

May 24 2018

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

Re: National Gene Technology Regulatory Scheme Review Interim Report

Introduction

The Australian Seed Federation (ASF) welcomes the opportunity to submit comments on the Department of Health's *Open Consultation for the Third Review of the National Gene Technology Scheme*. The ASF is the peak national body representing the interests of Australia's sowing seed industry. The membership of ASF comprises stakeholders from all sectors of the seed supply chain including; plant breeders, seed growers, seed processors and seed marketers, all of whom were consulted in the preparation of this submission.

In Australia, the seed industry is a vital link in the development of crops that are critical to the nation's agricultural productivity, sustainability and food security. The ASF is providing this submission in the interest of developing a nationally and internationally-consistent approach towards the regulation of Plant Breeding Innovation (PBIs) and to highlight current unintended consequences with the current scheme that are impacting ASF members' ability to deliver seed and technology to farmers who want it. In so doing, we hope this review can provide the industry with the necessary certainty to continue creating new plant varieties to provide better quality products for consumers, farmers and the processing value chain. Plant breeding has always responded to society's need for increased crop yields, better tasting varieties and pest and disease resistant crops. Ultimately, plant breeding fosters sustainable farming practices to meet the needs of a growing global population.

The ASF supports the Review's aims to improve and strengthen the National Gene Technology Scheme's (the Scheme) effectiveness whilst ensuring that it is appropriately agile and supports innovation.

Response to Findings

Overarching Findings (Findings 1 & 2)

The ASF agrees that the object of the *Gene Technology Act 2000* remains appropriate and should be maintained. We also agree that the Gene Technology Agreement (2001) should be maintained but believe that its full potential has not been realised to date due to inconsistencies resulting from State Government actions and to duplication of risk assessment tasks with other regulatory agencies/schemes. The sooner these aspects are addressed, the better.

Definitions (Finding 3)

The ASF agrees with the Finding that definitions in the *Gene Technology Act 2000* and Gene Technology Regulations 2001 have not kept pace with advances in gene technology. The ASF has long supported the position of the International Seed Federation that the underlying principle for regulating new breeding techniques should be that plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced



through earlier breeding methods. The genetic variation in a final plant product should not be covered under the scope of existing biotech/GMO regulations for plants if:

1. There is no novel combination of genetic material (i.e., there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or;
2. The final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;
3. The genetic variation is the result of spontaneous or induced mutagenesis.

The ASF would therefore strongly recommend to the Review that it seek to put in place the necessary changes to the Act that would allow the Gene Technology Regulator to implement Option 4 of the Office of the Gene Technology Regulator's Discussion paper on options for regulating new technologies. We would also like to note that the OGTR's Discussion Paper focussed only on gene editing techniques and did not address other new breeding platforms such as cisgenesis and the proprietary Seed Production Technology (SPT). We would encourage the Review to also consider specific exclusion of these techniques for the same reason.

Synthetic Biology (Finding 4)

The ASF agrees that synthetic biology is currently within the scope of the Scheme. The International seed industry has been active in discussions on this issue under the Convention on Biological Diversity and maintains the view that there are no examples of organisms developed using "synthetic biology" that could not be assessed using existing risk assessment and regulatory frameworks.

Environmental Release of GMOs (Finding 6)

ASF 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 Trigger (Finding 8)

As stated previously, the ASF believes that the regulation of plants produced through new breeding techniques should be focussed on the final characteristics of the plant product, and NOT on the breeding process used to produce that variety. Plant varieties derived from conventional breeding methods, such as those that harness spontaneous or induced mutagenesis, can already generate large amounts of genomic variation within an organism and are not subject to pre-market safety assessment. As such, we believe plant varieties derived from similar genetic variation generated using newer plant breeding innovations should not be subject to pre-market regulation simply because the process was different.

We would suggest that organisms should not be covered under the scope of any gene technology regulatory scheme for plants if:

1. There is no novel combination of genetic material (i.e., there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or;
2. The final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;
3. The genetic variation is the result of spontaneous or induced mutagenesis.

This would include implementing Option 4 of the OGTR's Technical Review of the Gene Technology Regulations. This could include retaining the broad definitions of the Scheme and the process-trigger but adding certain exclusions that are both process-based (SDN-1, SDN-2, ODM, cisgenesis used in plants) and



product-based (null segregants) from the scope of regulatory oversight. If there are to be exclusion lists, these should also be updated at regular intervals as technology advances and knowledge is gained about technologies and/or organisms. The Regulator needs to have the flexibility to do this quickly, as recommended in the last Review into the *Gene Technology Act 2000*.

Risk Tiering (Finding 9)

The ASF agrees that there are opportunities for additional risk tiering to be applied within the Scheme and is supportive of the Decision Tree concept submitted by CropLife Australia to Phase 1 of this review. This retains a process-based regulatory trigger and it incorporates process-based and product-based exclusions according to the risks posed by the resulting organism (product) as reference above.

GMO Register (Finding 11)

The ASF agrees that changes could be made to enable the GMO Register to be more effectively utilised as part of the Scheme. In particular, we believe that the Register could be used to address certain circumstances of low level presence (LLP) in breeding programs by listing GM crops that are no longer being commercially produced in Australia. A previously licensed GM crop could be placed on the Register at the point a company decides to surrender its licence, either by the Company or by the Regulator. For proteins that are well characterised in a number of crops, but for which certain crops types may not be commercialised in Australia, the Regulator could also decide to place such traits on the Register for the purpose of addressing LLP situations only. We discuss more about LLP under Findings 13 and 14.

Flexibility (Findings 13 and 14)

The ASF agrees that there is a need for increased flexibility within the Scheme to enable it to keep pace with change in technology, to appropriately respond to changes in scientific understandings of risk, and to be able to regulate 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.

For example, while the current Scheme allows for technical reviews of the Gene Technology Regulations to consider additions to the exclusion lists in Schedules 1 and 1A, this has as not been fully utilised to provide regulatory clarity for “new” breeding technologies. These exclusion lists should be reviewed more regularly. Forum has not proven to be an efficient and effective mechanism for oversight and guidance of the Scheme. To date, we would suggest that the Legislative and Governance Forum on Gene Technology has not proven to be the efficient and effective mechanism necessary for oversight and guidance of the Scheme, and there has not been implementation of recommendations from previous reviews of the Scheme. As such, the Scheme lacks the necessary agility to keep pace with the technologies it regulates.

We would therefore support a mechanism that enabled the Gene Technology Regulator to make determinations or orders on the applicability of regulation to any technological developments, as recommended by the last review of the Gene Technology Act 2000. In this context, the Regulator could perform the activities of the Legislative and Governance Forum on Gene Technology. We also call for the immediate implementation of Option 4 of the recent technical review of the Gene Technology Regulations and its extension to other plant breeding innovations such as cisgenesis, as the current regulatory scheme is severely hindering the progress of innovation in this space.

In addition, we would like to point out that currently under the Scheme, situations of LLP (where a trait approved in another country is detected in Australia) must be dealt with through emergency licences, with a view to complete removal of the unapproved trait. It is the ASF’s position that more flexibility for addressing LLP in seed needs to be introduced into the Scheme. In agriculture, as with all biological



systems, 100 per cent product purity is impossible and as agricultural biotechnology continues to be rapidly adopted around the world and trade in GM grains and seed increases, Australia's current legislation which imposes 'zero tolerance' to LLP will be unsustainable. A national seed LLP policy that incorporates both thresholds based on industry practices and existing varietal purity standards, coupled with the recognition of safety assessments from other countries, will provide both industry and the Regulator with a comprehensive policy that maintains safety standards while at the same time being proactive, transparent and science-based. The use of familiarity – including a history of safe use, availability of data and safety assessments – could be incorporated into such a policy to allow for a proactive approach to specify situations where or if a safety assessment is required, and the GM Register could potentially be used as a mechanism to deliver these decisions.

Market access and international trade (Finding 15)

The ASF agrees there is benefit in the Australian Government, including the Gene Technology Regulator on regulatory matters, continuing to engage with appropriate international fora and ensuring that any relevant international obligations continue to be met. Australia leads the way in global biosafety regulation and can play a strong leadership and capacity building role in this space internationally. The Australian seed industry is able and will continue to meet any international requirements relating to gene technology regulation but will thrive in a global regulatory environment for breeding innovation that is harmonised.

Credibility of Scheme (Finding 16)

The ASF agrees that the operation of the Scheme is credible, and that the Scheme operates with integrity and legitimacy. To maintain this credibility, the Scheme must keep pace with technology and introduce the flexibility to provide for proportionate regulation of risk and to address the presence of discontinued products in Australia and more and more products resulting from plant breeding innovations in international trade.

National consistency of Scheme (Finding 17)

The ASF agrees that national consistency of the Scheme is vital, but believes that this has not yet been achieved. We support the nationally consistent approach to regulation provided by the Intergovernmental Gene Technology Agreement and supports continued efforts to ensure that there is clarity in the regulatory environment, but are still disappointed that we are not still operating in an environment where a product approved for commercialisation in Australia can still not be transported across borders to be made available to Australian farmers when and where they need it.

Recognition of Designated Areas Principles 2003 (Findings 18 and 19)

As stated in our previous responses to this Review, the ASF's position on GM crops is that we support free choice by participants in the food supply chain and consumers in relation to crop biotechnology, provided that choice is based on sound science and respects the right of others to also choose. We are encouraged by how the industry is working together in Australia to ensure that the needs of different market segments continue to be met – be they organic, non-GM or GM. We are not aware of any trade or marketing issues experienced to date since the commercialisation of GM crops.

However, it is the ASF's view that the current restrictions on the transport of GM seed and grain through South Australia (SA) by the SA Government are imposing a logistical constraint on the operations of its members who are involved in this market sector, including significant additional costs being imposed on members who are actively working to supply the seed for sowing market nationally. The South Australian Government maintains a total ban on the transport of GM seed and grain through the State. This ban applies even to those products – including GM herbicide tolerant canola – that have been approved for



legitimate commercial release in Australia by the Gene Technology Regulator and would seem inconsistent with the spirit of the Intergovernmental Agreement on Biotechnology.

This ban is affecting the canola industry's ability to source seed from production areas in Eastern Australia in a timely manner to meet the increasing needs of Western Australian farmers, who have quickly adopted this new technology to help them address significant herbicide resistance issues. These same issues are also affecting SA canola growers. This situation effectively means that GM canola approved for planting in Australia cannot be transported directly by truck across Australia and must be either sent by road around to WA via the Northern Territory, shipped via sea around South Australia, or air freighted. All of this adds time and costs and has led to requested seed not being available for planting. Quality testing of seed has also been affected, with seed companies now having to send GM seed to testing labs further afield for results leading to further delays and increased costs.

We would therefore support the view that the focus of some moratoria legislation extends beyond marketing purposes and believe that restrictions on transport of GMOs are not appropriate and should be removed. The seed industry is developing best practice guidelines for the transport of such products to address these situations.

Consideration of benefits (Findings 20 & 21)

The ASF agrees that consideration of benefits should not be introduced. We believe that the Scheme should remain focussed on the risks posed by gene technology to human health and safety, and to the environment. We also agree 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.

Policy Principles (Findings 22 and 23)

The ASF would be concerned with the Review exploring opportunities for the Legislative Forum to lead a forward work program or provide clarity to the Scheme through the issuing of Policy Principles. As mentioned previously, to date the Forum has not proven to be an efficient and effective mechanism for oversight and guidance of the Scheme and is not able to provide it with the flexibility and agility it needs to keep pace with the technologies it regulates. In addition, the policy principle it has enacted that enables states and territories to enact GM moratoria has resulted in extensions of regulatory oversight above and beyond what was intended, with severe impact on Australian business and farmers.

Regulatory duplication (Finding 25)

The ASF would support work being undertaken to investigate solutions for addressing overlapping regulatory oversight between the Gene Technology Regulator and some product regulators. Such duplication is confusing to smaller businesses and can be cost prohibitive. We would also like to point out that where the Scheme excludes certain technologies from regulation, this must as a minimum be harmonised with any other regulators in Australia, to provide certainty and a clear path to market for plant breeders wanting to use such techniques in their research programs.

Communication (Findings 29 and 30)

The ASF believes that the amount of public communication currently undertaken by the Regulator is adequate. We are not sure what more could be done in relation to the Scheme.

Post-release review mechanisms (Finding 32)

The ASF believes that the current science and risk-based post-release review mechanisms implemented under the Scheme are sufficient, and we would oppose any moves to broaden the current science-based



approach. ASF members are not aware of any safety issues that have resulted from a lack of necessary post-release review mechanisms in over 20 years of GM crop cultivation in the country.

Transparency (Finding 33)

The ASF agrees that a high level of transparency for the Scheme is important, and that such transparency can be achieved through the Gene Technology Regulator continuing to make relevant information publicly available. However, we note that this should not come at the expense of protection of an applicant's intellectual property rights. Strong and effective Intellectual Property protection encourages the further breeding and research required to meet our increasing food, feed, fibre, and fuel needs whilst preserving the planet.

Yours sincerely

Bill Fuller
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Australian Seed Federation