

Better consultation is needed with scientists and other experts who have an expansive systems view of GM and the contexts within which genes exist, such as ecologists, etc.

Public right to know

Requiring notification to regulators is the only mechanism for the general public to know of GM release proposals. The food and feed products of all new GM techniques must also be labelled so farmers and shoppers are informed, as safety data is weak and there is minimal history of safe use.

The International Social Science Survey first canvassed Australian public opinion in 1994, on their attitudes to GM food labeling, and found 89% support. No GM crops or GM food products had by then entered our markets. Opinion polling since then has repeatedly found over 90% support for comprehensive GM labels and a majority say they avoid GM foods if labeling enables them to do so.²²

Primacy of the Public Interest

The Scheme should formally recognise the legitimacy of public concern over, and opposition to, GM techniques and their living products. Citizens are not receiving the benefits of the right to know and to choose, that GM farmers and their corporate sponsors demanded and received. Citizens should have access to the information necessary to avoid GM in food and the environment, should they decide to do so.

²² Food Standards Australia New Zealand (2003). Report on the Review of Labelling of Genetically Modified Foods, p. 5

The Review needs to establish and accept the validity of public opposition to GM. The notion that public opposition to GM persists out of ignorance is wrong. Some GM advocates falsely assume that more of the information they disseminate will change public sentiment.²³

Opposition and resistance are based on legitimate scientific data, and political and social realities that must be acknowledged and respected. Distrust of the technology is not a symptom of ignorance but based upon a known history of exploitation and even criminality by the companies operating the GM and chemical industries.

Global co-operation

Australia to sign, ratify and implement the Cartagena Biosafety Protocol to the Convention on Biological Diversity, to meet our obligations to ensure safe international transfer, handling and use of GMOs. The Scheme, including the OGTR's systems, should be made fully consistent and compliant with the Treaty.

Suitability - Sections 57 (2) and 58 of the GT Act

Stronger and clearer criteria for the fitness of applicants to hold GM licences should be mandated in Sections 57(2) and 58 of the Act.

A preliminary assessment of the applicant's fitness to hold a licence is required by sections 57 and 58 of the Act. This should be conducted before an application is even accepted, so that if the applicant were disqualified, the application would not proceed further.

The OGTR should require global information on all applicant conduct that may be against the public interest (including criminal convictions). The behaviour of parent organisations should also be assessed when its local branch makes an application. The reasons for judging an applicant fit to be licensed should be published.

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.

Local Government Participation

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.

Public processes of participation and engagement with local communities are the strength of local government. Councils are under-resourced and the frequency of release proposals in some shires makes it difficult for them to respond. As well as 'consulting' councils, the OGTR has a responsibility to fully inform and resource these engagements.

GTECCC recommended to the OGTR that opportunities be created for the GTR and GTECCC to pro-actively engage in meetings with councils and their constituents over release proposals in their areas but this was never done. Engagement is a legitimate and important role for GTECCC members who are supposed to be broadly representative of the community and its diverse views.

Appropriate agility, taking account of fast evolving society, science and commerce

Society

All new GM techniques and their living products should all be regulated, both those recently invented and others bound to be discovered in future. OGTR regulation publicly flags when new processes are added to the Genetic Manipulation tool kit, and that novel organisms with little safety evidence and no history of safe use, arrive in our community. Without such a trigger of public knowledge, recognition and response, no social licence to operate is issued.

Science

The best way for the Scheme to take account of rapidly evolving science and to ensure scientific

²³ Wynne, B. (2001). Creating Public Alienation: Expert cultures of risk and ethics on GMOs. *Science as Culture*, 10:4, 445-481

agility is to maintain definitions of GM that are broad enough to ensure that all new Genetic Manipulation techniques and their living products are notified to the OGTR and other regulators, and are well-regulated.

Certified institutions, researchers and their laboratories are only permitted to use GM techniques and organisms under the guidance and supervision of Institutional Biosafety Committees (IBCs) that oversee skilled operators doing approved laboratory experiments and trials to ensure safety and efficacy. But even then, things can go badly awry. Well-intentioned and regulated: “scientific research has the potential to be misused by state and non-state actors for nefarious purposes.” Australian researchers inadvertently created a lethal mousepox virus and a group of scientists in England had already made a genetically complete and lethal vaccinia virus. Both these events confirm the biothreat.²⁴

Biohacking, biopunk, or DIYBio (Do-It-Yourself Biology) are new challenges to the agility of the Scheme that appears likely to require legal changes. Some people, with little or no formal biological training or qualifications, are genetically manipulating a variety of organisms in informal and uncontained community laboratories, their homes and other unofficial locations. Biohacking kits and used laboratory equipment are cheaply available for sale on the web.²⁵

The Scheme does not appear to even require biohackers to operate according to the present law. Unregulated and unmonitored, such citizen experiments may pose serious hazards to the environment and human health. The OGTR claims these groups and their activities are kept under surveillance but the risks that these techniques and unregulated uses pose are unresolved.

US intelligence services see the new GM techniques, including CRISPR, as a serious threat to national security. In the [annual worldwide threat assessment report](#) of the U.S. intelligence community 2016, the Director of National Intelligence added new GM techniques to a list of threats posed by “weapons of mass destruction and proliferation.”²⁶

The ethics of people who would hack any living organism and treat the codes of living entities in the same way as electronic or computer codes also require review. Some digital hackers, on whom biohackers model themselves, create destructive computer viruses that infect the cyber world, for recreation and enjoyment. We need reassurance over their scruples about infecting the real world with GMOs.

Commerce

Commercial agility depends on well-informed shoppers who have confidence that the Scheme will take care of their interests, as it does applicants’ commercial goals. Worldwide, the strongest demand and fastest growing segment of the processed food industry is GM-free food.

Most GM crop products are sold at a discount and go into animal feedlots or biofuel production. The powers of state and territory governments to individually declare GM and GM-free Zones for marketing reasons within their own jurisdictions provides appropriate additional commercial agility to the Scheme.

Commercial agility would also be enhanced if Australia were a full and compliant member of the Cartagena Biosafety Protocol, a treaty designed to ensure the safe international transfer, handling and use of all GMOs.

Accommodates further technological developments

We strenuously argue in the Technical Review of the Gene Technology Regulations 2001, that accommodation must not mean deregulation, as the new GM techniques and their living products have no history of safe use and their use creates many off-target impacts in the genomes of

²⁴ The mousepox experience: An interview with Ronald Jackson and Ian Ramshaw of CSIRO on dual-use research <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2816623/> Accessed 25/9/17

²⁵ Friends of the Earth (2016). Biohacking Ban Needed. <http://emergingtech.foe.org.au/biohacking-ban-needed/>

²⁶ Antonio Regalado, MIT Technology Review, Rewriting Life: Top U.S. Intelligence Official Calls Gene Editing a WMD Threat, February 9, 2016: <https://www.technologyreview.com/s/600774/top-us-intelligence-official-calls-gene-editing-a-wmd-threat/> Accessed 25/9/17

manipulated organisms, the consequences of which cannot be foreseen or predicted with certainty.

The current Act and its definitions do accommodate further technological development without imposing any regulatory bias as to how those technological developments are treated.

The Technical Review process, like this review, should be multi-staged and more open and transparent than it has been to date. For instance, we seek reassurance that the process will not proceed to a conclusion without further iterations of the scope of any exemptions.

Financially sustainable but guarding the regulator's independence

The paper asserts that funding for the Regulatory Scheme must be at sufficient levels, with mechanisms aligned to the level and depth of activity, necessary to support the Scheme.

Applicants should meet the costs of the OGTR's regulatory system. However, any such fees for service must be made at arm's length from the regulators, into consolidated revenue and fully itemized in the OGTR Annual Report. The costs of regulation are just another part of doing science or conducting business, which are built into corporate, or science budgets.

The OGTR must be more, not less, independent when making weighty judgments on GM dealings. We are very troubled that the APVMA and NICNAS are unduly influenced in policy and decision-making as a result of their reliance on cost recovery to sustain their operations.

The risks, hazards and opportunity costs of GM techniques and their living products must be internalised and assessed within the regulatory system. The law should ensure that any negative short or long term impacts arising from the DIR licences issued are not a burden on the community generally - through tax increases, depleted or degraded resources, contamination of non-GM farms and crops, long term negative health or environmental consequences, or through the opportunity costs of more important Research and Development of other approaches to solving the same problems are ignored and unfunded.

Supporting innovation is not the role of Regulatory Schemes

Neither the Gene Technology Act 2001 nor the Inter-Government Agreement on GT 2001 mentions 'innovation'. Regulatory Schemes have no role in backing innovation as they are intended to be impartial, independent and fair to all parties, especially the public interest.

Good regulatory systems should in no way either hamper or promote innovation as they deal in the objective realities of applications lodged with them. Yet applicants repeatedly and selfishly clamour for expeditious approvals - a 'fast track through the regulatory system' and a 'clear path to market'. When the ground rules of good regulatory systems are clear, fair to all and unequivocal, they do not constrain innovation.

Supporting innovation might be construed to mean deregulating some or all of the new and emerging Genetic Manipulation techniques, such as CRISPR, Talen, ZFN, RNAi, etc., and the living organisms they will produce. Yet there is little evidence of their safety and they have no history of safe commercial or environmental release.

The public interest demands that, at the very least, scientific, rigorous, independent and dispassionate evaluation must be applied without fear or favour to every new technique and its products, prior to general commercial or environmental release. Exemptions from any notification, assessment, approval, licensing, and monitoring by any regulatory body would leave the community in the dark.

The OGTR's Technical Review of the GT Regulations 2001

The Technical Review of the GT Regulations is still underway, and as its outcomes: "cannot alter the policy settings of the Scheme", they are not strictly relevant here.

However, if Option 4 proposed in the Technical Review were adopted, the organisms and techniques proposed to be exempt under the GT Regulations would have substantive effects on the policies underpinning the broad definitions of GMO in the Act. Narrowing of the scope of current GMO definitions in the Regulations would in practice also narrow the policy itself.

In light of this, we recommend that any consultations on exemptions from the definition of GMO in the Technical review be moved into this Review of the GT Scheme 2017. Further, that responsive multi-staged public consultations on the Technical Review be also conducted.

Additionally, the OGTR should not alone take final decisions about which of the new GM techniques and GM organisms may be exempt from the GT Regulations, as any exempt techniques and organisms would fall completely outside any Scheme of regulation. The LGFGT, the GT Standing Committee of officials from all jurisdictions, and the Ministers and parliaments acting under their state GT Acts should jointly decide on any exemptions under the Regulations, after further consultation with all interested parties, including the public.

The Inquiry into Agricultural Innovation, 2016

The House of Reps Standing Committee on Agriculture and Industry made only one recommendation related to GM.

“Recommendation 15: The Committee recommends that the Department of Agriculture and Water Resources, in cooperation with Standards Australia, update the National Standard for Organic and Bio-Dynamic Produce to introduce a threshold for approved genetically-modified material consistent with comparable international standards.”

This is outside the remit of this inquiry to act upon or determine. However, international organic standards have zero tolerance for any GM – both the old cut-and-paste techniques and the new GM techniques and organisms. Australia is advised to maintain zero tolerance for GM in organic products if it hopes to supply organic markets in the 160+ countries which remain GM-free.²⁷

Productivity Commission Review of Australian Agriculture, 2016

The Productivity Commission’s recommendations are ill-conceived, lack substance, and reflect the GM industry’s wish list. They are way out of step with public opinion.

The Commission dismisses the public interest input to its inquiry, and our legitimate and documented concerns, saying:

“some participants raised concerns about the OGTR’s and FSANZ’s approach to risk assessment, as well as the health and safety of GM foods more generally (box 6.6).” The main concerns were that:

- the use of the weedkiller glyphosate on GM crops is harmful to human health (Chris Coughran, sub. DR93; Madge Australia, sub. DR224; Michelle McLaren, sub. DR256; Susan Moore, sub. DR168)
- GM foods could contain new allergens (Gene Ethics, sub. DR243, personal responses and views on gene technology)
- a precautionary approach or the precautionary principle is not being applied in the regulation of GMOs (Australian Food Sovereignty Alliance, sub. DR211; Chris Coughran, sub. DR93; Gene Ethics, sub. DR243)
- regulator risk analyses rely on data provided by applicants rather than their own scientific assessments and data (Gene Ethics, sub. DR243; Network of Concerned Farmers, sub. DR128; Miguel Pez, sub. DR177)
- FSANZ does not require animal testing for GM food (Nathan Laurent, sub. DR133; Madge Australia, sub. DR224)
- there is duplication between the processes and requirements of the OGTR and the APVMA (CropLife Australia, sub. 14; Veterinary Manufacturers and Distributors Association, sub. 79)
- the concept of ‘substantial equivalence’ is scientifically invalid (Gene Ethics, sub.

²⁷ IFOAM position on genetic engineering and genetically modified organisms.
http://www.ifoam.bio/sites/default/files/position_genetic_engineering_and_gmos.pdf

DR243; Madge Australia, sub. DR224; Michelle McLaren, sub. DR256).”

The Commissioners patronising opinion is that:

“Many of these concerns appeared to be based on a misunderstanding or lack of knowledge of the relevant regulatory processes for GM technology in Australia.”

We ask the GT Scheme Reviewers to examine and consider the submissions to the inquiry on their individual merits, without the Commission’s biases clouding their judgements.

The Commission itself displays just such lack of understanding and knowledge of the GT Inter-government Agreement and the laws flowing from it, that they make Recommendation 6.1:

“The New South Wales, South Australian, Tasmanian and Australian Capital Territory Governments should remove their moratoria (prohibitions) on genetically modified crops. All state and territory governments should also repeal the legislation that imposes or gives them powers to impose moratoria on genetically modified organisms by 2018.”

This entirely unacceptable proposal would gut a key aspect of the Agreement, undermine the co-operative nature of the whole Scheme, and lose any vestige of public trust.

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.

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 GM canola are fully justified and Gene Ethics supports them.

The Commission’s report also comments on the existence of uncertainty over the GM status of New Plant Breeding Techniques (NBTs). Its report quotes the OGTR as saying:

“... during the development of the [Gene Technology Act] it was felt that moving and rearranging genes between species constituted gene technology and therefore created GMOs, whilst techniques that either mimicked natural processes or worked through natural mechanisms did not create GMOs. At the time there was a clear distinction in this regard but technology has advanced and there is no longer such a clear distinction. (pers. comm., 27 May 2016)

We dispute this assertion and remind the OGTR that present exemptions from the GT Regulations, for certain techniques and organisms, were agreed to only after:

- consultations with all constituencies and government partners in the Scheme;
- substantial scientific evidence on the safety and environmental impacts of the methods and their products had been accumulated over a long time; and
- a history of safe use of the exempt dealings was documented.

We fully concur with Friends of the Earth’s Emerging Technologies Project that NBTs are ‘new GM techniques’ within the definitions in the GT Act, and that:

“... the current regulatory approach to GMOs should be the minimum requirement for these new GM techniques ... because it at least provides a basis for assessing any potential risks that result from the genetic engineering process. (2015, p. 7)”

Exempting the new GM techniques and their products would create a gaping hole in the present regulatory safety net, that none of the parties to the Inter-government Agreement or their parliaments envisaged. They defined GM, GMO and dealings in the GT Act with just this situation in mind, so that all new GM techniques and their living products would be regulated under the Scheme.

Free market economists staff the Productivity Commission. Their view appears to be that optimum outcomes for society as a whole are achieved from corporate decisions based on self-interest, plus market forces. If followed, this ideological support for deregulation may have many unforeseen impacts. They claim, for instance:

“Some regulations lack a sound policy justification and should be removed. Examples include ... **state bans on cultivating genetically modified crops**, ... , **mandatory labelling of genetically modified foods**,”

But farmers, seed producers, food processors, exporters, shoppers and state coffers all gain. For instance, SA GM-free lucerne seed is in strong demand in the USA, and in the Middle East, where GM is unwelcome.

According to Monsanto claims about GM canola plantings this season, where Roundup tolerant GM canola is grown, it is just 30% of the crop in WA and 11 and 14% in NSW and Victoria, respectively.

The reasons for a lack of grower interest in GM concern margins and profits. GM Technology User Fees add big costs to the seed; GM seed may not be saved for replanting; under contracts of GM seed sale, liability for its impacts on other growers or supply chains through GM contamination are transferred from the seeds owners and vendors, onto the growers; segregation and transport incur extra costs; and the harvest is discounted when delivered to the silo.

In August 2017, there were premiums for GM-free canola everywhere GM varieties are grown. The discount for GM was up to \$40/tonne in WA; \$24/tonne at Hamilton in Victoria; and \$11 at silos in NSW. Prices for GM-free canola in SA were comparable to those paid in regional Victoria, also representing a premium for SA growers.

This refutes the Productivity Commission’s assertion that:

“There is also limited evidence of GMO-free marketing benefits **at the bulk trade level**,” and their claim also ignores the benefits accruing to all the other food and beverage producers in GM-free states.

The Commission also concedes:

“The Tasmanian Government prepared a regulation impact statement (RIS) ... A marketing advantage in domestic and international markets was noted as one of the main benefits of maintaining Tasmania’s GM organism free status. ... The RIS concluded that the (unquantified) benefits were likely to be substantial and to exceed the costs of extending the moratorium from 2014 to 2019.”

Despite this, the Commission claimed in hindsight:

“(By contrast, a cost–benefit analysis conducted as part of the review of the moratorium on GM canola in Victoria estimated that the Victorian moratorium imposed a net cost. The moratorium was allowed to expire.)”

That guesstimate was made in 2007, before any commercial GM canola had been planted. The ‘analysis’ assumed the widespread uptake of GM canola and other GM crops. It was wrong.

South Australian Agriculture Minister Leon Bignell also released in September 2016 a University of Adelaide report he had commissioned, entitled: "Identification and Assessment of Added-Value Export Market Opportunities for Non-GMO Labelled Food Products from South Australia".²⁸ The report found much evidence that present and potential demand for South Australia's GM-free food and beverages is strong and demand for organic, which is also GM-free, growing well.

Our conclusion is that because of its false assumptions and inherent bias, this Productivity Commission Report’s recommendations should carry no weight in the Review of the GT Scheme.

²⁸ Identification and Assessment of Added-Value Export Market Opportunities for Non-GMO Labelled Food Products from South Australia http://www.pir.sa.gov.au/_data/assets/pdf_file/0004/282172/Executive_Summary_-_Adelaide_University_GM_Report.pdf

Endorsements

14 community groups and businesses, and 124 individuals, have endorsed this submission. Their names are supplied to the Reviewers in a separate document, which is not for publication.

Appendices

We also append our submissions to the National GT Scheme Review 2011 (Appendix 1) and the National GT Scheme Review 2005 (Appendix 2) to show the Scheme has some shortcomings, which continue to require revision. We urge the present reviewers to favourably reconsider these matters, as well as assessing the fitness of the Scheme to meet new and emerging social and technical challenges.