

Submission to the 2017 Review of the Gene Technology Scheme



Thank you for the opportunity to provide input to the Review of the Gene Technology Scheme. We make this submission in the hope that significant reform and improvement will occur.

Introduction

The Gene Technology Scheme is in need of serious reform. The scheme does not protect the public interest or public health. Its decisions merely serve as rubber stamps to allow industry to claim its products are safe.

Lawrence Lessig, a Harvard academic, describes this kind of conduct as institutional corruption. An agency, sometimes unconsciously, begins to redirect its functions towards 'agents of influence'. Evidence of institutional corruption is found in the everyday actions and decisions of an agency.¹

By any analysis, the Office of the Gene Technology Regulator (OGTR) suffers from institutional corruption.

In order to address this kind of corruption, legislative as well as cultural changes need to occur.

Some general comments on the Background Paper

The background paper notes that:

The Regulator regularly reviews the GT Regulations to ensure they reflect current technology and scientific knowledge. This is important to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as genetically modified organisms, and to ensure that new technologies are regulated in a manner commensurate with the risks they pose.

However, outcomes of the Technical Review cannot alter the policy settings of the Scheme. (p. 4)

While this may be technically correct, it does not conform to on-ground realities. The Australian Gene Technology Act² defines gene technology as "any technique for the modification of genes or other genetic material". This would clearly include all new GM techniques unless they were specifically exempted in the Gene Technology Regulations. As the OGTR's discussion paper for its Technical Review of the Gene Technology Regulations states:

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modified organism' in the GT Act was intentionally cast very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly changing technology."³

That is to say, as gene technologies are developed, the intended default setting of the scheme is to regulate all new gene modification technologies and their products.

However, the interpretation preferences expressed by the OGTR clearly narrow the intent of the scheme by recommending certain technologies that fit within the definition of gene technology and GMO not be regulated.

Recommendation 1: that the Gene Technology Scheme review examine the extent to which interpretations made in relation to new GM techniques contradict the broader policy of the Act to capture new technologies.

Similarly, the OGTR has provided advice to individual manufacturers that some of these new GM techniques are not GM.⁴ The effect of such ‘advice’ is to alter the policy setting as well, which intended a broad regulatory net to capture new techniques.

Recommendation 2: that the Gene Technology Scheme review investigate amending the Gene Technology Act (GTA) so that interpretations that have or are likely to have legal effect are made reviewable decisions.

While we find the quality of the regulatory system to be deeply flawed, we support the broad definitions of gene technology and GMO and are deeply concerned that the effect of proposed interpretations in the Technical Review would permit new technologies to enter the market place without safety assessment or labelling.

Recommendation 3: maintain the current definition of GMO – and the underlying policy - in order to capture new developments in biotechnology

Friends of the Earth strongly disputes the claim that gene technology is a precise technology as the Background paper claims (p. 6). As Fagan *et al.* note:

“The first steps of making a GM plant – isolating the desired gene and cutting and splicing it to form the GM gene cassette in the laboratory – is indeed precise. But the subsequent steps are not. In particular, the process of inserting a GM gene cassette into the DNA of a plant cell is crude, uncontrolled, and imprecise. It causes mutations – inheritable changes – in the plant’s DNA blueprint. These mutations can alter the functioning of the natural genes of the plant in unpredictable and potentially harmful ways. Other procedures associated with producing GM crops, including tissue culture, also cause mutations.”⁵

This myth of precision is a critical issue in this review. The myth of precision, which the biotech industry of course promotes, is a proxy for assertions of safety. It is deeply concerning that a claim so incontrovertibly false is presented as a fact in this paper.

Recommendation 4: That the starting point for this review be an analysis of the issues of dispute in the scientific community relating to the safety of GMOs.⁶

Specific issues for consideration in the 2017 review of the Gene Technology Act (GTA) and Scheme

Recommendation 5: It is critical that any review of the Gene Technology Scheme assess the shortcomings and benefits of the current scheme. This should include the structure and scope of the scheme; its ideological underpinnings; the rigour and effectiveness of assessments; the extent of monitoring to determine whether unintended effects are being detected; the state of the science; public views of GM and biotechnology; the interface between different bodies and rules governing the use of GM in Australia; and how overseas jurisdictions are dealing with current and emerging trends in gene technology. This critique should be informed by submissions critical of the current regime.

In addition to looking at fundamental issues that are contested amongst scientists, the review needs to show a better understanding of public opposition. The notion that public opposition to GMOs has persisted for so long out of ignorance – a common claim of the biotechnology industry – is incorrect. Opposition and resistance are based on legitimate scientific data, and political and social realities that must be acknowledged and respected. Distrust of the technology is not a symptom of ignorance but based upon a very clear history of exploitation and even criminality by many of those involved in this industry.

While the OGTR pays lip service to ethics and the social dimension of biotechnology, these issues have never formed part of the decision-making of the agency.

Recommendation 6: That the GTA be amended to formally recognise the right of Australians to oppose GMOs and to not to consume them.

Conflicts of interest

Is the OGTR properly managing potential and actual conflicts of interest? Are experts providing advice for purposes of regulatory reform independent and free of conflicts? To what extent is advice sought and received from individuals or institutions that are conflicted or potentially conflicted? Are the recommendations and decisions made on expert advice affected by those conflicts?

It is important that the OGTR do more than pay lip service to conflicts of interest. Such conflicts have potentially serious outcomes. Not only do such conflicts affect the advice that is received and the decisions subsequently made, they also undermine the public trust in both science and regulatory agencies.⁷

As we noted in a letter to the Gene Technology Regulator, a number of the members of the OGTR's Gene Technology Technical Advisory Committee (GTTAC) have clear conflicts of interest regarding new GM techniques.⁸

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.*

Despite their potential conflicts of interest, all of the GTTAC members were present during the discussion of whether these new GM techniques should be regulated.⁹

Hardly surprisingly GTTAC advised the Regulator that:

- Risks posed by organisms altered by SDN-1 [site-directed nucleases] are unlikely to be different to naturally mutated organisms.¹⁰
- SDN-2 and oligo-directed mutagenesis are unlikely to pose risks that are different to natural mutations, conventional breeding or mutagenesis.¹¹

These conclusions formed the basis of the discussion paper for the OGTR's Technical Review of its Gene Technology and the whole way in which it was framed. Importantly, these conclusions differ markedly from those reached in reports commissioned by government agencies overseas.¹²

Recommendation 7: Examine legislative changes to ensure that:

- 1. Experts with conflicts of interest do not form more than 25 per cent of any committee or panel providing advice to the OGTR;**
- 2. Experts do not take part in any decision making regarding matters that they have a potential conflict of interest in.**
- 3. Experts with conflicts of interest are not hired as consultants preparing advice for the OGTR;**

4. The OGTR publishes detailed information on conflicts and potential conflicts of interest of those providing advice or consultancy services to the OGTR and how the agency has addressed those conflicts.

Labelling

While labelling is not the responsibility of the OGTR it is a critical component of a coherent and consistent national scheme. It is failing badly.

Polling shows that over 90 per cent of Australians want GM foods labelled. The 2011 review of labelling¹³ received more submissions regarding GM labelling than any other issue, and yet, almost no foods containing GM are labelled. A combination of loopholes, exemptions and lack of enforcement means that virtually no foods containing GM ingredients are labelled.

GM soy, corn, sugarbeet, canola and cottonseed are in our food as oils, sugars or starches. FSANZ claims that none of these highly processed food ingredients contain DNA or protein. A bottle of canola oil made from 100 per cent GM canola will escape labelling. This is despite peer-reviewed science¹⁴ and the documents¹⁵ used to approve GM canola showing that DNA traces and protein¹⁶ are found in refined oils.

The other exemptions¹⁷ from GM labelling include dairy, meat, eggs, fish and honey from GMO-fed animals. This is despite GM DNA being found in the muscles and organs of animals eating GM feed.¹⁸ Research has also found “that there can be a residual difference in animals or animal-products as a result of exposure to GM feed...”¹⁹

GM contamination “unintentionally present” at less than 1 per cent does not require labelling. This has resulted in inaction from FSANZ after an infant formula tested positive to GM contamination.²⁰

GM flavours at less than 1 per cent; processing aids and additives; and food from restaurants, cafes and takeaway outlets are also unlabelled.

Compounding inadequate labelling requirements is the miserable lack of enforcement. FSANZ conducted a pilot study of GM labelling in 2003. 22 per cent of the tested samples contained GM DNA.²¹ None were labelled. Despite the high level of non-compliance, FSANZ has not followed that pilot study with further monitoring and labelling requirements remain poorly enforced.

In response to a customer query about the GM status of polenta in 2005 Woolworths incorrectly stated that polenta did not need GM labelling as it is a highly refined ingredient.²² Polenta is ground corn. Any GM DNA or protein would still be present and therefore require labelling. That one of the two main food retailers clearly misunderstands GMO labelling requirements is deeply concerning and reflects the lack of education as well as enforcement by the Federal and State Governments.

Recommendations from both the Productivity Commission report and the Smart Farming Inquiry relating to labelling are strongly opposed. They clearly favour industry and propose to ignore the ongoing, deep and persistent opposition of the public to GMOs.

Recommendation 7: Investigate the OGTR being made responsible for overseeing the proper implementation and enforcement of GM labelling. Ensure that the OGTR is responsible to the public and the Parliament for ensuring labelling provides accurate information on foods that contain or are produced using GM.

Recommendation 8: Eliminate current loopholes and exemptions in the GM labelling regime and bring labelling into line with the standards in the EU.

State GM moratoria

The current attack on state GM moratoria, reflected in both the Productivity Commission's Report and the House of Representatives' Smart Farming Inquiry is based on very little evidence.

The effort to eliminate the rights of states to declare moratoria not only ignores the nature of the agreement between the States and the Commonwealth that led to the national scheme, but ignores all the evidence from markets.

South Australia and Tasmania have recently reaffirmed their moratoria through review processes and both have decided the benefits of remaining GM free are real and established.

It is interesting to note that the biotech industry has been unable to convince either South Australia or Tasmania to lift their GMO moratoria and are now turning to the Federal Government to do their dirty work.

Contamination and overseas markets

The lifting of the state GMO moratoria would allow any GM crop, animal or microbe to be introduced - irrespective of whether they have been approved by Australia's key export markets. The risks of market rejection are very real. For example, the European Union (EU) has a zero-tolerance policy on the marketing of food containing GMOs or ingredients produced from GMOs if they are not approved for food use in the EU.²³ As Markos Kyprianou, EU Commissioner for Health and Consumer Protection notes:

"There is no flexibility for unauthorised GMOs - these cannot enter the EU food and feed chain under any circumstances."²⁴

The Tasmanian Government also observes that:

"China has a zero tolerance for GMOs that have not been approved and tests for contamination. China's increasingly slow and unpredictable approval level and lack of a low level presence (LLP) policy has resulted in a large increase in rejected shipments and trade disruptions."²⁵

Were Australia to clear new types of GM crops for growing before they were approved offshore, that could be very costly for food exporters and take years to recover from, as the US experience demonstrates. There are numerous examples of costly market rejection and disruption due to the presence of unapproved GMOs.

These include:

Triffid flax

Just on the suspicion that flax exports from Canada contained a very low level of an unlicensed GMO variety of flax, Canadian flax prices dropped by a third. When those rumours were confirmed with the findings of Triffid in a flax 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 that the cost to the Canadian flax industry in the first year alone was \$29 million due to demurrage, testing, and segregation costs.²⁶

Roundup Ready alfalfa

In 2015 three U.S. hay exporters were blacklisted from supplying hay to China after Roundup Ready alfalfa was found in hay shipments. Hundreds of containers of hay were turned away.²⁷

Viptera corn

In 2015, nearly 3,000 Indiana corn farmers launched a lawsuit against the Swiss company Syngenta claiming it released a genetically modified seed to market before it had been approved in key export markets, costing them millions in losses from plummeting corn prices and a Chinese import ban. The National Grain and Feed Association said "*nationwide the loss is estimated to be nearly \$3 billion.*"²⁸ China's response is particularly worrying for the US corn industry because its stance on GM "has the potential to transform agricultural markets."²⁹ "It's pretty dramatic if the U.S. can't supply the Chinese market", said a grain exporters' representative.³⁰ The clampdown not only affected US corn exports, but other commodities such as soy, in which traces of the unauthorised GM corn were found. This caused soy prices to drop, as China sought substitute grains to import.

According to the US National Grain Feed Association:

*"Given China's zero tolerance policy for unapproved biotech events, these disruptions effectively shut U.S. corn farmers out of China's feed grain import market, which previously almost exclusively had been supplied by the United States."*³¹

StarLink corn

This was a massive supply chain contamination incident involving a GM corn used for animal feed and not approved for human foods. It resulted in the largest food product recall in history and is estimated to have cost US companies US\$1 billion.³²

LibertyLink rice

In 2006, an unauthorised variety of GM rice was detected in US exports. It took eight years and a "thorough and painstaking industry campaign" to eliminate the GM rice from the supply chain before the US Department of Agriculture finally issued an "all clear".³³ The contamination was first discovered when traces of a GM herbicide resistant rice were found in a long grain rice export shipment. The strain (Aventis' LibertyLink 601) was not approved for growing or consumption anywhere in the world, including the US: in fact, the GM rice had only ever been field trialled and the experiments had been wound up five years before traces were discovered in export consignments.

According to the USA Rice Federation, "a robust long grain rice export market nearly vanished overnight".³⁴ Within two days, Japan had banned all US long grain rice imports; three days later, the EU followed suit, shutting its borders to US rice consignments unless

testing demonstrated they were free of the GM rice.³⁵ Other countries, including Mexico, Taiwan, South Korea, Philippines and Russia also closed their borders to US rice or required certification, testing or labelling. By August, “the global market for US long grain rice collapsed.”³⁶

The total cost to the US rice industry of the LibertyLink 601 contamination is estimated at around US\$1 billion.

Other countries that could guarantee GM free status stepped in to supply US markets. Thai and Vietnamese rice industries committed to maintain GM free supply chains, stating: “We should not waste this opportunity because the EU is seeking new sources of rice to replace the US”.³⁷ 95 per cent of exports to the EU were lost in 2007.³⁸ In 2013, the USA Rice Federation stated that:

“U.S. access suffered a devastating blow in August 2006, from which it has yet to recover...U.S. rice exports to the EU plummeted. Despite the successful effort of the U.S. rice industry to effectively remove the LL traits from the commercial supply, trade has not returned.”³⁹

Other contamination incidents

In 2006, a new type of GM corn was planted in just 1 per cent of US fields but managed to show up in 55 per cent of exports to Europe that year, a development that costs tens of millions of Euros as the corn was not then approved in the EU.⁴⁰ Another incident in 2009 saw three unauthorised GM corn varieties mixed with US soy exports to Europe, and led to hundreds of thousands of tonnes of soy being refused entry.⁴¹

New GM techniques now being considered for non-regulation raise even more serious market risks.

The European Union has yet to make a decision on whether it will regulate these techniques as GM. The final word on the matter is likely to come from the European Court of Justice. It will rule next year whether or not new GM techniques, including ODM, ZFN1, TALENs, and CRISPR-Cas, fall under EU GMO law.⁴²

If Europe declares these techniques GM, as is likely, then traceability would be mandatory as would testing protocols allowing the GM to be detected. With no regulation in Australia, traceability cannot be assured and without traceability Europe’s zero tolerance policy could see a halt to food imports from Australia, not just imports of GM crops and food.

Rather than participating in the biotech industry’s attempt to bully populations to accept GMOs, Australia should take advantage of the opportunities to secure GM free markets.

The lifting of the state moratoria would allow the commercialisation of GM wheat

Australia is among the world’s top wheat exporters. GM wheat has been rejected by all of the other major wheat growing nations. However, the lifting of the state GMO moratoria would mean that if GM wheat was approved by Federal regulators it could be grown here without restriction, threatening Australia’s global wheat markets.

In 2004, North American farmers blocked GM wheat commercialisation. According to the Canadian Wheat Board, the biotech industry could not ensure that GM wheat would not

contaminate Canada's conventional wheat supply and GM contamination would "virtually destroy the \$3.5 billion industry in Western Canada."⁴³ Furthermore, key buyers in Europe warned that they would stop buying any wheat from North America if GM wheat was introduced.⁴⁴

Like Canada's Wheat Board, the Australian Wheat Board rejected GM wheat because of the biotech industry's inability to guarantee segregation of GM wheat in the field and "clear market signals from international and domestic customers that strong reservations exist concerning GM wheat."⁴⁵

However, the Australian Wheat Board has since been privatised and no analysis of the potential for GM contamination of our wheat supply chain, or the potential impact of this on Australia's wheat export markets, has been published since the Australian Wheat Board surveyed Australia's export markets in 2003.

Our key export markets don't want GM crops

In 2015, the Tasmanian Government's Department of Primary Industries, Parks, Water and Environment (DPIPWE) conducted a snap shot of Tasmania's ten major trading partners. This concluded that "for the majority of our significant trading partners, consumer attitude remains sensitive to GE food products." The review concluded that the primary reason that there are no GM crops grown by Australia's main agricultural competitor New Zealand is consumer resistance to GM foods.⁴⁶ The review also noted that:

"Interestingly, here in Australia, sentiment in the dairy processing sector is changing around the potential use of GM pastures with the Australian Dairy Products Federation stressing caution as their future use due to the potential to provide a non-tariff barrier for Australia's milk products."⁴⁷

If the GM bans are lifted in Australia and GM rye grass is commercialised this would obviously have major implications for sensitive export markets such as Europe and Asia.

Lucerne

The Australian lucerne seed industry has a moratorium on GM so that producers are unable to grow GM lucerne in Australia. One of the biggest concerns that the lucerne industry has is the potential impact on the industry's export markets, the biggest of which is Saudi Arabia, a country that does not accept GM seed.⁴⁸ The lifting of the state moratoria would mean that as long as GM lucerne was assessed as safe by Federal regulators it could be grown.

There is a marketing advantage to remaining GM free

The Productivity Commission appears to have based its calls to lift the state GM moratoria solely on anecdotal evidence provided by the GM industry lobby groups AusBiotech and CropLife and has failed to consider the wider issues affecting agricultural exporters.

The Tasmanian Minister for Primary Industries declared the whole of Tasmania a GMO-free area by the *Genetically Modified Organisms Control (GMO-free Area) Order (Tas)* on 31 October 2005. According to AgriGrowth Tasmania "the aim was to position the State in the global marketplace as a producer of food that is genuinely GMO-free."⁴⁹

In 2013 Tasmania reviewed its moratorium on GM crops. moratoria, this review involved broad consultation with Tasmanian producers. The final review report found that:

“Many submissions focussed on the importance of being GMO-free to Tasmania’s image, stating that the “clean and green” attribute is critical to the State’s brand, without which both markets and individual businesses would be damaged and future opportunities lost. Point of difference was a recurring theme: that is, removing the moratorium and allowing GMOs would mean Tasmania loses a significant point of difference in current and potential future markets for our produce.”⁵⁰

The report also found that:

“Tasmanian industries – like beef, fruit, honey, organics and food tourism – argue that they rely on Tasmania’s GMO-free status as a key component of their marketing and branding and for market access generally.”⁵¹

When the Tasmanian Government extended the GMO moratorium in 2013 it instructed its Department of Primary Industries, Parks, Water and Environment (DPIPWE) to conduct an annual review to consider whether there were new grounds to lift the moratorium. The agency’s 2015 review determined that **“there is no need to trigger a review of the commercial release of GM into Tasmania’s environment at this time.”⁵²** [emphasis in original]

As we pointed out in our submission to the Technical Review of the Gene Technology Regulations, it appears that industry with the complicity of regulators is seeking to define new GM techniques as non-GM, which will effectively bypass state moratoria. We note that this is another example of an OGTR interpretation potentially overturning a policy position in the current scheme.

The biotech industry asserts the lack of consistency between states is bad for business, but provides no evidence for that claim. In any even, that is not the position of either SA or Tasmania, which maintain that they have benefitted from their reputation for clean and green food. In fact, one is hard pressed to find in either the Productivity Commission report or the Smart Farming Inquiry evidence that GM crops have been the boon both promised and claimed. Attempts to dismiss consistent evidence of premiums for non-GM as anecdotal are simply false.

An unmentioned risk of overturning the right of states to impose moratoria, is that those states which are GM free and wish to remain that way may well withdraw from the Gene Technology Agreement, which would result in a dangerous fragmentation of GM regulation.

Recommendation 9: Leave the policy that permits States to declare areas GM free in place.

GM Contamination

We strongly disagree with the Productivity Commission statement that:

“there is evidence that industry (both in states without regulatory restrictions and internationally) can successfully manage the co-existence of GM and non-GM products.”⁵³

In fact, the Smart Farming Inquiry Report doesn't buy into this myth. It notes that:

*"The Committee heard that, due to the practical limitations of supply chains, and as the global trade in GM crops increases, incidents of the unintended low-level presence of GM plant material in non-GM commodities will become more common."*⁵⁴

The experience in North America has shown that the coexistence of GM and non-GM crops is impossible. Contamination happens wherever GM crops are grown.⁵⁵

According to the Canadian National Farmers Union:

*"GM crop agriculture is incompatible with other forms of farming—non-GM and organic, for instance—because GM crops contaminate and because segregation is impossible."*⁵⁶

GM canola has been found to cross-pollinate with non-GM canola more than 26 km away.⁵⁷ It is therefore not surprising that the use of GM canola varieties in Canada has also led to the widespread genetic contamination of non-GM seed production. In 2003, Canadian researchers tested 33 samples of certified non-GE canola seed and found that 32 samples were contaminated with GM varieties. Three of the samples had contamination levels above 2 per cent. Furthermore, a significant number of seedlings were found to be resistant to both Liberty and Roundup herbicides. The authors concluded that cross contamination with various herbicide resistant traits was at a very high level and that purchasing pedigreed seed would not guarantee that the crop would be uncontaminated with GM traits.⁵⁸ Another study in the US found that similar problems have occurred in other GM crops, with virtually all samples of non-GM corn, soybeans, and canola seed being contaminated by GM varieties.⁵⁹

Widespread GM contamination is driving seed production out of the prairies to other parts of North America. In some cases it is being driven out of Canada altogether, relocating to GM free producer nations such as New Zealand.

Similar problems are also already occurring in Australia, with non-GM seed imports from other Australian states unable to meet Tasmanians zero tolerance requirements for GM contamination.⁶⁰

Industry is proposing eliminating the organic industry zero tolerance for GM. This would be an extraordinary interference in one industry for the benefit of another. It is completely opposed by Friends of the Earth.

The organic industry seeks to meet the needs of that portion of the public concerned by current agricultural practices. On what legal, ethical and policy basis – except the utter failure of the biotech industry to segregate their GM – would government force organic farmers and consumers to bear the penalty for a failure that isn't theirs?

How easily regulators appear to forget that the industry – and the government - promised segregation systems that would prevent contamination.

Those promises have now been shown to be lies. As many commentators pointed out when segregation measures were being discussed and developed, the object for the biotech

industry was to contaminate in order to leave consumers no choice.⁶¹ This has now become the foothold from which they seek to further water down the standards of other agricultural sectors.

In 2004, it was pointed out that the provisions of the Gene Technology Act were inadequate to prevent harm to non-GM farmers and that contamination and liability issues would have to be fought on an inequitable field, where those harmed would bear the burden of proof. It was also argued that Common Law remedies in tort were unlikely to work.⁶² The Steve Marsh case has confirmed the reality of contamination, the inequities of the current system and the failure of the Gene Technology Act and Regulator and the Common Law to address those problems.

When the Gene Technology Act was passed the agency insisted that buffer zones of five metres as well as other segregation measures would be adequate to protect non-GM farmers. It was always a nonsense, although the Productivity Commission persists in perpetuating what is at best a myth.

The response to contamination has been to implement a contamination threshold and then to see the industry attack the organic industry for maintaining a zero tolerance policy on GM contamination in Australia.⁶³

The public clearly wants and has a right to access GM free foods. Shoddy segregation systems or lies about the potential to segregate should not be rewarded.

Recommendation 10: Amend the GTA to recognise that the public is entitled to choose GM free foods and that strict segregation measures must be part of recognising that right.

Strict liability legislation is necessary

Liability legislation that protects organic farmer and farmers who want to maintain their GM status is sorely needed. A strict liability regime based on the polluter pays principle should be implemented. The preferred option of Friends of the Earth is a levy on GM growers to create a Farmer Protection Fund that can be paid out to farmers immediately upon proof of harm or loss. That fund will also be used for remediation and to ensure farmers suffer no loss of markets or revenue as a result of contamination.

Recommendation 11: Amend the GTA to impose strict liability on the biotech industry for contamination regardless of harm.

Public rights and review provisions

Section 179 of the Gene Technology Act makes it eminently clear who has rights and who doesn't in relation to the authorisation and release of GM. Applicants and licence-holders may take decisions made under sections 43(2)(f), 55, 68, 70, 71, 84, 86, 87, 88, 89A, 92, 94, 95, 96, 185, 186 to merits based review, in other words a substantive rather than a procedural review. Citizens cannot take any decision to merits review and must rely on judicial review instead, a far weaker adjudication and one that does not permit arguments regarding the merits of a particular approval or licence.

Because this Act allows the imposition of GMOs on the entire population, citizens should have the right to merits review. The bias in favour of the biotech industry must be addressed.

Recommendation 12: Amend the GTA so that the public has the same rights of review as industry and licence holders.

Precautionary Principle and safety first

A 'soft' form of the Precautionary Principle is found in section 4 of the GTA. His Honour Justice Paul Stein has summed up the difficulties:

“the inclusion of the principles in Australian legislation has been largely confined to objectives of statutes or agencies without any real guidance to decision-makers as to whether and how to apply the core principles or what weight to give them. Moreover, some of the principles contain vague statements, some might call them aspirations, as well as ambiguities, inconsistencies and uncertainties. Difficulties of interpretation and application are manifest. There is even discussion on whether the principles are merely guiding or whether they are also operational.”⁶⁴

The weaknesses in this definition are many. Firstly, it requires a 'threat of serious or irreversible environmental damage'. Neither 'threat' (as opposed to risk) 'serious' nor 'irreversible' is defined. Secondly, the response to such a threat is deeply flawed. It firstly requires 'cost effective measures' to 'prevent environmental degradation'. Note that this doesn't require prevention of the serious or irreversible harm. 'Cost effective' isn't defined. It isn't clear what is required if no 'cost effective' measures are available. The language also presupposes that the precautionary principle is only triggered after a decision to authorise has been made.

Recommendation 13: Strengthen and operationalise the precautionary principle in the GTA. Friends of the Earth recommends wording along the following lines: *In the absence of scientific consensus that an activity is safe, the burden of proof that such an activity is not harmful falls on those proposing to take the action. Proponents for release of a GMO into the environment must demonstrate to a reasonable certainty that the GMO poses no risks to the environment and human health.*

The legislation must explicitly recognise that an absence of evidence of harm IS NOT the same as evidence of safety. A precautionary approach should therefore be adopted whenever there is a recognised risk of harm or uncertainty regarding the harm that may occur.

The precautionary principle should apply to safety assessments, how the agency addresses new information, conditions imposed on approvals and monitoring. If new information credibly raises concerns regarding the safety of a GMOs or the validity of an approved dealing, the Agency must undertake or commission an independent review of that information.

The Gene Technology Act must make the precautionary principle enforceable and develop guidelines to operationalise the principle throughout the Act.

Safety assessments

Australia is one of the few countries in the world that has never rejected a GMO application. It has also never reviewed an authorisation in response to a peer reviewed paper indicating harm.

Safety assessments are seen by Friends of the Earth as rubber stamping exercises intended to validate an assumption of safety rather than to determine whether a GMO is safe.

There are four aspects of safety assessments that Friends of the Earth would like to see assessed in this review:

1. Reliance on industry data in making assessments

At its heart, institutional corruption begins with a corruption of good scientific practice. The least reliable science is industry-funded science.⁶⁵

The OGTR consistently relies on industry-funded science as the basis for approving GMOs. The OGTR, in fact, often relies exclusively on industry-funded science in its safety assessments, most of which is unpublished and therefore not peer-reviewed or publicly available.

In the natural sciences a single publication is usually insufficient to convince other scientists of the validity of a claim. Yet, as Professor Jack Heinemann notes “unpublished work from developers are used to make regulatory decisions that affect what we put in our bodies.”⁶⁶

This review should examine the extent to which the OGTR relies on industry funded or produced data in making assessments of safety. Potential legislative changes that reduce this reliance should be examined.

Recommendation 14: Amend the GTA or regulations to ensure that industry data is not the primary or exclusive data upon which regulators rely in making a safety assessment

2. Scope of safety assessment

Safety assessments of GMOs should consider all of the downstream effects associated with the introduction of the GMO. This includes factors such as the dramatic increase in herbicide use associated with the introduction of GM crops and the resulting environmental and human health impacts.⁶⁷

A full range of “omics” molecular profiling analyses should be carried out (genomics, transcriptomics, proteomics, and metabolomics). Profiling of siRNA (gene-silencing RNA) and microRNA (miRNA) molecules should be conducted, to look for intended and unintended changes brought about by the genetic engineering process.⁶⁸

These “omics” profiling tests must be done on the GMO and the isogenic non-GMO grown at same location and time, in order to highlight the presence of potential toxins, allergens, and compositional/nutritional disturbances caused by the GM transformation. There must be no spurious use of non-isogenic controls, as is often done by industry in tests conducted for regulatory purposes.⁶⁹

If a pesticide-expressing crop is being assessed for safety (e.g. a Bt crop), the pesticide product (e.g. Bt toxin) isolated from the GM crop must be assessed for safety, as well as assessing the whole Bt crop. It is not adequate to assess the Bt toxin protein produced by bacteria, which is the current practice of industry in its applications for regulatory authorisation. Bt toxin produced by GM crops may have undergone post-translational modifications giving it a different toxicity profile.

3. Review procedures

The OGTR has not responded with a formal review to any of the peer-reviewed studies showing potential harm associated with GMOs. A formalised process for reviewing new information that raises potential concerns regarding the safety of GMOs is needed. This should include clear criteria for triggering reviews and clear standards of review, including external peer review.

Recommendation 15: Amend the GT regulations to set out clear triggers for review of approvals based on new information. This should include the criteria that will apply to the review and provision for the public to seek review of a review decision.

4. Monitoring

One of the persistent and profound concerns with GMOs are their potential unintended effects. Neither the OGTR or FSANZ have adequate surveillance measures in place to detect any unintended environmental or human health effects associated with the introduction of GMOs.

Recommendation 16: Institute a comprehensive health and environmental monitoring regime paid for by industry and conducted independently.

Recommendation 17: This review should consider the downstream impacts of GMOs. In particular:

- **The extent and implications of herbicide resistance in weeds due to the introduction of GM crops and associated herbicides;**
- **The scale of human exposure to herbicides for which maximum residue levels have increased by factors of between 10 and 15 since the introduction of GM plants;**
- **The likely human impacts associated with exposure to chemicals that have been assessed by the World Health Organisation as a probably carcinogen.**
- **The environmental impacts of such a large increase in the use of such herbicides, on non-target species, including soil microorganisms.**
- **The likely externalised costs associated with these issues.**

Interaction with other legislation

Too often in cases where legislation is the responsibility of multiple agencies, there is 'turfing' – agencies passing responsibility for an issue to another agency which also denies responsibility.

Recommendation 18: The GTA be amended so that the OGTR is ultimately responsible for all aspects of Gene Technology implementation and enforcement even if the agency is not

responsible for the day to day aspects of that implementation. This responsibility must be enforceable by the public.

The recent amendment to the Food Standards Australia New Zealand Act not only weakened the regulation of GM in that Act it ensured that Food Standards Australia New Zealand is now using a weaker and different definition of GMO than the OGTR. This lack of harmonisation should be rectified by ensuring that the definition of GMO (as it is currently written) in the Gene Technology Act is a definition across all other agencies that regulate GMOs.

Recommendation 19: Ensure that the current definition of GMO in the GTA applies across all agencies responsible for GM.

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⁹ Pers comm Gabrielle O'Sullivan, OGTR GTECCC meeting 10/11/16

¹⁰ Site-directed nuclease (SDN) techniques-1: non-homologous end joining repairs DNA cleavage, which can result in random insertions, deletions and substitutions, often of only a few nucleotides.

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¹⁴ Hellebrand, M., Nagy, M., Morsel J-T. (1998). Determination of DNA traces in Rapeseed oil (1998) *European Food Research and Technology*, **206**:237-242

¹⁵ ANZFA DRAFT RISK ANALYSIS REPORT APPLICATION A363 Food produced from glyphosate-tolerant canola line GT73. In the Executive Summary of its Final Risk Analysis Report, ANZFA (as FSANZ was previously known) states "all protein and DNA are removed" from the oil. But in the Final Safety Assessment Report Attachment the level of protein actually found in the refined oil was stated: "Total protein present in refined oil of 1992 field trial of GT73 - 0.29 ppm" – p. 25, <https://www.foodstandards.gov.au/code/applications/documents/A363%20FA.pdf>

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