# Civil Society Groups Joint Submission on the Third Review of the Gene Technology Scheme Preliminary Report, May 2018

**Introduction**

The Precautionary Principle is at the heart of the Gene Technology Act and with good reason. Genetic modification (GM) techniques and their living products pose unique risks that need to be fully assessed and regulated before genetically modified organisms (GMOs) are released into the environment and used in food and medicine.

We reject the Department of Health's apparent attempts to undermine the precautionary principle, by facilitating the environmental release of GMOs containing gene drives and deregulating a number of risky new GM techniques. These findings lack credibility, since they rely on advice from experts who have serious conflicts of interest.

A recent report by the Swiss Federal Committee on Non-Human Biotechnology (ECNH) examining these new GM techniques concluded that:

> *"If serious damage is not merely conceivable, but there is also a scientifically plausible foundation for the fear that such damage could occur, then a precautionary obligation exists."*[1]

The members of the committee were unanimous in their conclusion that in these circumstances:

> *"it is the responsibility of those whose actions give rise to the fear of damage occurring to demonstrate plausibly why such damage is extremely improbable or scientifically absurd."*[2]

The report stresses that the scientific institutions charged with assessing plausibility:

> *"must be independent so as to ensure that plausibility is assessed impartially and according to scientific criteria."*[3]

The report concludes that:

> *"given both the plurality of scientific opinions and the fact that the state may not delegate decisions in such matters, it follows that* ***neither the decision-making authorities nor jurisdiction automatically accept the expert opinions of specialised advisory bodies****."*[4]

By their over-reliance on the highly conflicted advice of their expert panels, the OGTR, FSANZ and the Department of Health clearly fail in their duty of care to the Australian public and our environment.

**Key recommendations**

- Leading proponents of gene drives now say they are too risky to release in the wild, because of their serious and potentially irreversible threats to biodiversity, national sovereignty, peace and food security. There should be a moratorium on the environmental release of gene drives.
- We oppose the proposed deregulation of new GM techniques such as CRISPR in animals, plants and microbes. These techniques are fundamentally different to natural breeding and do not have a history of safe use. Products derived from new GM techniques should therefore be regulated in the same way as those created using older GM techniques and require a comprehensive case-by-case risk assessment.
- There should be a moratorium on human germline gene therapy – in other words genetically modifying people - until there can be a broad societal discussion on what (if any) applications of this technology would be socially acceptable.
- 'Removing barriers to trade' should never be used as a justification for accepting lower levels of safety assessment than exist in Australia, or allowing unapproved GMOs in our food. Reducing or removing regulations is actually more likely to create barriers to trade for Australian exporters.
- We support the rights of states and territories to protect their markets by maintaining their GM crop moratorium legislation.
- To preserve important checks and balances, all proposed changes to the Gene Technology Act and Regulations should undergo full consideration by all appropriate Ministers and state and territory parliaments.
- Regulations designed to prevent scientists with conflicts of interest from being the main source of advice to regulators must be enforceable.
- DIY 'biohacking' kits are now available to buy online, making the Government's claim that GM experiments must only be undertaken "within a certified containment facility" meaningless. Urgent enforcement action is required to ensure that genetic experiments are not conducted without adequate safety measures and containment in place, and only with Institutional Biosafety Committee supervision.

**Comments on Specific Findings**

**Findings 1 & 2:**

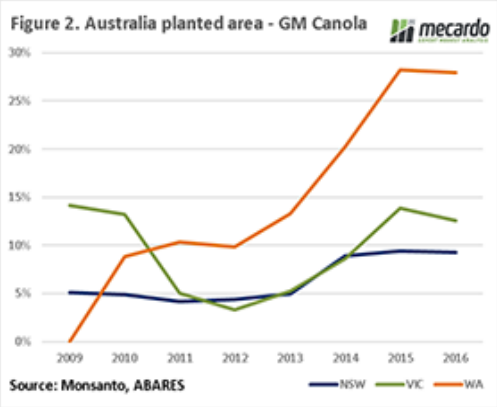
We agree with findings 1 and 2. The object of the *Gene Technology Act 2000* remains appropriate and should be maintained, while the Gene Technology Agreement (2001) is working well and continues to facilitate effective national cooperation on gene technology.

Some stakeholders claim the Scheme is overly precautionary. But we assert that the inclusion of the Precautionary Principle in the Gene Technology Act is vital, since most biotechnology applications are experimental and inherently unpredictable.

Some stakeholders also claim that the potential for products of gene technology to protect human health or the environment may not be fully realised if potential 'benefits' of gene technology are not brought into the equation. But the potential benefits of gene technology are frequently overstated.

For instance, the biotechnology industry has promised for decades that GM drought and salt tolerant crops would enable increased yields and so 'feed the world'. But there is very little to show for the tens of billions of dollars spent on GM research to date, except for increased corporate profits.

One analysis provided to the Review (notably from 2005) estimated that the state and territory moratoria on the commercial cultivation of GM canola could result in an economic loss to Australia's canola growers of $3 billion, in the period 2005 to 2015.[5] This early projection was not based on any data as commercial GM canola was not yet grown, and it was unrealistically assumed that GM canola's uptake would be far higher than it has been. The uptake of GM canola peaked in 2015, at less than 30 per cent in WA, less than 15 per cent in Victoria and less than 10 per cent in NSW.




A recent CSIRO estimate found that the benefits to non-GM canola growers has been around $100 million per year for the past decade, as a result of the typical $20-40/tonne premium that EU buyers pay for non-GM canola.[6]

Big opportunity costs have been incurred as scarce public and private Research and Development (R&D) resources were wasted on GM, instead of invested in creating sustainable agricultural systems that can permanently feed and clothe future generations of Australians.

Claims made for the new GM techniques such as CRISPR e.g. cheap, simple, precise and faultless, are even more exaggerated than those made for older GM techniques. CRISPR is purported, for example, to cure diseases from malaria to HIV, repair faulty genomes, feed the world and eliminate invasive species.

The possible future benefits that applicants claim, backed with their own data, should never be sufficient to justify releasing potentially dangerous experimental GMOs into our environments, food, drugs and other products. Where other management or technical methods exist to solve a problem, that pose few of the GMO's risks, the default should be to prefer the non-GM means, e.g. Gene Drive (extinction) techniques should never be used as biocontrol agents.

Some stakeholders claim that, "an overly precautionary scheme may restrict the availability of health solutions" but evidence does not support this. Research using CRISPR and other new GM techniques to develop GM vaccines and gene therapies has greatly increased but there is no evidence that our gene technology regulatory scheme has any chilling effect on the setting of R&D priorities or their funding.

**Finding 3: classification of new technologies**

The Australian Gene Technology Act (GT Act)[7] defines gene technology as "any technique for the modification of genes or other genetic material". This clearly includes all the new GM techniques unless they are specifically exempted in the Gene Technology Regulations, which they are not.

As the OGTR's discussion paper for its Technical Review of the Gene Technology Regulations says:

> *The Explanatory Statement to the 2001 GT Regulations (the 2001 Explanatory Statement) states that, "The definition of 'genetically modified organism' in the GT Act was intentionally cast very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly*

*changing technology."*

That clearly means that when the Gene Technology Agreement was entered into, all Australian parliaments envisaged new GM techniques being developed and fully intended that the scheme would be designed to regulate all new GM techniques and their products, by default. This includes, for example, all dealings with RNA interference (RNAi) since RNA is clearly 'genetic material' and RNAi can result in heritable genetic changes.

Yet this review process is evidently designed to narrow the scope of the Gene Technology Act. Under these proposed changes, the law would no longer have the breadth necessary to ensure that all dealings with all new GM techniques and their products are notified, assessed, regulated, licensed and monitored within the national GT Regulatory Framework. This is contrary to the purpose of the GT Act so we oppose it.

We strongly recommend that the OGTR and end product regulators treat all new GM techniques and null segregants, as well as their living products, as GMOs. The Department of Health should dedicate its efforts to enhancing, not weakening, the present GM regulatory system through limiting its scope and scale to exempt some GM techniques and their GM products.

Some GM industries and scientists argue that the new GM techniques are used to make only small changes to the genome, similar to those made using mutagenesis. However, unlike mutagenesis - which results in random mutations – these techniques can be used sequentially to make profound, targeted changes to a genome. For example, using SDN1 a bacterial genome may be re-engineered sequentially to create an organism able to produce anthrax or other toxins.

Gene editing techniques such as CRISPR/Cas9 were deemed "weapons of mass destruction and proliferation" in the US Government's 2016 annual worldwide threat assessment report.[8] The changes that the OGTR has proposed in its technical review would leave certain applications of these techniques unregulated - despite the present paucity of scientific evidence of their safety.

*The government relies on conflicted advice*

The OGTR has consulted its Gene Technology Technical Advisory Committee (GTTAC) on how new GM techniques such as CRISPR should be regulated.[9] The rules around conflicts of interest are clearly outlined in the Gene Technology Regulations 2001 (paragraph 20). These state that:

*(1) Before the Minister appoints a person as a member of the Gene Technology Technical Advisory Committee, the Minister must obtain from the person a declaration setting out all direct or indirect interests, pecuniary or otherwise, that the person is aware of having in a matter of a kind likely to be considered at a meeting of the Committee.*

*(2) A member of the Gene Technology Technical Advisory Committee who is aware of having a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.*

*(3) Disclosure must include interests that could be perceived to represent a possible conflict of interest in relation to:*

*a. for subregulation (1)—a matter likely to be considered at a meeting of the Committee; or*

*b. for subregulation (2)—the matter being considered or about to be considered.*

*(4) A disclosure under this regulation must be recorded in the minutes of the meeting and the member must not:*

a. *be present during any deliberation of the Committee about the matter, except to give information requested by the Committee; or*

b. *take part in any decision of the Committee about that matter.*

A number of the members of GTTAC that advised the OGTR on how new GM techniques should be regulated had clear conflicts of interest regarding these techniques. These include Dr Ian Godwin from the University of Queensland who is using these techniques to develop GM cereal crops and whose school collaborates with Monsanto.[10] However, all of these members were present during the discussion of this topic.[11]

Unsurprisingly, GTTAC advised the Regulator that:

- *Risks posed by organisms altered by SDN-1 are unlikely to be different to naturally mutated organisms.*[12]

- *SDN-2 and oligo-directed mutagenesis are unlikely to pose risks that are different to natural mutations, conventional breeding or mutagenesis.*[13]

GTTAC's advice formed the basis of the OGTR's discussion paper[14] on this topic and the way it was framed. No scientific evidence was offered in support of GTTAC's advice or the OGTR's proposal.

Dr Mark Tizard who is currently an expert advisor to the Department of Health on the present review of the national GT Scheme also appears to have commercial conflicts of interest, in relation to new GM techniques and gene drives, which should disqualify him from filling this role.

We strongly disagree with GTTAC's claim that "organisms altered by some site-directed nuclease techniques and oligo-directed mutagenesis are unlikely to pose risks that are different to natural mutations, conventional breeding or mutagenesis."[15] This conclusion is at odds with those drawn by overseas government agencies.[16]

Austrian government agencies are among the few globally to consider the biosafety risks that new GM techniques pose. Their conclusions, over three separate, high-level reviews, are that there is insufficient knowledge of the biosafety risks that these techniques pose to be confident of their safety. On this basis, they argue that products derived from new GM techniques should be regulated in the same way as those created using older, transgenic GM techniques and that comprehensive case-by-case risk assessments should be required.[17]

Site-directed nucleases (SDNs) rely on the natural DNA repair systems of living organisms, which are poorly understood and the way these techniques work is still hotly contested, even among scientists with highly relevant expertise and experience. According to a recent review that the Norwegian Environment and Development Agencies commissioned, there are "many uncertainties connected to mode of action as well as potential unintentional effects."[18]

*Site directed nucleases 1 (SDN-1)*

We oppose the deregulation of GM techniques such CRISPR (SDN-1) when used to make naturally repaired DNA breaks.

SDNs - also referred to as site-specific nucleases (SSN) - use enzymes to cut DNA at specific sites so that genes can be deleted or new genes inserted. The cut DNA is repaired by the natural DNA repair systems of

the plant. There are currently four major classes of SDNs: meganucleases, zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and clustered regularly interspersed short palindromic repeats (CRISPR)/Cas9 reagents.[19]

- **Zinc-finger nucleases (ZFN)**
    - This technique involves the use of an engineered enzyme to introduce site-specific mutations into the plant genome. Depending on the type of ZFN technology deployed, mutations can either be restricted to one or a few nucleotides or involve the insertion of a new piece of DNA;
- **Transcription activator-like nucleases (TALEN)**
    - These enzymes are similar in structure in ZFNs but have longer DNA binding sites;[20]
- **Meganucleases/homing endonucleases**
    - These are naturally occurring DNA cutting enzymes that have been isolated from a range of organisms including yeast and green algae;[21]
- **CRISPR/Cas9-Nucleases**
    - These are synthetic enzymes developed from a bacterial enzyme that is part of the bacteria's immune system, used to recognise and destroy foreign DNA;[22]
    - This technique has only been developed in the last few years. Scientists have been excited by its versatility leading many to inaccurately characterise it as a 'precise gene editing tool'.[23]

SDN-1 cuts the DNA without the presence of a donor DNA repair template. This can result in site-specific random mutations or deletions but can also result in the deletion of whole genes and even parts of chromosomes. It can also cause genomic inversions or translocations.[24]

The ways in which DNA double strand breaks are repaired and the potential consequences of mis-repair are still not fully understood.[25] A review commissioned by the Norwegian Government observed that our understanding of these mechanisms is still in its infancy and that the majority of the studies have been done on mammalian cells not plant, microbial or other animal cells.[26]

The Austrian Environment Agency's recent review found that SDNs can result in a number of possible unexpected effects. However, there is a current lack of knowledge regarding the mechanisms involved in these techniques, so significant uncertainties are associated with assessments of unintended effects.[27]

And the review commissioned by the Norwegian Government found that:

> *"There are several factors that influence both DNA binding and DNA repair, unfortunately they are to a large extent not fully understood. The lack of mechanistic understanding is a severe limitation for identifying potential hazards from SDNs and more research in this field is greatly recommended. Identifying unintentional effects in a system which is not fully understood becomes very difficult."*[28]

According to the Austrian Environmental Agency[29] unexpected effects caused by SDNs can result from:

- Unexpected mutations in genes sharing similar DNA sequences to the target gene;
- Knock-out mutations that result in fusion genes which could create potentially toxic fusion proteins;
- Unintended mutations as a result of the methods used to introduce SDNs into the target cells. This usually involves older GM techniques such as *Agrobacterium*-mediated transformation or bombardment using a gene gun;
- Changes in gene expression;
- Genes introduced using SDN-3 techniques behaving differently when inserted into different parts of the genome.

*Off-target effects*

These techniques can produce unexpected mutations, due to the SDNs cutting DNA outside the target site. This has been observed with the ZFN, TALEN and CRISPR techniques.[30] Agapito-Tenfen and Wikmark (2015) observe that small deletions can cause gene knockout and some mutations. While these may not lead to easily detectable changes they can still trigger safety concerns. Furthermore, it is unsafe to assume that these changes will not be heritable.[31]

The Austrian Environment Agency's review also found that ZFNs result in significant unexpected mutations.[32] This is also an important problem for the TALEN technique and, according to another recent review, it can result in severe side effects.[33] Fine *et al.* (2014) highlighted that identifying off-target mutations for ZFN and TALEN is a daunting task because of the size of genomes and the large number of potential mutation sites to examine.[34]

Studies suggest that CRISPR results in even more off-target mutations than ZFN and TALENs.[35] For example, a recent study found that CRISPR/Cas9 can result in hundreds of unexpected mutations.[36]

Agapito-Tenfen and Wikmark (2015) conclude that off-target mutations occur with all SDN techniques and it is impossible to predict what these might be,[37] therefore:

> *"comprehensive untargeted profiling methods (such as omics) should be applied in order to detect and identify unintentional mutations in the entire host genome."*[38]

Deregulating techniques such as CRISPR, given the knowledge gaps that exist around the risks they pose, is completely at odds with the Precautionary Principle embedded in the Gene Technology Act.

*Mutations created using these techniques are fundamentally different to natural mutations*

The statement in the Review's Preliminary Report, that there is a "growing body of literature suggesting that for gene editing applications, where no 'foreign nucleic acid' is introduced, any changes in the edited genome are equivalent to those that could have arisen during conventional breeding,"[39] is demonstrably false. Furthermore, the reference provided[40] to substantiate this claim isn't even about gene editing.

The argument that these mutations could occur naturally, and therefore do not need to be regulated, is disingenuous. The natural mutation rate is extremely low. One plant study found that the probability of any letter of the genome changing in a single generation is about one in 140 million. In contrast, these new GM techniques can cause hundreds of unwanted mutations in some organisms.[41]

Similarly, the Preliminary Report refers to "studies that have quantified the frequency of off-target effects, and found them to be less frequent compared with those found after random mutagenesis or conventional breeding". [42] Again, the paper that is referenced makes no such claim. In fact, it concludes that:

> *"regulators and policy planners need to support research on detection/prediction of off-target sites and unintended effects to help establish a safety assessment paradigm based on molecular characterization and phenotypic attributes of the derived products."*[43]

The Preliminary Report also states "it has also been noted that the off-target effects are no different than those which occur in nature." [44] But the paper cited makes no mention of off-target effects.[45] However, it predictably calls for the deregulation of these techniques, since Monsanto, Syngenta, the Biotechnology Innovation Organization and CropLife International funded its authors.[46]

We find it deeply concerning that the Department of Health has so clearly and selectively cut and pasted

references from industry submissions that purport to back their claims, without even bothering to check that the references corroborate the claims that are made.

We expect a far higher degree of rigor from a health agency charged with assessing whether or not new GM techniques should be regulated. If the techniques and their products are deregulated, the potential consequences may be catastrophic, so an exhaustive review of all the risks that may arise from their use is a basic requirement that the Preliminary Report does not deliver.

An extensive, independent review, that canvasses all the scientific data and the diverse opinions available in the published literature, is a key component of any credible review.

Also absent from the paper is any discussion of the use of these techniques in animals, microbes and humans. Mutagenesis is not used in these organisms and the use of gene editing techniques in animals and humans raises serious ethical issues, since off target mutations that could result in adverse animal welfare outcomes or human rights abuses.

Similarly, the OGTR has noted that even small changes to the genome of microorganisms and viruses can result in large differences in pathogenicity. For example, it has been found that a single mutation in the prM protein of the Zika virus made the virus more virulent, thus contributing to the increased incidence of microcephaly in recent epidemics.[47]

Not all natural mutations are "safe" and most of them - if they would occur at all - are not used for straightforward and rapid commercial development and use.

Furthermore, no good criteria are available to distinguish risky mutations from less risky ones. The size or specificity of a genetic change has relatively little relevance to the extent of change in the whole organism and consequently to the risk that it poses to the environment or food safety.

*Mutagenesis techniques do not have a 'history of safe use'*

The argument that the GM techniques create similar results to chemical and radiation mutagenesis, which it is claimed have a history of safe use, does not stand up to scrutiny. Neither of these techniques has been safely used in humans, animals or microbes.

Chemical and radiation mutagenesis could also result in the production of allergens and toxins and so should be regulated, pending commercial use. Arguing that new techniques such as CRISPR should be deregulated because of the Government's failure to regulate other potentially risky techniques sets a dangerous precedent.

*All of these techniques rely on older GM methods with the same associated risks*

All of the new GM techniques rely on older GM methods such as protoplast creation, biolistics, electroporation, tissue culture, and *Agrobacterium*-mediated gene transfer. These can all cause unexpected mutations that would be extremely unlikely to occur in nature. This is why organisms that are produced using them need to be assessed for safety.[48]

All of the new GM techniques can also result in the accidental incorporation of bacterial or synthetic DNA into the chromosome. With no regulation, these unexpected effects won't be looked for or observed.[49]

*Detectability*

The GM industry makes the nonsensical claim that organisms modified using the new techniques would be indistinguishable from natural organisms, so regulation would be unenforceable. Existing SDN-1 products such as non-browning mushrooms are patented – requiring full molecular characterisation to enable traceability.

Claims that GMOs produced using SDN-1 are not detectable only consider the current easily detectable signatures of GMOs created through transgenesis. These signatures of course help using "cheap" and "rapid" detection methods but there are a number of techniques that can be used to identify organisms produced using SDN-1.[50]

The development of further protocols and techniques (including advances in the robustness of whole genome sequencing) may allow for better, cheaper and more reliable detection of small changes (e.g. single base pair changes) in genome edited organisms. These include 'BATCH-GE', a bioinformatics tool for batch analysis of DNA sequence data and spectroscopy methods for differentiating between genome-edited and conventionally bred plant varieties.[51]

It is evident that advances in detection technologies are needed, not only for genome-edited organisms, but also for other techniques such as RNAi. Already networks of laboratories exist that coordinate and develop techniques to detect GMOs. In Europe, there is the European Network of GMO Laboratories (ENGL). ENGL could play a role in the discussion on the detectability of new organisms generated with new GM techniques, if it were commissioned to do so. The political and commercial will to develop suitable detection technologies is essential.

Even if claims that such changes could not be detected were true, not having an analytical control / enforcement method for tracing any product is not an acceptable legal argument. Documentary traceability tools and paper trails are used to trace numerous products through supply chains, including free range, organic and fair trade products, and those from specific countries or regions of origin.

As the regulator of these techniques, the OGTR should mandate that developers supply a detection test prior to commercialisation. Releasing untested GMOs into the environment and our food chain without a detection test available is a recipe for disaster. It is astonishing that the Government would even consider allowing this.

*Unintended gene drive creation – a unique risk*

In stark contrast to mutagenesis and natural breeding techniques, CRISPR also raises the potential prospect of gene drives being accidentally created. Zhao and Wolt point out that if CRISPR sequences are accidentally left in plants (and the same would likely be true of animals and bacteria as well) then researchers could inadvertently create a gene drive i.e. the sequence could copy and paste itself to all subsequent generations and the trait could spread rapidly through the population. Of course, if the new GM techniques aren't regulated, there will be no way of detecting these accidental inserts.

Zhao and Wolt warn that:

> *"Unintended release of plants containing global gene drives from confinement under conditions where there is outcrossing, a relatively short generation time, the stability of the driving genetic elements and suitable population structure could allow entry into wild populations to introduce undesired phenotypes and perhaps affect plant diversity."*[52]

*Regulatory status*

*USA*

The Preliminary Findings paper incorrectly claims that, "The USDA APHIS has adjudicated that a number of food crop varieties produced using some recently developed techniques are not GMOs, and thus are not regulated."[53] APHIS's regulation is quite restricted in that it only regulates the importation, interstate movement and environmental release (field testing) of certain GM organisms that are, or have the potential to be, plant pests.

APHIS has made no judgment on whether crops produced using new techniques are GMOs, only on whether they have to be assessed under its existing regulation. APHIS has also pointed out that GM crops produced using the new techniques "may still be subject to other regulatory authorities such as FDA or EPA." [54]

In January 2017, the U.S. Food and Drug Administration released a proposal to update the regulation of GM animals. This proposes categorising GM animals under the definition of a "new animal drug" and subjecting them to the agency's approval process, even if they don't contain DNA from another species, and even if their genome sequences could have been created with conventional breeding. If this proposal is adopted in the USA, it could have serious implications for Australian meat exports to the US if new GM techniques are deregulated in animals here.

*Europe*

The European Union has yet to make a decision on whether it will regulate these new GM techniques and their products as GM. The decisive view on the matter will be made in the European Court of Justice. It will rule in the next month on whether or not new GM techniques, including ODM, ZFN1, TALENs, and CRISPR/Cas9, fall under current EU GMO law.[55] If it rules that these techniques are not GM the European Parliament could still amend the current legislation so they are included.

Article 2.2 of directive 2001/18 defines GMOs as "an organism, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". This regulation focuses heavily on the unnaturalness of the genetic modification process, which requires precaution owing to the unknown risks that it poses.

The European Court of Justice advocate general considered the definition of a GMO provided in the 2001/18 directive. He recognised that, according to European regulation, organisms created through mutagenesis are GMOs since they have been modified "in a way that does not occur naturally by mating and/or natural recombination". He stressed that, "the directive does not require the insertion of foreign DNA into an organism in order for the latter to be characterised as a GMO"

*Market impacts*

If these techniques were deregulated in Australia, before being approved in key export markets, the impacts on Australia's commodity exports could be disastrous.

Australia's key trading partners have zero tolerance policies for unapproved GMOs in commodity trade, as illustrated by this statement from the EU Commissioner for Health and Consumer Protection:

> *"There is no flexibility for unauthorised GMOs - these cannot enter the EU food and feed chain under any circumstances."*
>
> Markos Kyprianou, EU Commissioner for Health and Consumer Protection[56]

A survey of country governments conducted by the Food and Agriculture Organisation (FAO) found that 73% of them have zero tolerance for unapproved GM varieties.[57] The FAO found that between 2002 and 2012 there were 200 cases of trade disruptions due to the presence of unapproved GMOs. The majority of the cases happened between 2009-2012, indicating increasing market sensitivity and trade problems.

Were Australia to deregulate the new GM techniques, it could have dramatic impacts on our access to overseas markets for all food exports.

If, for example - as appears likely - Europe declares all the new techniques are GM, traceability and zero tolerance for any GM contamination would be mandatory - as would testing protocols to detect the GMO. Without regulation, traceability cannot be assured, and without traceability Europe's zero tolerance policy could see a halt to EU food imports from Australia.

There are numerous examples of costly market rejection and disruption due to the presence of unapproved GMOs in export shipments. These include:

*Triffid flax*
When an unlicensed GM flax variety was found in a shipment to Japan, 35 countries closed their borders to Canadian flax exports, including 28 in the EU which accounts for 60 per cent of Canada's flax export market. A University of Saskatchewan study estimated the cost to the Canadian flax industry in the first year alone to be $29 million.[58]

*Viptera corn*
In 2015 the Swiss company Syngenta released a GM corn variety to market before it had been approved in key export markets, resulting in a Chinese import ban. The National Grain and Feed Association calculated *the loss to farmers to be nearly US$3 billion.*[59]

*StarLink corn*
This was a massive supply chain contamination incident involving a GM corn approved for animal feed but not for human foods. It resulted in the largest food product recall in history and is estimated to have cost US companies US$1 billion.[60]

*LibertyLink rice*
In 2006, an unauthorised variety of GM rice was detected in US exports. According to the US Rice Federation, "a robust long grain rice export market nearly vanished overnight".[61] The total cost to the US rice industry of the LibertyLink 601 contamination is estimated at around US$1 billion.

All the new GM techniques involve *in vitro* nucleic acid techniques and so fall under the Codex Alimentarius and Cartagena Biosafety Protocol definition of 'modern biotechnology'.[62]

Other countries could therefore reject shipments containing products derived from these new GM techniques that haven't been assessed for safety, without fear of World Trade Organisation reprisals. They are also subject to Liability and Redress under the Cartagena Protocol - which could prove very expensive.

Regulatory standards have proven to be the minimum standards that food exporters must meet. Market requirements are often far more stringent than regulatory requirements. For example, in Europe more than 40 GM foods are approved for human consumption, but barely any are actually present in the human food supply, because of the policy positions of food companies. Ultimately, food companies in overseas markets will determine whether new GM techniques are viewed as GM - not only governments or our regulators.

Food companies are a long way from coming to any final position on the products of these new GM techniques and it could be some time before they do. Therefore, the prudent position from a food exporting perspective is to regulate all the new GM techniques and their products, then wait to see how the marketplace responds - not to commit supply chains to new GM products until there is more clarity.

Already a number of non-GM and organic certifiers have stated that they consider these new techniques GM. These include Verband Lebensmittel ohne Gentechnik (VLOG) - a German Industry Association representing over 350 companies with combined annual sales exceeding 170 billion euros.[63] The association recently released a statement arguing that plants and animals produced using these techniques

should be regarded as GMOs. The association stated the products should be assessed for safety and labelled to ensure supply chain integrity.[64]

The European branch of the global peak organic industry body IFOAM (International Federation of Organic Agriculture Movements) has also released a position paper stating that it classifies these new techniques as GM.[65]

In the US, the Non-GMO Project has stated that it considers all the new techniques GM.[66] The US National Organic Standards Board (NOSB) has also recommended that the US Department Agriculture prohibit the use of these techniques in organic agriculture.[67]

It was in recognition of the potential market impacts of these new GM techniques that the New Zealand Government announced that it will regulate them as genetically modified organisms (GMOs). On making the announcement New Zealand's then Environment Minister Dr Nick Smith stated:

> *"The rationale for our cautious approach is that New Zealand is an exporter of billions of dollars of food products and we need to be mindful of market perceptions as well as the science. We will continue to monitor global rules around the regulation of GMOs and adapt our system over time in line with international developments."*[68]

**Finding 4: Emerging applications: Synthetic biology**

The widespread support for Synthetic Biology to remain within the scope of the scheme confirms that the definitions in the Act are robust. The definitions should therefore be interpreted to include all new GM techniques and their products.

Synthetic biology differs from "conventional" genetic engineering in its techniques, scale, and its use of novel and synthetic genetic sequences that may not have existed in nature before, raising new human health and environmental risks.

There has been no scientific effort to thoroughly assess the safety to the environment or human health of synthetic organisms. Its techniques can create thousands of novel organisms in a day.

Most of the organisms being engineered through synthetic biology (algae, yeast, E. coli, viruses) naturally and regularly swap genes, so genetic contamination from escaped or liberated organisms should be expected. Synthetic organisms could also displace wild organisms, interfere with existing ecosystems, become a new class of invasive species, or directly introduce toxins into the environment.

Whilst the Act is likely to cover all current synthetic biology applications it is not clear that it is robust enough to adequately assess all the future uses of the techniques, nor the potential risks posed by synthetic biology – particularly those posed by gene drives.

The Australian Council of Learned Academies (ACOLA) appears to be conducting its work on Synthetic Biology[69] in secret. Unless they open up their processes to citizen participation and criticism, their findings should be ignored.

**Finding 5: Emerging applications: Human germline gene therapy**

Human germline GM is promoted as desirable 'therapy', to fix genetic defects and their consequences. But such interventions also raise the prospect of human enhancement to satisfy personal or social desires. Scant consideration is given to the fitness of such enhanced humans - who cannot be consulted - to fit into present and future societies.

Germline manipulation is likely to have eugenic consequences. It would almost certainly increase the social and economic disparities between privileged elites and the great majority of the general population.

New GM techniques such as CRISPR are way too risky to use for human germline gene manipulations that may enter the human gene pool. It would be impossible to anticipate fully the effects of inserting genes into human cells and any adverse effects would be not only irreversible but also potentially inheritable.

There should be a moratorium on human germline gene interventions, even for ostensibly therapeutic purposes. A broad society-wide discussion is essential, on what (if any) applications of this technology may be socially, ethically and morally acceptable.

Some scientists make the case for a moratorium, including "an open discussion involving experts as well as the general public."[70]

Some ethicists also assert that human somatic cell gene manipulation may pose as many hazards and ethical pitfalls as germline modification and should therefore be approached with equal caution and critical assessment.[71]

**Finding 6: Intentional environmental release: Biological control**

GTTAC lacks the current expertise to adequately assess the environmental risks posed by GM biological control agents, let alone the raft of ethical and environmental issues raised by genetically modifying threatened native species "to be more resistant to disease or other threats."[72] The Preliminary Report claims that a current member of GTTAC has ecological expertise. This is certainly not evident from their biographies.[73]

The environmental release of GMOs raises serious potential risks that need to be adequately assessed. Ecologists and environmental scientists must be engaged in this work. Such scientists are often noticeably absent from work in this area, with other, unqualified specialists being accorded the status of experts on the environment, outside their areas of expertise.

Strict regulations are needed to ensure the safety of GM biological control agents - not the use of policy principles, guidelines or codes of practice. These should include post release monitoring and the use of genetic markers to ensure traceability.

The EPBC Act should contain a trigger for general environmental GMO releases, especially where the purpose of the release is biocontrol of non-native invasive species. There is a risk that such agents could be inadvertently introduced into ecosystems in which the target organism is a native, with essential functions in those ecosystems.

A new, more stringent licence category may be appropriate for biological control agents but we emphatically maintain the position that a permanent ban on the release of organisms modified with gene drives is justified.

Precaution and prevention are more rational and essential than post-release monitoring of environmental releases, as the cane toad and calicivirus fiascos among others amply attest.

We are strongly opposed to the genetic modification of threatened native species under the guise of conservation.

**Finding 7: Emerging applications: Gene drives**

Gene drives carry the same biosafety risks that other genetically modified organisms (GMOs) pose and

considerably more, since they are designed to spread rapidly through populations. There is nothing in the natural world to compare them to and that limits expert capacity to predict their behavior.

Because of their serious and potentially irreversible threats to biodiversity – as well as national sovereignty, peace and food security – Southern countries and over 170 organisations have called for a UN moratorium on gene drives.[74] Some leading proponents of gene drives have also now said that they are too risky to release in the wild.[75]

**Finding 8: process-based trigger**

The genetic modification process creates unique risks that need to be fully assessed so we support the use of the current process-based trigger. If the OGTR were to adopt product triggers, many potentially risky scientific, laboratory and commercial processes would likely go unregulated.

When the living products of GM production processes are proposed for release from the laboratories in which they are created, triggers for product regulation become relevant. Then the assessment processes of product regulators such as the TGA, FSANZ and APVMA should be conducted in partnership with the principal gene regulator, the OGTR.

New GM techniques such as CRISPR do not have a history of safe use and pose unique environmental and human health risks that need to be assessed.

**Finding 9: regulations commensurate with risk**

No good criteria are available to distinguish risky mutations from less risky ones. The size or specificity of the genetic change has relatively little relevance to the extent of change in the organism and consequently to the risk that it poses to the environment or food safety. We therefore oppose the proposal for further risk tiering within the Scheme.

Risk tiering creates opportunities for failures of precaution, miscalculations and resulting harm, especially where hazards and potential harms are poorly documented or understood.

There is also the potential for more regulatory loopholes to be created by tiering, through which GM entrepreneurs may deploy their living creations without due precautionary process.

Moving GMOs between existing risk categories is already possible, after consultation, so we see no case for changing the present arrangements.

**Finding 10: streamlining**

We oppose proposals to remove Notifiable Low Risk Dealing (NLRD) reporting requirements to the OGTR and to devolve some Dealings Involving Intentional Release to Institutional Biosafety Committees. Such proposals pose unnecessary risks, and deny stakeholders access to this information and the right to have their say.

We support establishing expiry dates for Confidential Commercial Information to aid in transparency.

A balance must be struck between haste, accountability and due process when questioning the OGTR's efficiency and timeliness. The regulator does not appear to routinely or often breach mandated deadlines.

The focus of any streamlining review should ensure that any changes do not become the fast track to poor or compromised decisions.

**Finding 11: GMO Register**

We oppose removal of the provision for a dealing to have been authorised by a license before being included on the GMO register.

We also oppose the OGTR alone being given the power to add dealings to the GMO register. The OGTR has a demonstrated pro-industry bias and we believe it is important that parliament has oversight over any proposed changes to the GMO Register.

Since the Register has rarely been used, presents other problems that are acknowledged in the Preliminary Findings, and as there are other exemption and exclusion provisions in the Act, the Register clauses should be removed from the Act instead of being amended.

When the GT Regulatory Scheme was being designed, we saw the GMO Register as a potential back door to fast track approvals and therefore opposed it. We expected the OGTR may wrongly assume that some GM event, similar to one already on the Register, would serve as a precedent that justified truncating regulatory approval processes, including the issuing of a licence.

We are angry that Finding 11 explicitly proposes removal of "the requirement for a dealing to have been authorised by a licence before being included on the GMO Register." This is precisely what we envisaged and rejected.

We oppose all proposed shortcut means of adding dealings to the Register, on the spurious pretext that it would be "more time and resource efficient". We would redouble our opposition if the mechanism of review, a disallowable legislative instrument, were removed from the law.

**Finding 12: Biohacking**

DIY CRISPR kits are now available to buy online, making a mockery of the Government's claim that such experiments must be undertaken "within a certified containment facility"[76]. Urgent enforcement action is needed to ensure that genetic experiments are not going on without adequate safety mechanisms in place.[77]

We recommend that the GT Act be amended so that all biohacking (so-called DIY Biology) people, activities and institutions are subject to the GT Act's provisions. There is no rational, policy or evidence basis for exempting biohackers from the law, when all other GMO dealings are subject to the Act, including an IBC in all R&D institutions to monitor and report on GM dealings, trained scientists, security and certification of laboratories and other facilities, the management of trial sites, providing secure transportation for all GMOs, and so on.

*Nature* reports that "In some parts of Europe, genetic engineering is illegal outside of professional facilities."[78] That is how it should be in Australia too.

We reject the Preliminary Report's definition of biohacking as, "DIY biology - The use of gene technology by hobbyists outside the traditional research and industry structures, also referred to as 'biohacking'."

Even the popular press is issuing measured warnings that unless there is regulation, "someone is going to get hurt."[79] The military and security services also see biohacking as a serious threat.[80]

**Findings 13: and 14: Future-proofing regulation and principles based regulation**

We strongly oppose enabling the OGTR to make determinations or orders on the applicability of regulation to any technical developments. This would remove important checks and balances. The federated nature of

the Scheme means that all parties to the Agreement should maintain responsibility for any binding decisions.

We strongly oppose principles-based regulation, having seen it fail miserably in other jurisdictions – such as Food Standards Australia New Zealand's unenforceable requirement that food be 'safe'.

We strongly oppose the proposed delegation of "agreeing consequential amendments to the Act, or endorsing the outcomes of periodic reviews of the Regulations"[81] to the Gene Technology Standing Committee. Such important decisions should be reserved for the Forum Ministers.

**Finding 15: Market access and international trade**

For trade, biosafety and biosecurity reasons, Australia should join and ratify the Cartagena Protocol.

'Removing barriers to trade' should never be used as a justification for accepting lower levels of safety assessment than exist in Australia. Reducing or removing regulations is actually more likely to create barriers to trade for Australian exporters.

All the new GM techniques involve *in vitro* nucleic acid techniques, so fall under the Codex Alimentarius and Cartagena Protocol definition of 'modern biotechnology'.

Other countries could therefore reject shipments containing products derived from these new techniques that haven't been assessed for safety, without fear of World Trade Organisation reprisals.

In recognition of these potential market impacts, the New Zealand Government announced that it would be regulating these new techniques as genetically modified organisms (GMOs). On making the announcement New Zealand's then Environment Minister Dr Nick Smith stated:

> *"The rationale for our cautious approach is that New Zealand is an exporter of billions of dollars of food products and we need to be mindful of market perceptions as well as the science. We will continue to monitor global rules around the regulation of GMOs and adapt our system over time in line with international developments."*[82]

Australian policymakers should heed this sage advice and legislate accordingly.

**Finding 16: Credibility, integrity and legitimacy of the Scheme**

While the LGFGT is a forum for diverse opinions to discuss and contest new policy, the role of the Standing Committee and the means by which decisions are reached (consensus, majority or other) should be more open and transparent.

The Gene Technology Regulations clearly require all advisory committee members with conflicts of interest over particular matters not to take part in any decisions pertaining to those issues. However, FOI documents show that GTTAC members with serious professional and commercial conflicts of interest have engaged in discussions and participated in making recommendations on the deregulation of a range of new GM techniques.

Regulations designed to prevent conflicted decision-making must be enforced and all advice that is compromised by conflicts of interest should be open to challenge.

More open invitations to nominate for advisory committee membership should be published when occasional vacancies occur or when committee memberships come up for renewal at the end of their terms. Committee members should be selected so that more diverse opinions as well as a broader range of expertise are represented among committee members.

**Finding 17: National consistency of the Scheme: Governance**

We support a mirror approach to the uniformity of the national scheme. However, the states and territories ceded only some of their powers to the Federal government when the scheme was established.

It is therefore essential that all proposed amendments to the Commonwealth GT Act, Regulations and the Agreement should be subject to state, territory and public review prior to any changes being made which would flow onto the other jurisdictions. Thus, important checks and balances would be maintained.

**Findings 18 and 19: state powers**

State powers to establish GM and GM-free Zones for marketing purposes were created under a policy principle. This has been a robust and useful provision that all jurisdictions have used. For instance, five-year moratoria on commercial GM canola were imposed after the OGTR granted 2 commercial licenses in 2003. Some states later chose to lift their bans but others did not, for marketing reasons.

Substantial evidence shows non-GM crops attract premiums that benefit farmers and the food industry, refuting claims that other agendas motivate GM moratoria.

The Australian Oilseed Federation and Export Grain Innovation Centre commissioned a CSIRO report on the economics of grain exports. It concluded that non-GM canola earned $1 billion extra for Aussie farmers over the past decade, as: "We've achieved a $100 million per year premium for our farmers, given the extra $20-$40/tonne paid for Australian non-GM canola."[83]

The association of a non-GM label with “safer and greener” is not “confusion” as the discussion paper states[84] but a sensible, precautionary conclusion that fits the worldviews, preferences and aspirations of many people. 80 per cent of GM crops are herbicide tolerant – mostly to glyphosate - which is a probable human carcinogen[85] so many shoppers seek to avoid exposure.

The assertion that Australia is falling behind in the “development and adoption of biotechnology innovations, in relation to its key export competitor countries” is baseless. New Zealand is one of our key export competitors and has no commercial GM crops.

**Finding 20: Harnessing the economic and health benefits of gene technology: Benefit consideration**

We oppose the Regulator considering any purported benefits of GMOs. Most possible benefits of GMOs are highly speculative and the proponents vastly exaggerate them.

For instance, GM crops failed to deliver most of the promotional claims made for them – drought and salt tolerant crops, nitrogen fixation in grains, higher yields etc.[86]

**Finding 21: economic and health benefits of GT: Regulatory burden**

We agree that it is important for the Scheme to keep pace with technological advances, however, there is no evidence that its failure to do so would have any stifling effect on gene technology research or development.

New GM techniques such as CRISPR pose potential risks to the environment and human health and should be assessed under the Scheme. There is no scientific justification for deregulating any of the uses of these techniques.

**Findings 22 and 23**

Any work program to develop Policy Principles, Policy Guidelines and Codes of Practice must be open to independent scientific and public review.

If the Gene Technology Standing Committee is to be engaged in such work then its openness, transparency and public engagement must improve.

We oppose the proposal to use the GMO Register to excuse cases of the Low Level Presence of unapproved GMOs. GMOs that have not undergone an OGTR and a product regulator's safety assessment must be actively excluded from the food chain.

All proposed changes to Commonwealth GT legislation and associated legal instruments must undergo full Forum consideration, full state and territory parliamentary review, and public consultations.

**Findings 24,25 and 26: Coordination with other regulators**

Because of its specific expertise in the field of GM techniques and GMOs, and their regulation, the OGTR should be lead regulator in the regulation of all GMOs and their diverse uses.

We strongly oppose the APVMA being the lead agency, for example, in regulating live GM vaccines, or gene drives and RNA interference sprays for pest control. The agency has no demonstrated expertise in these fields, limited access to independent expert advice, and its fee for service cost recovery system exposes its decisions to influence.

The lack of consistency between the definitions of GM, GMO and dealings that the OGTR, FSANZ and other product regulators use creates unnecessary uncertainties in the national uniform system.

FSANZ should readopt the OGTR's definition of GMO and GM product which were deleted from the Food Standards Act in 2016, so its reasoning and decisions are congruent with those of the OGTR.

We support the interagency sharing of data on the downstream environmental and health effects of GMOs, to inform the Regulator's future decision-making, or post-market review actions.

**Findings 27 and 28: Funding model**

We support the Federal Government continuing to fund the OGTR.

We oppose the introduction of a cost recovery model. Making the OGTR reliant on funding from the biotechnology industry has the potential to further erode the Regulator's independence.

The OGTR must be adequately funded to avoid any regulatory failures.

**Findings 29 and 30: Public understanding and confidence in the Gene Technology Scheme**

No Governments have a legitimate role promoting GMOs. The biotechnology industry is extremely well resourced and is already allocating millions of dollars to promoting and marketing its products. This will be further intensified now that the ownership and control of GM seed has fallen under the control of just three giant global entities. The OGTR's reporting should be confined to its regulatory work.

Public concerns about GMOs and their impacts are not due to a lack of education or information. A range of genuine, unresolved environmental, social, economic, ethical and health concerns are the reasons for public disquiet.

**Findings 31 and 32: Public understanding and confidence in the Gene Technology Scheme: Safety concerns and post market review**

We disagree that the use of herbicides associated with GM crops is beyond the powers of the Act, since the majority of GM crops are genetically engineered to be herbicide tolerant. They are therefore likely to contain much higher levels of these herbicide residues and their metabolites than their conventional counterparts. The herbicide regimes associated with GM crops therefore need to be considered as part of their safety assessments. This could be a collaborative project between OGTR, APVMA and FSANZ.

We support a review of current post-release review mechanisms, to determine whether they are sufficient and increased resourcing for the OGTR to undertake additional surveillance activities is required.

We support additional public communication of the OGTR's regulatory activities, to increase transparency.

**Finding 33: Transparency and access to information for the Australian public**

The OGTR has not been as transparent in its communication with the public as we expect. Its Review of the Gene Technology Regulations has been opaque, so the remainder of the process should be open to public participation and scrutiny.

Civil society stakeholders were only able to deduce the inner workings of this corrupt process as a result of costly Freedom of Information requests.

The review rejects calls for the general public to be able to appeal regulatory decisions. This is unaccountable and further entrenches the Regulator's deep and entrenched pro-industry bias.

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