

24 May 2018

Gene Technology Review
Department of Health
MDP 1060
GPO Box 9848
CANBERRA ACT 2601

Email: gene.technology.review@health.gov.au

Re: National Gene Technology Regulatory Scheme Review Interim Report

Introduction

Grain Trade Australia (GTA) appreciates the opportunity to provide this submission in response to the interim report of the Department of Health's Review of the National Gene Technology Regulatory Scheme.

As indicated in previous submissions, GTA supports the importance of a functioning regulatory system for gene technology and believes that the Office Gene Technology Regulator (OGTR) and the supporting legislation that is in place in Australia delivers an effective and efficient system. As such, any changes should only enhance the scheme that is in place and working.

GTA supports the National Gene Technology Regulatory Scheme (Scheme) and believes that it has been effective in providing certainty and confidence to the industry and community in relation to GM crops. GTA also believes that Australia is seen as a model for other parts of the world in terms of its approach and regulatory outcomes. It is critical for the grains industry that there are effectively functioning regulatory systems in the countries with which it trades.

GTA supports the current scope of the Scheme i.e. application to human health and environment. GTA does not support any extension to economic or trade issues. These are commercial issues and the Australian grains industry's market choice approach has provided an effective mechanism to meet domestic and global market requirements. GTA has recently updated the industry's market choice Framework (*Market Choice Framework with GM Crops 2016*).

Interim report findings

Object (Findings 1 & 2)

GTA agrees that the object of the *Gene Technology Act 2000* remains appropriate and should be maintained. GTA agrees that the Gene technology Agreement (2001) should be maintained but recognises that there remain potential for inconsistencies with state Government actions and potential duplication of risk assessment tasks with other regulatory agencies/schemes.

Definitions (Finding 3)

GTA agrees that definitions in the *Gene Technology Act 2000* and Gene Technology Regulations 2001 have not kept pace with advances in gene technology. GTA supports minor amendments to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene

Technology Regulations (Schedules 1 and 1A) that would give effect to 'Option 4' in the 2016 Technical Review of the Gene Technology Regulations 2001.

Environmental Release of GMOs (Finding 6)

GTA supports the current scope and approach (risk analysis framework and risk assessment and risk management plan undertaken by the OGTR) to regulation of environmental release of GMOs and would be concerned if this finding led to an increased and scientifically unjustified regulatory burden.

Regulatory triggers, risk tiering and streamlining (Findings 8, 9 & 10)

As highlighted in previous submissions to this review, a major challenge for the grain trade is the lack of consistency in regulations regarding gene technology regulation globally. GTA works with the global grain industry to try and achieve global harmonisation in the approach to regulation and encourage adoption of a similar approach across jurisdictions leading to legal certainty as this will provide for the lowest chance of trade disruptions. Alignment and regulatory coherence will assist governments to avoid unnecessarily eroding the value of the innovation and/or driving up costs and complexity in the global food system.

GTA's submission to the 2016 Technical Review of the Gene Technology Regulations 2001 supported Option 4 i.e. to exclude certain new technologies from regulation based on the outcomes they produce. GTA supports the principle that plants developed through new breeding technologies should not be differentially regulated if they are similar to, or indistinguishable from, those that could have been produced through earlier breeding methods and where the risks to the environment or human health posed by products developed using such techniques are comparable to those of earlier (non-regulated by the OGTR) breeding methods.

Again, as highlighted in previous submissions for this review, GTA supports a tiered risk approach. This tiered risk approach will be a combination of process and product based risks and triggers. On this basis, a process-based trigger may not be the most effective entry for the Scheme, and in fact, the current Scheme is somewhat a hybrid approach with mix of process (i.e. trigger for regulation) and product (i.e. trigger for exclusion from the Scheme) based regulation.

GTA supports the principle of seeking opportunities to streamline current regulatory requirements, however, GTA is not in a position to comment on these. GTA members may highlight such opportunities in their individual submissions.

Flexibility (Findings 13 & 14)

GTA agrees that there is an opportunity for increased flexibility within the Scheme to enable it to keep pace with change in technology, appropriately respond to changes in scientific understandings of risk and apply the regulation differently based on relative risks. It is important the Scheme has in place processes to ensure that it keeps pace with technology and innovation and that the level of regulation remains proportionate to the risk.

International coordination (Finding 15)

GTA supports and encourages the Australian Government and Regulators to proactively engage with its global counterparts and to remain engaged with global initiatives.

As indicated in earlier submissions and above, a major challenge for the global grain trade is the lack of consistency in regulations regarding gene technology regulation globally. GTA supports the harmonisation of regulation and encourages Australia to remain involved in international forums on gene technology related issues including Cartagena biosafety protocol, low level presence, regulation of new technologies and other similar initiatives.

As indicated above, GTA works with the International Grain Trade Coalition (IGTC) to try and achieve global harmonisation in the approach to regulating such activities. The main aim of IGTC efforts is to

achieve international alignment, i.e. adoption of a similar approach across jurisdictions leading to legal certainty as this will provide for the lowest chance of trade disruptions. Alignment and regulatory coherence will assist governments to avoid unnecessarily eroding the value of the innovation and/or driving up costs and complexity in the global food system.

GTA has supported Option 4 proposed in the Technical Review of the Gene Technology Regulations as we believe this will provide greater alignment with trading partners and assist in facilitation of trade with minimal disruption.

State moratoria legislation (Findings 17, 18 & 19)

GTA members are involved in growing, handling and marketing GM crops approved for commercial release. The industry has supported a position of market choice and has in place processes and tools across the grain industry supply chain to ensure that choice is enabled for producers, grain handlers and marketers and consumers.

The grains industry has a demonstrated track record in delivering market choice with GM canola. The systems to deliver this are based on proven systems and processes that the industry utilises to meet a range of quality and customer requirements. Thresholds are a common feature of standards in grains and these thresholds are essential in preventing unnecessary disruptions to trade. The existence of practical thresholds for GM and other production systems is vital in allowing different production systems to coexist.

There is overwhelming evidence that the market choice framework for GM canola has been effective in maintaining access to both commodity and non-GM markets and has benefited the industry, economy and community through enabling growers to access productivity improvements through GM technology where appropriate and also enabling ongoing access to markets that wish to purchase non GM product. There is no evidence that commercial production of GM canola has impacted Australia's reputation or other grain/agricultural sectors' access to markets.

The extension of some moratoria legislation beyond marketing purposes such transport bans on GM seed are imposing unnecessary costs on the industry and GTA would contend that these are outside the scope of the authorising policy principle.

Consideration of benefits (Findings 20 & 21)

GTA agrees that consideration of benefits should not be introduced. GTA does not believe that 'benefit' considerations should be part of the Scheme, but rather this should remain focussed on risks posed by gene technology to human health and safety, and to the environment.

GTA agrees that for the economic and health benefits of gene technology to be harnessed now and into the future, the Scheme should not impose unnecessary regulatory burdens.

Strength of Scheme (Finding 26)

Australian Gene Technology Scheme is seen as a strong and robust system and currently has the flexibility to deal with matters requiring accelerated access through mechanisms such as the Emergency Dealing Determinations. GTA does not support any increase in level of regulation in the absence of a demonstrated failure of the existing system.

Funding and cost recovery (Findings 27 & 28)

While this is more an issue for users of the system, as a principal GTA believes that independence of the regulator is very important in providing confidence in the integrity of the system. Any funding arrangement should ensure that trading partners and the public's confidence in the Scheme is maintained.

Communication (Review theme 4: social and ethical issues)

GTA recognises that public understanding and confidence in the Scheme is important and that there is opportunity to undertake more activity in this area. It is also important that communications distinguish

between perceived public misunderstandings of gene technology regulation and the safety of approved GMOs.

It is critical that trading partners, the industry and community have confidence in the rigour and integrity of the Scheme. Confidence requires not only that the Scheme is appropriate and well managed but also that there is compliance with the Scheme.

Public concern regarding the Scheme should be addressed through effective risk communication and information. It is not a basis for extension of the regulations.

In terms of broader understanding by the community of the benefits and risks of GM technology, this is also important as misinformation about the technology may result in benefits of such technologies not being captured. Governments are well placed to provide information about GM technologies and to provide information in relation to the regulatory processes and in relation to safety of approved GMOs.

Thank you for your consideration of this submission.

Regards

A handwritten signature in black ink, appearing to read 'P O Shannassy', with a long horizontal flourish extending to the right.

Pat O'Shannassy
CEO

