Gene Ethics | Mothers are Demystifying Genetic Engineering | FOODwatch WA | SA Genetic Food Information Network
Friends of the Earth, New and Emerging Technology Project | GM-Free Australia Alliance

Comments on Phase 2 Questions for the 2017 Review of National Gene Technology Scheme

Preamble:

This Review of the Gene Technology Scheme inappropriately elevates other irrelevant matters above the core goals and objectives that all the governments of Australia set for the regime in 2000 – exercising precaution to protect human health, safety and the environment. The questions posed in Phase 2 go far beyond the brief to review the existing Scheme.

We contest proposals for radical change to the Scheme and the Regulations. The proponents carry the onus of proof to produce evidence in support of their case for amendments to the Act, Regulations and Intergovernment Agreement. They have failed to make such a case.

We contest the OGTR's provisional finding that some new GM techniques should be deregulated now and reject the GM industry's view that all new techniques may be deregulated.

This Scheme Review appears to accept as a fait accompli the interim findings of the OGTR's Technical Review of the GT Regulations 2001, and seeks to enshrine them in policy. Since the OGTR's review is incomplete and the proposal to adopt Option 3 is strongly contested, many of the Health Department's proposed policy changes are also premature.

Some technical and scientific advisors to the Scheme Review and the Technical Review of the Regulations, and the organisations for which they work, have clear conflicts of interest that should disqualify them from giving advice to the Review Team, the Legislative and Governance Forum on Gene Technology, the Standing Committee on Gene Technology, and the OGTR. The advice offered during parts of the Scheme Review show that they are not dispassionate participants or informants in the review process.

Definitions in the Gene Technology Act are broad and robust and deliberately do not confine themselves to transgenic processes or organisms. So they in no way restrain the Scheme or the OGTR from requiring the Regulation of all present and future new GM techniques and their products.

The reviewers should recommend that the Australian government sign and ratify the Cartagena Biosafety Protocol to the Convention on Biodiversity, to make Australia a full member of the international regime that seeks the safe international transfer, handling and use of GMOs, to protect biodiversity and public health.

The recommendations in public interest submissions on amending the Scheme appear to be ignored in favour of deregulation. When, where and by whom will our submissions be discussed?

The following are our responses to the Phase 2 review questions presented online and in the Phase 2 document.

Theme 1 - Technical Issues

What technological advances can be foreseen that might pose regulatory challenges for the Scheme?

- In its Technical Review of the Gene Technology Regulations, the OGTR proposes deregulation of some genetic modification and manipulation (GM) techniques and their products now. This would create unacceptable precedents for the exclusion of new GM techniques in the future. We know there will be innovations - but there is no means to predict these or the risks associated with them. The default position should therefore be, that all new techniques for the manipulation of the genetic material (DNA, RNA, Plasmids, etc.) of any organism should continue to fall within the present definitions in the Gene Technology Act and be regulated.
- It is claimed that organisms created using new genetic engineering techniques, such as CRISPR and RNA interference may be hard, but not impossible, to detect in modified organisms. However, they pose similar and maybe even greater risks than older transgenic genetic modification (GM) techniques. So when used in a diverse array of living organisms they must be regulated from the outset.
- A recent study concludes, "Emerging evidence indicates that plant miRNAs can present within human circulating system through dietary intake and regulate human gene expression."[1] Such findings reinforce the strong case for the continued regulation of RNAi.

We recommend that:

- All present and future *in vitro* techniques, technologies and processes for modifying genetic material are regulated under the Scheme.
- The Scheme apply the precautionary principle that is embedded in the Gene Technology Act in its regulation of all GM organisms – humans, animals, plants and microbes.

What are the potential impacts of the capability to make small edits in the DNA of an organism using no foreign DNA?

- The present reviewers should take the full history and record of Australian oversight and regulation of GM R&D and commercial use into account in the Scheme review. There is no case to radically amend the Scheme in light of what went before.
- The Recombinant DNA Monitoring Committee (RDMC) was formed in the 1970s[2] but was superseded in 1987 by the Genetic Manipulation Advisory Committee (GMAC) which had a brief to advise the Environment Minister on all Genetic Manipulation R&D and release proposals, not only recombinant techniques and their products, This change reflected the emergence of new techniques, beyond recombinant DNA.[3]
- No-Gall[4] and Ice-Minus[5] were both GM microorganisms produced in the 1980s, using gene deletions not dissimilar in effect to the proposals for 'gene-editing'. Both mimicked organisms that occasionally occur in nature. By deleting a single gene, No-gall (a disarmed and non-pathogenic strain of agro-bacterium tumefaciens) went on to be widely accepted as an innoculant in orchard trees. In contrast, Ice-minus research was promptly discontinued as it posed a potential hazard to global climates by interfering with ice-nucleation in clouds.

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[1] Liu, Y.C. *et al.* (2017) Plant miRNAs found in human circulating system provide evidences of cross kingdom RNAi. *BMC Genomics*, 18 (Suppl 2):112. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5374554/pdf/12864_2017_Article_3502.pdf,

[2] Recombinant DNA Monitoring Committee, Dept. of Science and Technology. https://trove.nla.gov.au/people/631980?c=people

[3] Polya, R, Chronology of genetic engineering regulation in Australia: 1953-2008, Science, Technology, Environment and Resources Section, Parliamentary Library, 17 October 2008. https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/BN/0809/ChronGeneticEngineeringA

[4] NOGALL™ http://www.newbioproducts.net/nogall-.html

[5] Ice-minus bacteria. https://en.wikipedia.org/wiki/Ice-minus_bacteria

- Both required precautionary assessment of their risks and hazards, as well as potential benefits, to decide their respective fates. This precautionary treatment must also be applied to all new GM techniques and GMOs, now and into the future. Even those that involve apparently small genome changes can have very large impacts.
- All the new gene editing tools and processes - including CRISPR, TALENS and zinc finger nucleases - are prone to off target effects i.e. they can affect other genes than the target gene.[6] This could lead to the production of unexpected toxins or allergens – multiply environmental impacts or increase pathogenicity in the case of microbes. Hence these techniques and their products must all be assessed, regulated and licensed.
- Even a small expected change to the genome of a plant, animal, microbe or human may have unexpected micro or macro effects - changing biochemical pathways within the organism. They can also affect the organism's interaction with the rest of an ecosystem or host metabolism once released.
- The 1989 L-Tryptophan (LT) case confirmed that even small gene changes could have very serious and unforeseen impacts. "Showa Denko produced L-Tryptophan through a fermentation process involving bacillus amyloiquefaciens. In December, 1988, Showa Denko began to use a new, genetically-altered strain of bacillus amyloiquefaciens called Strain V, and in1989, reduced the amount of activated carbon in the purification process by one-half." By 1994, there were 1,500 cases of the permanently disabling disease eosinophilia-myalgia syndrome (EMS) in the USA, including 38 fatalities[7] and an unknown number of EMS cases in other countries where L-Tryptophan was sold. In 1996, a US National Institutes of Health review concluded, "Evidence from an array of scientific studies strongly supports the conclusion that ingestion of products containing L-Tryptophan (LT) produced by Showa Denko KK caused the 1989 epidemic of eosinophilia-myalgia syndrome (EMS) in the United States."[8]
- 'Omics' testing has shown that GM corn assumed to be 'substantially equivalent' to non-GM was very different.[9] GM product evaluations should no longer be based on the assumptions of 'equivalence'. Thus not only is it obligatory to conduct whole genome sequencing to identify all off-target mutations from CRISPR-based genome editing, but it is also essential to ascertain the effects of these unintended changes on global patterns of gene function. Therefore one needs to follow up the whole genome sequencing with other molecular profiling analyses: transcriptomics — gene expression profiling, proteomics — protein composition profiling, metabolomics — profiling of metabolites, and miR-omics – microRNA profiling.
- Those who develop new GMOs will seek to secure and enforce Intellectual Property Claims over their inventions. They will include selectable and detectable markers in order to enforce their claims. Thus, there can be no valid barriers to the detection and regulation of new GMOs and their products.

We recommend that:

- The OGTR assess, regulate and licence all new GM techniques and their products.
- Full molecular characterisation and 'omics' analyses are conducted to check for any unintended and unforeseen off-target effects resulting from use of the new techniques.
- GMO developers be required to provide a detection test for each organism produced using the new techniques.

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[6] Latham, J. (2016) *God's Red Pencil? CRISPR and The Three Myths of Precise Genome Editing*. https://www.independentsciencenews.org/science-media/gods-red-pencil-crispr-and-the-three-myths-of-precise-genome-editing/

[7] McGowan, C.A. (1994) . Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of Amino Acids, *Cornell Journal of Law and Public Policy,* 3(2) . Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of Amino Acids. http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=1169&context=cjlpp

[8] Kilbourne E.M. *et al.* (1996) Tryptophan produced by Showa Denko and epidemic eosinophilia-myalgia syndrome, *J Rheumatol Suppl.* 46:81-8; discussion 89-91. https://www.ncbi.nlm.nih.gov/pubmed/8895184

[9] Mesnage, R. *et al*. (2016) An integrated multi-omics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process. Nature *Scientific Reports* 6, Article number: 37855 https://www.nature.com/articles/srep37855

Under what circumstances might it be practical, efficient or appropriate to regulate gene editing under the GT Act when, from an enforcement perspective, it may not be possible to distinguish the products of gene editing from the products of conventional methods?

This is a hypothetical and highly speculative question. Industry has provided no evidence for its claims that the products of these techniques are indistinguishable from those produced using traditional breeding techniques. Such claims are disingenuous, since developers will use molecular information to enforce the intellectual property claims associated with their products.

We recommend that:

- All organisms produced using new GM (so-called gene editing) techniques and RNA interference are GMOs. They must be assessed for safety and regulated before being released into the environment and the food chain.
- The OGTR require developers to provide detection tests for all organisms produced using these GM techniques.

The emerging applications, and their definitional implications for research purposes, are another area the Review will consider:

Do these applications of gene technologies present unique issues for consideration? If so, how might these issues be best addressed by the Scheme?

Synthetic biology

Several synthetic biology applications pose challenges to current risk assessment processes. For example, organisms may have no clear non-GM parent for comparison purposes and the unscientific concept of substantial equivalence is itself problematic. Since these organisms have never existed before their genotypes and phenotypes will be hard to predict.

Human germline gene therapy

Genetically modifying human embryos raises a raft of ethical issues and current new GM techniques are not precise enough to ensure that this can be done safely or ethically.[10]

We recommend that:

- Risk assessment regimes be adapted so all the risks that synbio organisms pose can be adequately assessed.
- Moratoria on human germline gene manipulation for any purpose be maintained pending a society-wide discussion into whether and under what circumstances it may be used.

The Review is seeking further input on the prospect of the intentional release of a GMO or organism with changed characteristics, delivered by one of the new breeding technologies, into the environment:

What are the potential implications of the release of a GMO targeting an invasive species in Australia?

- The release of cane toads, cane beetles, rabbits, fire ants, camels, goats, horses, buffalo, prickly pear, lantana, and a multitude of other invasive plants, animals and micro-organisms have had very disruptive and irreversible ecological impacts.
- Releasing a GMO as a biocontrol agent to target an invasive species could compound the original problem or become an invasive species itself, as in the case of cane toads.[11]

[10] Schaefer, G O. Why treat gene editing differently in two types of human cells? The Conversation, December 7, 2015 https://theconversation.com/why-treat-gene-editing-differently-in-two-types-of-human-cells-51843

- Because of the serious and potentially irreversible threats to biodiversity – as well as national sovereignty, peace and food security – 170 global groups have called for a moratorium on gene drives,[12] including Australian civil society organisations. Though the 2016 UN Convention on Biodiversity did not accede to our request for a moratorium on the controversial genetic extinction technology we continue to press for its global adoption.
- Emails released under FoI in the US show the US Military is the biggest funder, and has the lead role in backing gene drive R&D globally. The U.S. Defense Advanced Research Projects Agency (DARPA) has given approximately $100 million for gene drive research to various researchers and is now also directly funding gene drive researchers in Australia. Funds awarded to the Genetic Control of Invasive Rodents (GBIRd) are being channelled to CSIRO and the University of Adelaide.[13]

We recommend that:

- A moratorium be placed on all gene drive research, both contained dealings and those involving environmental release.
- Australia strictly observe the conditions and intent of the Biological Weapons Convention (BWC)[14] which Australia signed on 10 April 1972, and ratified in 1977.[15]
- Australia and Australian institutions be prohibited from accepting any funds from foreign governments or military organisations, for any GM research or development, regardless of its purported purposes.
- That the new CRISPR GM techniques be regulated as they enable gene drive research.

What are the technical issues to consider in the scenario of a GMO used to target an introduced plant, vertebrate or invertebrate pest?

- Australian feral animal biocontrol through immunosterilisation research killed all experimental animals when a virulent strain of mousepox virus was inadvertently created. Researchers worried that the method could also be used to make biological weapons.[16]
- A recent paper by the Australian Academy of Science concluded that:

> *"Significant technical and knowledge challenges remain which must be overcome to engineer a successful synthetic gene drive, and these challenges should not be underestimated. The four proof of concept studies published over 2015 have all been in laboratory organisms which are highly uniform and unlike wild populations. The genetic constructs produced in controlled laboratory conditions are unlikely to perform in the same way in natural environments where conditions are much more variable and unpredictable."*

- Similar concerns led gene drive proponent Dr Kevin M. Esvelt, Assistant Professor at the Massachusetts Institute of Technology, to conclude that gene drives are too risky for field trials. His team modelled the results of releasing CRISPR-engineered organisms with gene drives and found the unacceptable risk that altered genes may spread to places where target species are a key part of ecosystems.[17] [18]

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[11] http://www.environment.gov.au/biodiversity/invasive/weeds/management/biological-control.html
[12] ETC Group (2016) 170 Global Groups Call for Moratorium on New Genetic Extinction Technology at UN Convention, http://www.etcgroup.org/content/160-global-groups-call-moratorium-new-genetic-extinction-technology-un-convention
[13] SynbioWatch (2017) Gene Drive Files Expose Leading Role of US Military in Gene Drive Development, December 1, 2017. http://genedrivefiles.synbiowatch.org/2017/12/01/us-military-gene-drive-development/
[14] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. https://www.un.org/disarmament/wmd/bio/
[15] DFAT. Biological Weapons Convention (BWC). http://dfat.gov.au/international-relations/security/non-proliferation-disarmament-arms-control/biological-weapons/pages/biological-weapons-convention-bwc.aspx
[16] The mousepox experience, *EMBO reports*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2816623/
[17] Zimmer, C. 'Gene Drives' Are Too Risky for Field Trials, Scientists Say. New York times, Nov. 16, 2017 https://www.nytimes.com/2017/11/16/science/gene-drives-crispr.html
[18] Esvelt KM, and Gemmell, NJ, Conservation demands safe gene drive, Nov 16, 2017. http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2003850

We recommend that:

- A moratorium be placed on all gene drive research, both contained dealings and those involving environmental release.

Theme 2 - Regulatory Issues

The Review is considering the issue of regulatory triggers, and how best to undertake future policy design processes with both process and product trigger considerations in mind.

What do you think is the most appropriate regulatory trigger for Australia in light of extensions and advancements in gene technologies?

- The current 'process-trigger' ensures that all projects using GM techniques to make GM organisms must be notified to the OGTR, to assess, approve and licence all dealings with them. This is entirely appropriate for regulating the risks and hazards that GMOs pose.
- Pharmaceutical, Agribusiness and Industrial corporate arguments for a 'product-trigger' are self-serving and would ignore the importance of considering the processes of new GM creation and production that may have off-target effects and lack a documented history of safe use.
- Canada appears to be one of a few countries to have adopted a regulatory approach in which only products rather than processes are reviewed.[19] [20] If Australia were to adopt a similar system we would be out of step with the rest of the world, raising very significant and complex compliance issues, with impacts on both export and import trade.
- Australia's approach, in which the OGTR reviews all dealings with genetically manipulated and modified organisms and product regulators review the GM products of those dealings, is rational and economical. It also gives greater assurance that the Scheme's safety goals can be effectively achieved.

We recommend that:

- The current 'process-trigger', to initiate OGTR regulation, continue to be applied.

What factors need to be taken into account in the design of a product-based or a hybrid process/product regulatory scheme?

The current 'process-trigger' for dealings with GMOs – from their creation to use and final disposal - is appropriate. Without the process trigger, none of the dealings prior to the creation of a product would come under rigorous regulatory scrutiny and the OGTR would be rendered irrelevant. This is essential to ensure the safety of both the research and development processes and the product.

We recommend that:

- The current 'process-trigger', to initiate OGTR regulation, continue to be applied.

[19] Library of Congress, Restrictions on Genetically Modified Organisms: Canada https://www.loc.gov/law/help/restrictions-on-gmos/canada.php

[20] Tetsuya Ishii and Motoko Araki, A future scenario of the global regulatory landscape regarding genome-edited crops. GM Crops and Food, 8:44-56, 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5592978/pdf/kgmc-08-01-1261787.pdf

Phase one consultations identified a number of functional efficiencies that could be applied to the Scheme. The Review is exploring these issues from perspective of the existing process-based regulatory scheme:

Are there any 'fixes' the scheme needs right now to remain effective?

- The scheme is not now fully effective.
- Assessments of the safety of GMOs rely too heavily on unpublished and non-peer-reviewed industry data. The evidence that such data is inherently unreliable is strong and compelling.[21]
- Regulators ignore or discount many peer-reviewed studies that find harm.[22] Such studies should be a trigger for regulators to question applicants' evidence and require further research.
- Monitoring and surveillance to determine the impacts of current GMOs in complex environments and on human health are inadequate.[23]
- Enforcement is poor and GM product labelling is virtually non-existent. The scheme needs to serve the public interest - not the goals of industry.

We recommend that:

- The assessment regime and its processes all be updated and strengthened.
- New monitoring and surveillance systems be implemented with the specific purpose of detecting any long term and flow on effects of new GM techniques and their products.
- Data gaps be filled with independently generated evidence, not assumptions.
- GM contamination incidents be redressed through strict liability or similar legal provisions.
- The precautionary principle in the Act be strengthened and operationalised.
- The required expertise of the members of the Gene Technology Technical Advisory Committee should be revised, to include experts with a broader view and analysis such as ecologists and epidemiologists.

How would you streamline the existing scheme?

- This question is inherently biased, especially as every GMO release application submitted to the OGTR has been approved. We would prefer to be asked how the Scheme could be made more precautionary, as that is a principle embedded in the Act
- There is no evidence that current regulatory processes impede or prevent innovation or stand in the way of industry development.
- This question (like others) points to a clear deregulatory/industry, science and government agenda which should be outside the scope of reviewing a system that has human health, safety and environmental protection as its primary goals.

We recommend that:

- The Review focus solely on how best to ensure that the Scheme will be made more precautionary, to protect public health and the environment, rather than 'removing regulatory barriers for industry' by streamlining the system.

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[21] Diels, *J. et al.* (2011) Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products. *Food Policy*, 36(2):197-203. http://www.sciencedirect.com/science/article/pii/S0306919210001302?via%3Dihub

[22] e.g. FSANZ (2013) Response to a feeding study in pigs by Carman *et al*.. July 2013. http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman%27s-study.aspx; FSANZ (2013) Response to Heinemann et al on the regulation of GM crops and foods developed using gene silencing, May 2013. http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Heinemann-et-al-on-the-regulation-of-GM-crops-and-foods-developed-using-gene-silencing.aspx

[23] e.g. Pastrello, C. *et al.*, Circulating plant miRNAs can regulate human gene expression *in vitro*, https://www.nature.com/articles/srep32773

What efficiencies could be gained through adjusting the interface between the Scheme and other regulators?

- A single consistent definition of gene technology, GMO and GM product should be adopted across all agencies, based on the inclusive definitions enshrined in the present Gene Technology Act. Common language would improve the partnerships, communication and interactions between the OGTR and end product regulators.
- The OGTR should be the lead agency in assessing the safety and impacts of all dealings with GMOs – from lab bench to release and beyond - since it has greater expertise and experience in these areas than other product-focused agencies.
- Product regulators – FSANZ; APVMA; TGA; NICNAS; etc. – should have a remit to assess only the commercial end products of GM creation and production processes.

The Review is exploring whether greater alignment of regulation with risk should be further developed for environmental releases:

What support exists for a regulatory framework providing for tiered risk?

- The framework should ensure that contained research dealings with all genetic manipulation techniques should continue to fall under robust and consistent IBC surveillance, appropriate notification, and OGTR assessment and approval or licensing.
- We oppose tiered risk systems because, as proposed and used in Australia, such mechanisms tend toward deregulation by prematurely concluding that most risks are minor or manageable.

We recommend that:

- A tiered risk system not be adopted as it would complicate and weaken the regulatory regime.
- Any further moves toward industry self-regulation be rejected.

What examples exist of licence applications to the Regulator that could be 'fast-tracked', under a risk tiering system, with evidence of scientific and technical integrity that the aims of the Scheme (protection of human health and the environment) will be delivered?

- Fast-tracking is inconsistent with the Precautionary Principle enshrined in the Gene Technology Act so we reject it.
- This loaded question derives from a decision (apparently already taken), to incapacitate the current (inadequate) regulatory scheme in the interests of corporate science and commerce. For example, the OGTR supports the deregulation of new GM techniques in the Regulation Impact Statement (RIS) for its Technical Review of the GT Regulations, arguing without any evidence that there is a risk that:
    - *"ambiguity will inhibit use of the technologies, (so) that basic research may be held back, and that products (such as food crops or human or animal therapeutics) may not be commercialized," and that:*
    - *"delays in bringing new products to market, … could hamper industry development and affect the international competitiveness of Australian businesses."*

  These commercial issues are not legitimate matters for the OGTR's Technical Review of the Gene Technology Regulations or this Scheme Review to consider, as they both fall outside the scope of the Act and the Scheme.

We recommend that:

The Department of Health review should instead prioritise precautionary regulation to protect public health, safety and the environment - which are at the core of the Scheme.

Under a regulatory framework to tier risk for environmental release, what efficiencies might be delivered to regulated stakeholders?

- Those regulated under the existing regime are well treated, with the OGTR apparently meeting its statutory obligations to meet mandated deadlines, etc.
- The public will not accept governments weakening the GM Regulatory Scheme and making it subservient to corporate interests. The backlash against this trend is global and trenchant.

We recommend that:

- The Department of Health review should instead prioritise precautionary regulation to protect public health, safety and the environment - which are at the core of the Scheme.

How could efficiency gains to the Regulator be quantified?

- 'Efficiency' is an overused euphemism for deregulation. The Department of Health provides no evidence that increased efficiency is needed or has been effective. The present case-by-case approach to assessing applications ensures that each receives due consideration.
- Deregulation merely transfers the costs associated with the introduction of new technologies and their products from industry to society more broadly.
- Society as whole indirectly pays the environmental, human health and remediation costs when the inadequately assessed and regulated products of new technologies are marketed.

We recommend that:

- The Department of Health should instead prioritise public health, safety and the environment - which are at the core of the Scheme.
- The existing case-by-case approach to assessing applications should be retained.

The Review is exploring whether a distinction can be made between classes of organisms so the necessary controls can be applied to the highest risks, rather than applying a one size fits all approach:

What justification is there to regulate animals, plants or microbes differently?

- Genetically manipulating and modifying all living organisms poses risks that must be fully assessed. There is no justification for different GM regulations as all applications use variations of the same generic GM techniques, posing similar risks, hazards and costs in every context.
- Genetic engineers envisage using the new GM techniques to create, manipulate and modify any organism in the biological universe. So regulating the same techniques and processes differently would create greater complexity and uncertainty in the Scheme without any benefit.
- The consultation paper (p. 25) shows that the GM crop industry prompted this question - while the many recommendations that other submitters made appear to have been ignored.
- No evidence is provided to back up the assertion that 'lower levels of risk are inherent to plants, or at least plants with a long history of commercialised release'.
- We strongly challenge this statement as unforeseen off-target impacts may arise from any and all uses of the new GM techniques, and dangerous outcomes can occur with any of the techniques or organisms.

We recommend that:

- All GMOs and their products should be assessed for safety using rigorous research and trials.

In what way might different applications be treated differently (e.g. medical, agricultural, industrial, environmental, etc)?

- Different applications of the same techniques are already treated differently by each having a regulator of its own end products.
- The environmental release of GM animals, plants and microbes require a high level of scrutiny, as the risks and hazards that may arise from these dealings are poorly understood, characterised, assessed and monitored. This needs to change radically.
- Human gene manipulation dealings must be more open to public scrutiny due to the myriad ethical, moral and social issues that these dealings raise. The activities and decisions of bodies such as the TGA, AHEC, NHMRC, etc. are now opaque and this must change.

We recommend that:

- All GMOs be assessed for safety, irrespective of the uses to which they are to be put.

How might the Scheme accommodate the DIY-biology movement?

- Biohacking poses the same serious risks and hazards to the environment and human health as officially sanctioned research so should be accommodated within the existing system by requiring its compliance with the existing laws, regulations and rules.
- Biohackers should be required to meet the same standards of training and behaviour as all other genetic engineers. Their facilities and institutions should be required to meet the same standards as those that are formally approved and licensed under existing laws and regulations, including the required supervision of Institutional Biosafety Committees.
- The report of James Clapper, U.S. director of national intelligence, adding gene editing to a list of threats posed by "weapons of mass destruction and proliferation,"[24] must not be ignored or dismissed. The US military's engagement in funding research into new GM techniques and their products signals the potential for state or non-state actors to use the latest developments as weapons.

We recommend that:

- Biohackers be subject to the same laws and regulations as all other GMO creators, developers and users.

What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?

- The OGTR should require long-term environmental and epidemiological research to fill any gaps in the data that applicants provide. Non-military funding must be found for such research, if the new GM techniques are to be used as anticipated. The GM industry and establishment science must not be allowed to hinder this quest for sound evidence.

We recommend that:

- A wide range of independent environmental and human health studies should be conducted to determine the potential long-term and 'down-stream' effects of new gene technologies and their products on humans and the environment.

What opportunities are there for principles-based regulation in the Gene Technology Scheme? What advantages could be gained from doing this? What drawbacks are there from such an approach to regulation?

[24] Worldwide Threat Assessment of the US Intelligence Community Senate Armed Services Committee, Statement for the Record Worldwide Threat Assessment of the US Intelligence Community Senate Armed Services Committee, James R. Clapper, Director of National Intelligence, February 9, 2016
https://www.dni.gov/files/documents/SASC_Unclassified_2016_ATA_SFR_FINAL.pdf

- Regulatory regimes that are guided and triggered by required health, safety and environmental outcomes are needed. In order for Principle based regulation to succeed, the principles must have clearly articulated goals and outcomes, clear triggers, rapid enforcement, and stringent monitoring and surveillance. Principles that are vague will become motherhood statements with no legal teeth.
- The precautionary principle should permanently remain as the central tenet of the regulatory scheme. Properly defined and fully implemented, precaution should underpin all decisions.
- The principles of transparency and democracy should dictate that all major decisions involve genuine public consultation and are amenable to public challenge.
- The principle of universality should apply. The default setting in the Gene Technology Act 2000, that the OGTR will require all new GM techniques and their novel products to be notified, assessed and appropriately regulated, should remain in force.

We recommend that:

- Some high-level policy changes are needed including, "No data no market". Data gaps must be filled with sound scientific data, sufficient to determine safety to a high degree of certainty. In the absence of high degrees of certainty, no approvals should be granted.
- Every intentional release be monitored and tracked for unanticipated impacts, for at least a decade following release.
- The Precautionary Principle in the Act is clarified, strengthened and operationalised,
- The principles of transparency, democracy and GM universality apply.

Are there any non-science aspects that would enhance the object of regulation, that do not place unnecessary burdens on the regulated community? How might these be considered?

- GM raises ethical, social, cultural, economic and political issues that regulators have no clear brief to address (any ethical, moral and community input that the OGTR receives is routinely ignored as outside the scope, and the same applies to end product regulators).
- The principal goals of the Scheme are not well-served when no-one in the system has clear responsibility to consider and advise on such matters as biodiversity protection, maintaining the integrity of the human germline, or the environmental impacts of GMOs - such as less controllable weeds, insects or pathogens.
- The socio-economic impacts of the GMOs released have been poorly researched and sparsely reported in the scientific literature. "The importance of socio-economic impacts (SEI) from the introduction and use of genetically modified (GM) crops is reflected in increasing efforts to include them in regulatory frameworks."[25] Yet, when state governments exercise their responsibilities to evaluate the economic impacts and opportunities for their citizens, they are derided, scorned and berated.
- The industry proposal that state powers of economic review should be rescinded is self-serving and against the public interest.
  Some other key questions that are ignored in the present system include: environmental contamination; liability for unforeseen impacts; the public's right to avoid eating GM foods; and the right to eschew products from unsustainable agricultural systems.

We recommend that:

- The right of states to have GM moratoria on marketing grounds be maintained.
- The rights of states and territories to establish GM and GM-free Zones on marketing grounds also be retained.
- Strict liability legislation be passed in all jurisdictions to ensure that GMO developers are held accountable and liable for any adverse effects that their GM products may have.

[25] Georgina Catacora-Vargas, et al, Socio-economic research on genetically modified crops: a study of the literature, Agriculture and Human Values. https://doi.org/10.1007/s10460-017-9842-4

The Review is exploring the practical implications to the Scheme of harmonising Australian regulation with the regulatory needs of trade partners:

What are the potential impacts on market access for exporters of GM animal or plant derived food products?

- Experience with European and Chinese importers shows decreased access for exporters that do not conform to their traceability, regulatory and quality assurance requirements
- Countries, which regulate new GM techniques such as CRISPR and their products, may have zero tolerance for any products from such sources, and require traceability for imports from those countries that do not regulate the techniques and their products.
- For example, Australian GM-free canola must be uncontaminated to guarantee EU access, even for ethanol production, and access is now contingent on it also being certified as produced within sustainable systems. GM-free canola, around 90% of Australian production, has favoured access to Europe at premium prices and is a $1billion pa export market that would be at risk if GM regulation were compromised, as the GM seed and chemical industries propose.
- Segregation and traceability in unregulated systems will be more likely to fail. If traceability cannot be guaranteed then countries will likely block imports. This was recently the case with US corn and hay exports to China.[26] [27]
- Without the disclosures required by regulatory notification, assessment and licensing, there would be no systematic means by which foods, fibre or industrial materials produced using the new GM techniques could be identified in commerce.
- Australia could face market rejection if it deregulates these techniques in defiance of the preferences of its trading partners. For this reason New Zealand has decided to regulate all the new techniques as GMOs. This will have Trans-Tasman trade implications.

We recommend that:

- The OGTR assess, regulate and license all new GM techniques and their products.
- GMO developers be required to provide a simple and cost-effective detection test for each organism produced using the new GM techniques, for traceability and enforcement purposes.

Theme 3 - Governance Issues

The Review is exploring opportunities to maintain and enhance the transparency of, and trust in, the governance arrangements of the Scheme:

What will reassure the Australian public and regulated communities of the integrity of the Scheme?

- When an agency approves every GM application and does so mainly on the basis of industry data, trust is compromised. The closeness of the OGTR to industry is well established in documents released under FoI and is evidence of institutional corruption that will not be remedied with rhetoric or token gestures.
- When committees that provide advice to regulators are stacked with people who appear to unreservedly favour weak and compromised regulation, and who have obvious conflicts of professional and commercial interest, the regulatory system cannot gain public trust.

[26] Tiezzi, S. (2013) The Latest Threat to China-US Relations: GMOs, *The Diplomat*, 21/12/13, https://thediplomat.com/2013/12/the-latest-threat-to-china-us-relations-gmos/
[27] Newman, J. (2014) China's Hard Line on Biotech Burns U.S. Hay, *The Wall Street Journal*, 15/12/14, https://www.wsj.com/articles/u-s-hay-exports-to-china-shrivel-up-1418598477

- Research refutes the deficit model of public communication about new technologies and their regulation, which proposes that more information will win trust.[28] The conduct of this Scheme review is a classic example of how not to win public confidence or trust.
- The public expects our governments and regulators to exercise caution when new GM techniques such as CRISPR are invented and then quickly deployed. Swinburne University research shows that Australians are less comfortable with GM animals than with nuclear power plants, and GM food crops are just slightly more trusted.[29]
- Deregulation of new GM techniques and their products now, before there is strong evidence of safety and a history of safe use, is a recipe for discrediting the Regulator and the regulatory scheme, which are largely unknown to the general public and are held in relatively low esteem by those who know of their work.

We recommend that:

- The OGTR assess, regulate and licence all new GM techniques and their products.
- The applications and supporting documents for all GM applications to the OGTR and end product regulators be posted on the web so the interested public has full access.
- The Department of Health and the OGTR remove all people with conflicts of interest from their advisory panels and consultancies, and urgently review and strengthen their conflict of interest policies and practices.

What mechanisms could address the challenges that making changes in the Scheme might entail: Domestically – across a federated government system experiencing different political agendas and community sentiments? Internationally – relating to other agreements, trade agreements, and harmonised regulatory approaches?

- The Legislative and Governance Forum (the Forum) on Gene Technology is an appropriate body to negotiate any necessary changes to the scheme. However, its processes are insufficiently open to public scrutiny and engagement to win our full confidence. We have real concerns, given the compromised advice that it receives, that the Forum can provide the necessary checks and balances to ensure that changes will genuinely serve the public interest.
- The role and influence of the Standing Committee of Officials on Gene Technology Regulation is likewise opaque and hidden from public gaze.
- The tone and tenor of the whole scheme review raises concern that the core tenets of the system – protecting public health and safety and the environment - are being treated as peripheral. They appear to be over-shadowed by a reckless, global, industry agenda that would streamline and fast track the regulatory system to serve commercial goals.

We recommend that:

- All proposed legislative and regulatory changes go through the Federal, State and territory Parliaments, as well as the Forum, for full review and consideration.
- All states party to the Scheme retain the right to oppose any proposed changes, especially those that are designed to gut GM regulation.

The Review is exploring how to ensure the rate of adaptation of the Scheme keeps pace with changes in technology and community values:

What principles should guide the level at which a decision is made within the Scheme?

[28] Sturgis. Science in Society: Re-evaluating the Deficit Model of Public Attitudes. http://repository.essex.ac.uk/9772/1/fulltext.pdf
[29] The Swinburne National Technology and Society Monitor http://www.swinburne.edu.au/lss/spru/spru-monitor.html

We recommend that:

- The precautionary principle (properly defined and fully implemented) should underpin all decisions.
- The principles of transparency and democracy should dictate that all major decisions involve genuine public consultation and are amenable to public challenge.
- The principle of universality should apply. The default setting in the Gene Technology Act 2000 would remain in force so that the OGTR will require all new Genetic Manipulation techniques and their novel products to be notified, assessed and appropriately regulated.

Does reviewing the Scheme every five years best address the needs of the Scheme? Is there a preferable option?

Five-yearly reviews of the Scheme are appropriate but a more genuinely independent and diverse body should conduct the reviews. It should consider the case for reform without sectoral interests unfairly exercising undue influence over the process and its outcomes.

We recommend that:

- A genuinely independent body conduct future five-yearly reviews of the Scheme.
- The key goals and principles of the scheme must be respected and their centrality kept intact so that present and future GM innovations are effectively regulated.

Is the existing role of the Forum the most suitable way of providing oversight and guidance for the Scheme?

We strongly oppose any changes to the Scheme without Parliamentary oversight and the agreement of all parties to the Intergovernment Agreement on Gene Technology. Given the potentially far-reaching environmental, human health and economic impacts of new GMOs, it is essential that all the states and territories are full partners in deciding all new GM techniques and their products are regulated.

We recommend that:

- All proposed legislative and regulatory changes not only go through the Forum but are also reviewed in all Australian Parliaments.
- All states party to the Scheme retain the right to oppose any proposed changes, especially those that are designed to gut GM regulation.

What criteria should be used to determine what legislative amendments are minor and could be progressed without going to the Forum?

We strongly oppose any changes to the Scheme without Parliamentary and Forum oversight. The Forum should discuss all proposed amendments to legislation and regulation, as every jurisdiction has its own Gene Technology Act, the terms of which will also be influenced by any changes to Commonwealth law or the Regulations.

We recommend that:

- All proposed legislative and regulatory changes not only go through the Forum but also the Federal and State Parliaments for review.
- Drafts of all proposed amendments should be published and open for public review and comment.
- All states party to the Scheme retain the right to oppose any proposed changes, especially those that are designed to gut GM regulation.

GM moratoria remain a debated element of the Scheme and the Review is seeking to understand the factors and practical implications for all stakeholders:

What evidence is there to support economic and trade advantages of GM moratoria – or indeed, the absence of GM moratoria?

- The Tasmania and South Australian Governments both conducted reviews that concluded there are economic and trade advantages to their status as GM-free states.
- The University of Adelaide also produced a report in 2016 for the SA government entitled: "Opportunities for Non-GMO Labelled Food Products from South Australia".[30] It found strong and growing demand for the state's GM-free food, beverages and organic products and said, "opportunity lies in promoting a broad-based platform of 'naturally healthy' products (GM-free) from South Australia with claims that can be underpinned by traceability and verification systems."
- The South Australian government also recently passed a law to extend its GM moratorium until 2025 so its primary producers can reap the benefits, including the lucerne seed export industry, the wine industry, organic growers, millers and most dairy and food processors.
- Massive economic benefits, predicted before the state moratoria on GM canola in NSW, Victoria and WA were lifted, have failed to materialise. GM canola costs more to grow than conventional canola, sells for less, and has no yield benefits compared with the best conventional varieties.

We recommend that:

- The right of states to declare GM moratoria, and GM and GM-free Zones, on marketing grounds, be maintained.
- This Review raises questions that seek to make markets a pretext for amending the Scheme. But it would then also seek to deny any State party the right to consider markets and marketing issues in the interests of their own constituents. The GM industry and its government backers cannot have it both ways!

How could regulated stakeholders access the benefits of a national scheme, whilst ensuring jurisdictions are able to effectively trade in the international context?

The GM crop industry's push to remove the state GM moratoria also appears have prompted this question. An end to state government discretions to establish GM-free zones for marketing purposes may benefit the owners of GM seed varieties but it would be to the detriment of many other sectors that reap market access and premium price benefits from remaining GM-free. We are concerned that the Department of Health appears to be pursuing the GM industry's agenda for deregulation, against the interests of over 98% of farmers and all shoppers.

We recommend that:

The right of states to declare GM moratoria, and GM and GM-free Zones, on marketing grounds be maintained.

What other mechanisms could be utilised in order to realise the outcomes currently achieved through moratoria?

There are no superior mechanisms to achieve these ends. Segregation with zero tolerance for contamination is impossible and overseas GM-free buyers will increasingly deny market access to any supplier that does not fulfil their requirements.

[30] University of Adelaide (2016) *Identification and Assessment of Added-Value Export Market Opportunities for Non-GMO Labeled Food Products from South Australia,* http://www.pir.sa.gov.au/__data/assets/pdf_file/0004/282172/Executive_Summary_-_Adelaide_University_GM_Report.pdf

We recommend that:

- The right of states to declare GM moratoria, and GM and GM-free Zones, on marketing grounds be maintained.
- All governments co-operate and pool their resources to win GM-free export markets for the benefit of their citizens.

The Review is exploring how the Scheme can harness the emerging benefits of gene technology, that were not anticipated at the establishment of the Scheme:

Are existing mechanisms, when used effectively, sufficient to ensure the emerging health, environmental and manufacturing benefits of gene technology that were not anticipated at the establishment of the Scheme, can be harnessed for Australians?

- The purpose of the Gene Technology Act 2000 and the GT Scheme are the protection of public health and the environment, and must remain its key goals. Assuming that there will be benefits, while ignoring the inevitable costs, risks and hazards, is a certain recipe for compromising the regulatory system and losing public trust and confidence in it.
- With earlier generations of GM techniques and their products, governments echoed industry's baseless propaganda that promised GM would deliver vast benefits. Yet the results for many areas including agriculture have been modest - five broad-acre crops with two traits. These have resulted in: increased synthetic pesticide use; intensified corporate ownership and control of all key inputs to industrial food and fibre production; biodiversity impacts (e.g. Monarch butterflies); a costly tsunami of unmanageable weeds from the injudicious and repeated spraying of glyphosate-based herbicides; insect resistance to Bt toxins; and emerging evidence of long-term health impacts (e.g. lymphoma among farm workers from associated glyphosate use).

We recommend that:

The Government not act as the propaganda mouthpiece for the GM and agrichemical industries, making glowing claims for the benefits of new GM techniques and their products, most of which will never be realised and have never been reality tested.

Should other policy principles be developed that are tailored to horizon technology management?

- In 2013 the European Environment Agency reviewed several case studies (Late Lessons from Early Warnings)[31] and found no evidence that precautionary regulation hampered innovation as industry repeatedly claims.
- Early exposure of Research and Development projects and priorities to public review and criticism would help meet society's needs. As most agricultural R&D is farmer levy and tax funded, there is no justification for secrecy as it creates public and producer suspicion, and slows eventual acceptance. Claims of the need to gain commercial advantage and protect intellectual property through secrecy are over-rated.
- A comprehensive evaluation of new GM techniques and their products should include a thorough review of available evidence. Regulators should have the power to commission research to fill regulatory requirements or information gaps.
- Early intervention allows a broader discussion about technological needs and uses to benefit the general public. Such conversations rarely occur in a timely and measured way. The response to public scepticism is sham regulation to allow tech products to be marketed with minimal constraints such as labelling, or deregulation (as the OGTR proposes) based

[31] Late lessons from early warnings: science, precaution, innovation, January 22 2013. https://www.eea.europa.eu/publications/late-lessons-2

on general assertions of safety and efficacy which credible scientific evidence either refutes or does not support.

We recommend that:

- The precautionary principle be at the core of health and environment assessments and regulation of all new GM horizon technologies and their products.
- The US Office of Technology Assessment, which gave frank and fearless advice to the US Congress from the late 1970s to the mid-90s be considered as a potential model for trial in Australia.[32]

What other factors could be considered in the regulatory decision?

- Regulatory decisions are now too constrained with the application of so-called 'regulatory science'. In this regime, knowledge and information gaps are filled with best guesses. Instead, our regulators should be empowered, and required before an application can proceed, to requisition independent scientific data to fill any gaps. The OGTR was conceived as a gap-filler but was given no powers to require the filling of gaps.
- In its review of its regulatory science strategy, the APVMA said it: "involves a pragmatic application of the scientific method for the purpose of making a decision about whether to allow something (e.g. chemicals) to be used within the defined legislative framework and timeframes." We are dismayed that the APVMA and other regulators use the conceptually lax and practically flawed notion of 'regulatory science', as defined here, to reach decisions.
- In contrast, the scientific method has an internally consistent and rigorous methodology and rationale that philosophers and scientists have developed and refined over at least the past millennium. It has withstood the test of time, peer-review and informed public criticism to be universally accepted as the way to conduct scientific work, to progress towards a robust understanding of how the world's systems function, including our understanding of risks, hazards and harms.
- By departing from the scientific method, APVMA and others compromise their objectivity, credibility, authority, and decisions.

We recommend that:

- The APVMA, OGTR and other regulators make a 'precautionary' and 'principled' - not 'pragmatic' - application of the scientific method.
- Regulators be given the power to requisition new research data to fill knowledge gaps and complete the regulatory picture before granting approvals or licences.

What data sets are required to assist the regulator to consider benefits in addition to the risks?

- Another poorly conceived question. If the Regulator is going to consider potential benefits it must also consider the potential social costs, risks and hazards. A proper cost benefit analysis would include an assessment of cultural and social issues, externalities, plus the level of ignorance and uncertainty attached to the particular technology and its proposed use.

- The development of new GMOs is often accompanied with grandiose claims about their potential benefits. These are seldom borne out by reality. The purported benefits of a GMO expoused by its developer should never be used as a justification to not adequately assess it for safety before release.

[32] The Congressional Office of Technology Assessment https://www.princeton.edu/~ota/

The Review seeks to identify areas where clear policy positions could enhance the Scheme and support compliance with regulation:

What aspects of gene technology would benefit from greater policy position clarity?

- The intent of the Gene Technology Act is clearly to require the comprehensive notification, assessment and regulation of all new and emerging GM techniques and their products. The OGTR confirms this in the discussion paper for its Technical Review of the Gene Technology Regulations. We are therefore deeply disturbed to see the OGTR, and now the Department of Health, seek to undermine this policy principle with the immediate and premature deregulation of some new GM techniques and their products.

We recommend that:

- The policy principle of comprehensive regulation of all GM techniques and their products should be made explicit and applied.
- The goal of the scheme, to protect public health and safety and the environment should be reinforced, not compromised or undermined.
- The precautionary principle should apply to all GM regulatory processes and decisions.

The Review is seeking to identify any regulation gaps and overlaps at the interface of the Scheme and other product regulators:

What are the pressure points at the boundaries between regulatory schemes that are caused by regulatory gaps or overlaps?

- The regulation of GM techniques (OGTR) and their products (the end product regulators) are presented in public as discrete processes with different priorities and criteria for notification, assessment and regulation. Collaborations between the OGTR and regulators of the end products should be open and transparent.
- The OGTR should take a lead role and its licensing process should be a necessary but not sufficient condition for GM products to reach the market.
- Inconsistent definitions of GM, GMO, environment, health etc. between regulators create ambiguities at the interface between the OGTR (which regulates the processes of research and development) and the regulators of diverse bio-products.
- There appears to be a lack of policy and regulatory settings to deal with, for instance, GM crops that entail particular pesticide use so the OGTR can also consider impacts on natural environments, not only on farm environments.
- There is a lack of clarity between agencies e.g. AQIS, FSANZ and/or the Department of Agriculture, over the responsibility to test for and prevent the importation of unapproved GMOs from overseas.

We recommend that:

- A single consistent definition of gene technology, GMO and GM product should be adopted across all agencies, based on the inclusive definitions enshrined in the present Gene Technology Act. Common language would improve the partnerships, communication and interactions between the OGTR and end product regulators.
- The OGTR should be the lead agency in assessing the safety and impacts of all dealings with GMOs – from lab bench to release - since it has greater expertise in these areas than other agencies.
- Product regulators – FSANZ; APVMA; TGA; NICNAS; etc. – should have a remit to assess only the commercial end products of GM creation and production processes.

What amendments to the funding model would support an agile Scheme that will cope with increased future activity?

- We reject a 'user pays' system for the OGTR as such funding of other regulators facilitates Agrichemical, Pharmaceutical and Industrial corporations that pay for product regulation to deploy undue political influence for favourable determinations.
- Modeling of the anticipated volume of future demand for regulatory services would be helpful to inform the present reviews, rather than relying on assumptions.

We recommend that:

- Government continue to adequately fund the OGTR to perform its duties effectively, regardless of the level of demand for its services, so that public health and safety and the environment are fully protected.

How could some aspects of the Scheme be funded through other mechanisms that will support innovation and competition in gene technology, whilst retaining public confidence in the Scheme?

- Supporting innovation and competition in gene technology is not the province of regulators. That is the job of industry departments, CRCs, universities, Ausbiotech etc.
- Through their dependence on expert advisory panels and consultants, the OGTR and other regulators are already too exposed to potential sources of undue influence from people with undeclared professional and commercial conflicts of interest.

We recommend that:

- Government continue to adequately fund the OGTR to perform its duties effectively, regardless of the level of demand for its services, so that public health and safety and the environment are fully protected.

Theme 4 - Social and Ethical Issues

How do we help the community to best understand the benefits and risks of a complex, science-based technology?

- Ask instead what Governments can do to recognise that public concerns and skepticism about GM techniques and their products are not the result of ignorance. Many people have a good understanding of food, farm and pharmaceutical politics, corporate power, and social inequality. They know that most benefits from GM will accrue to owners of the techniques, but everyone will bear the costs when deregulated products are released.[33]
- Government Departments with regulatory responsibilities have no role in product promotion. Techno-optimist propaganda and incredible promises for the benefits of new technologies and their products are the province of commercial interests, not regulators.
- Understanding costs and benefits is not easy when members of the interested public are marginalised and have little engagement with the processes that lead to official decisions. Citizens require access to balanced and objective information and data from the early stages of GMO development,so there are no surprises when new GM products are proposed for release.
- Citizens need time and forums to debate the risks, hazards and costs, as well as possible benefits, of new technological processes and products, so we can all reach fully-informed positions that enable rational and reasoned decisions.
- Media bombardment with misleading claims that GM will, for instance, cure malaria and myriad other ills; solve climate change; end human hunger; eliminate cane toads and other

[33] Bray, H. & Ankeny, R.A. (2017) Perceptions of genetically modified food are informed by more than just science. *The Conversation*, 16/2/17, https://theconversation.com/perceptions-of-genetically-modified-food-are-informed-by-more-than-just-science-72865

invasive species; make drought and salt tolerant crops; and fix nitrogen in grains, lead our society to misallocate its scarce R&D resources - falsely raising public expectations, while undermining trust and confidence.

We recommend that:

- The Government produce genuinely neutral information materials on gene technology and facilitate a genuine public dialogue regarding these new techniques. Public interest groups should be consulted on the case for precaution as our positions are usually misrepresented, with straw arguments that trivialise and marginalise our arguments. This has not happened to date.

Where does the community have confidence in the gene technology regulatory scheme? How can this be maintained?

- The public would further lose trust and confidence in the regulatory scheme if some new GM techniques such as CRISPR are deregulated and their products are not assessed for safety. Deregulation would leave the public in the dark about what GMOs are being developed and released.
- Deregulation would be seen as a way to hide contentious GM processes and products, and to mislead the community. The vast majority of Australians have consistently said they want all GM food and food ingredients labelled (including those exempt under Food Standard 1.5.2).[34]

We recommend that:

- All GM techniques be assessed for safety as the Gene Technology Act 2000 mandates.

Where is there a lack of community confidence in the gene technology regulatory scheme? Why might this be, and how can confidence be built?

- There is a lack of public confidence in the long-term safety of GMOs in the environment and in the human diet, due to the lack of research in these areas. As regulators, it is wholly appropriate and important for the OGTR and others to commission research to fill data gaps. Relying only on the existing suite of corporate data and published research and state of knowledge is unprofessional and unconvincing. It is an *ad hoc* approach to what should be an orderly and rigorous scientific process.
- It should be unacceptable that applicants submit information to support their safety claims which is plainly produced for purely commercial purposes (such as chicken breast meat weight). Confidence cannot be restored while such unscientific practices are condoned.

What does the public need to know?

- The public needs to know from their inception all the GM projects being conducted in the nation's laboratories and what their purported purposes are.
- Interested citizens should have a central role in the processes of setting R&D priorities where public money is being spent.
- We should be promptly told of all new proposals to assess and approve GMOs, and the raw information on which those proposed approvals are based. The goals of new experiments being conducted and the location of approved field trials should also be published.
- All the raw data and scientific evidence submitted in applications should be electronically available on the web. Pre-digested, summary public exposure drafts of RARMPs and other documents are insufficient for serious independent reviews of proposals.

[34] *Ibid.*

- Applicants must be required to disclose all that they know, not only the positive and potentially beneficial aspects of their proposals.
- Commercial GMOs, GM products and ingredients, should all be required to carry a label so those who wish to avoid such products are enabled to do so.

Who is best placed to provide that information?

- While GM proposals are passing through their regulatory processes, the OGTR and all other regulators should make all information available to the interested public.
- Those who produce and market all commercial GM products must label them, and also provide objective, factual information about them – including all of the disparate uses and products of the new GM techniques.

The Review is seeking to better understand how to balance consumer choice within the scope of the Scheme:

What does the public need in order to accept the increasing availability and range of use of gene technologies?

- Governments have no legitimate role in promoting gene technologies or their products, or to massage public opinion in favour of GM products. Already multi-billion dollar GM industries promote and sell their GM wares.
- Governments and their regulators must be impartial watchdogs and referees, serving the public interest with a precautionary approach to health, safety and the environment through a robust regulatory Scheme.

What does the public need in order to determine whether to provide social license for the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector?

- The public needs control and engagement in decisions over all new technologies which may bring massive and complex changes to our society, but are marginalized and ignored.
- Every technology and its products must take their chances in the court of public opinion, while passing through rigorous regulatory processes and possibly entering commerce. The national regulatory scheme should not seek to address or resolve the adoption and embedding of gene technology in Australian culture, lifestyle, economy and health as these are not regulatory matters.
- The OGTR is charged with assessing the fitness of applicants to hold a license before granting it. We have never been satisfied that the regulator acquits this responsibility adequately. That's an important matter that should be under discussion here.

What are the ethical considerations for enabling access to medical treatments?

- Fully informed consent and professional transparency must amount to much more than mere 'consumer choice'.
- Precautionary regulation, rigorous surveillance, and timely review, are all essential.
- The costs of development, prices of treatment, accessibility and a range of other practical considerations should be informed by considerations of fairness and equity.
- International human rights law, such as the Covenant on the Rights of the Child should be applied along with the law of this land.
- Various government, professional and expert bodies already promulgate and administer a great variety of ethical rules, standards and guidelines for the application of new and emerging medical technologies and treatments and these should be brought to bear here.
- Which ethical rule or guideline applies will be determined on a case-by-case basis and very much depend on by whom, how, when and why a particular 'treatment' is proposed for experimental or clinical use in human reproduction, human germline or somatic gene therapy, body modification, illness prevention, public health promotion, or surgery, etc.

The Review is seeking to explore and better understand factors relating to choice and the potential impacts on trade, alternate farming techniques and the broader environment:

How do we ensure that information is available to the community on the value of GM and what it can do? Who is responsible for providing this, and why?

- Again, governments have no legitimate role in promoting genetic manipulation techniques, processes or their products. That is a matter for commerce.
- The multi-billion dollar GM industry is already promoting its processes and wares.
- GM products and processes do not necessarily deliver benefits. To serve the scheme's goals, regulations which assess the risks, costs, hazards and uncertainties inherent in every technological innovation and its products must be the core focus.

Is the Scheme putting up barriers to research and development and commercialisation of agricultural applications?

- The Scheme imposes no barriers or impediments to R&D and commercialization of the agricultural or other applications of new GM techniques. We are not aware of the OGTR, FSANZ or the APVMA ever rejecting any application for GM experimental or commercial use that was put to them. Occasionally they have imposed a minor restraint, such as GMAC's prohibition on GM cotton being grown in Northern Australia over a lack of data on its capacity to outcross with native and weedy relatives. This was later reviewed and lifted.
- Claims that GM regulation or public critiques of GM in agriculture impede crop deployment are baseless, except where State Governments appropriately use their powers to protect the legitimate interests of other primary producers. The rights of the states to declare GM and GM-free Zones for marketing reasons protect the interests of the 98% of Australian growers who remain GM-free and do not want to grow GM cotton or canola.
- The OGTR reportedly struggles to meet the demands on its services but that does not justify any deregulation. The office should be better resourced to do its critical work if it is unable to cope.
- In 2013 the European Environment Agency reviewed a series of case studies[35] on the failures and harm that earlier technology has caused and found no evidence that precautionary regulation hampered innovation, as industry constantly claims.

[35] European Environment Agency, Late lessons from early warnings: science, precaution, innovation, 22 Jan 2013 https://www.eea.europa.eu/publications/late-lessons-2