CropLife AUSTRALIA

*Representing **the best** of the plant science industry*

Submission to the 2017 Review of the National Gene Technology Regulatory Scheme

29 September 2017

1 INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both IP patent holding and generic companies that are both Australian and international, and small and large; and advocates for policy positions that deliver whole of industry benefit. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, environmental sustainability and international competitiveness. The plant science industry is worth more than $18 billion a year to the Australian economy and directly and indirectly employs thousands of people across the country. CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 national associations globally.

The *Gene Technology Act 2000* (Cth) ('the Act') as administered by the Gene Technology Regulator, with assistance from the Office of the Gene Technology Regulator (OGTR), is currently working well for the identification and management of risks posed to human health and safety and the environment by live and viable genetically modified organisms (GMOs). However, a *Nationally Consistent Scheme* for the regulation of gene technology as was envisaged by the inter-governmental Gene Technology Agreement in 2001 has never eventuated due to inconsistent state government interventions and duplication of risk assessment tasks with other regulatory agencies and schemes.

It is appropriate at this point in time to assess whether the Act and the National Gene Technology Regulatory Scheme (the Scheme) remain 'fit-for-purpose' some 17 years' post-enactment. The Background Paper to this Review notes that previous reviews in 2005-06 and 2011 focused on the operation of the Scheme and made minor and technical amendments to the Act to make the regulation of gene technology more efficient, effective and clear. The 2017 Review is timely to reassess the policy framework that sits behind the Scheme and to ensure the Scheme and the Act can achieve a better balance between regulating the process involved in creating products of gene technology, and regulating the risks (if any) to human health and safety and the environment associated with the final products.

CropLife's submission to the 2016 Technical Review of the Gene Technology Regulations reflected our member companies' collective concerns about the prospect of pre-market regulation of products developed using new technologies (referred to as plant breeding innovations [PBI] by the plant science industry), based simply on the technique employed during the development of specific traits and not on the characteristics of the final product. CropLife noted that this presents a challenge for the Australian regulatory scheme given it has a 'process'-based trigger, relying on whether a product was created using 'gene technology'. While the Scheme has provided one of the most robust and independent, science-based regulatory systems in the world for established techniques for genetic modification, gene technology has

evolved and the Scheme no longer provides regulatory clarity for the continuum of techniques and applications that exist today.

Genetically modified (GM) crops derived from established techniques of genetic modification have been commercially cultivated since 1996 without unexpected effects on ecosystems or a single documented adverse effect on human or animal health. As predicted by scientists early on, these GM crops have posed no unique or incremental risks different from those posed by crop varieties produced through conventional breeding techniques, including mutagenesis.

The starting point for the 2017 Review of the National Gene Technology Regulatory Scheme must undoubtedly be the implementation of the outstanding agreed recommendations from the 2011 Review. Several of these recommendations remain relevant and their implementation should be the priority for this review to avoid duplicating work that has previously been agreed to by the Commonwealth, States and Territories.

Recommendation 9 should be implemented as a matter of priority as it will go towards ensuring the Scheme can accommodate continued technological development:

> **Recommendation 9:** *"The Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined."*

The commentary associated with this recommendation noted that all governments considered the need for legislation to keep up with and allow for expeditious responses to technological advances. The discussion raised two issues that remain relevant to the 2017 Review:

- "Whether current definitions of what is or is not a GMO under the Act are sufficient to provide clarity around the intended scope of regulatory coverage in light of ongoing technological advances; and
- That the process for introducing legislative amendment to clarify what is and is not regulated under the Act is complex."

These issues and others are explored in greater detail below.

2 RESPONSE TO TERMS OF REFERENCE

CropLife's submission identifies a range of issues that should be considered to improve the National Gene Technology Regulatory Scheme to ensure it continues to be 'fit-for-purpose' in the future. A priority for this Review is to improve the existing risk-based regulation to achieve a better future balance between regulating the process involved in creating products of gene technology, and regulating the risks (if any) to human health and safety and the environment associated with the final products.

2.1 Current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continued technological development

2.1.1 Improving risk-based regulation

The implementation of Recommendation 9 from the 2011 Review could have the effect of giving the Gene Technology Regulator greater discretion to determine what is or is not a GMO under the Act, and make the process for introducing necessary amendments to the Gene Technology Regulations (such as which techniques and organisms are excluded in the Schedules) far simpler.

The 2016 Technical Review of the Gene Technology Regulations focussed on providing regulatory clarity in relation to new technologies, specifically oligo-directed mutagenesis (ODM) and site-directed nuclease (SDN) techniques. A number of submissions, including CropLife's provided detailed scientific rationale in support of Option 4 provided in the Discussion Paper for the review, which in effect excludes the ODM, SDN-1 and SDN-2 categories from the scope of the regulatory scheme. CropLife made detailed scientific argument in its submission to that Review as to why products created using SDN-1, 2 and ODM breeding methods should be treated in the same manner as natural mutations and the products of induced mutagenesis (e.g. by chemicals or irradiation), which are currently excluded from regulation as gene technology by the Schedules to the Gene Technology Regulations 2001.

CropLife, in agreement with many of the other submissions received by the Regulator, considered that Option 4 provided the best long-term approach to accommodate both current and future technological advancements. Option 4 was also considered the most consistent with the original intent of the Scheme and the principle that best practice regulation should be commensurate with risk.

The Discussion Paper noted that one of the cons of Option 4 was that it was beyond the scope of the Review of the Regulations to change the process regulatory trigger of the *Gene Technology Act* to focus on the properties of the final organism. Fortunately, it is within the scope of the current Review of the Scheme to consider how best to improve risk-based regulation.

CropLife recommends that Option 4 could be implemented with only minor amendments to definitions in the *Gene Technology Act* 2000 and the lists of excluded gene technologies (Schedule 1A) and genetically modified organisms (Schedule 1) in the Gene Technology Regulations, provided that technology categories are defined broadly.

Box 1: Proposed amendment to the definition of "gene technology" in the *Gene Technology Act*

gene technology means any technique for the modification of genes or other genetic material, but does not include:

(a) sexual reproduction; OR

(b) homologous recombination; OR

(c) techniques that do not result in the integration of one or more genes in a defined genetic construct into the genome; OR

(d) any other technique specified in the regulations for the purposes of this paragraph.

The inserted text (underlined) in Box 1 above gives effect to Option 4 in that it excludes upfront from regulatory scope the technique categories of ODM, SDN-1 and SDN-2 when used in any organism. It also does not change the regulatory status of organisms that are currently, and have historically been within regulatory scope as originally intended by the Scheme (namely, transgenic organisms). In addition, the newer SDN-3 category of techniques is captured within regulatory scope, as these involve the integration of a gene construct. The term "integration" is intended to include the mechanisms of "insertion", as used in relation to transgenic organisms developed using established recombinant DNA techniques and "copying", "addition" or "incorporation" of sequences with the use of SDN-3.

The proposed amendment to the definition of "gene technology" in Box 1 would capture the application termed "cisgenesis" used in plants within regulatory scope. While cisgenesis was not directly in the scope of the Technical Review of the Regulations, the submissions of CropLife and some of our member companies provided detailed scientific rationale for its use in plants to be excluded from regulation as gene technology. The exclusion of cisgenesis from regulation as gene technology is consistent with CropLife's core position of support for regulation that is commensurate with risk, as plants created by cisgenesis are analogous to those that can be created using conventional plant breeding methods given the transfer of the same genetic material would be possible.

CropLife again proposes in this submission that cisgenesis be considered for exclusion from regulatory scope. This can be achieved through amendment of Schedule 1A of the Gene Technology Regulations, as proposed in Box 2 below.

Box 2: Schedule 1A Techniques that are not gene technology

Item	Description of technique
1	Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
2	Electromagnetic radiation-induced mutagenesis.
3	Particle radiation-induced mutagenesis.
4	Chemical-induced mutagenesis.
5	Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.
6	Protoplast fusion, including fusion of plant protoplasts.
7	Embryo rescue.
8	*In vitro* fertilisation.
9	Zygote implantation.
10	A natural process, if the process does not involve genetically modified material.

Examples

Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

11	Cisgenesis, when used in plants to transfer whole genes from the same or a cross-compatible species.

The inserted text (underlined) in Box 2 above applies to cisgenesis used in plants only, which may be achieved using established recombinant DNA or SDN technologies, and this exclusion is intended to apply irrespective of the technology used.

Null segregants

In the Technical Review of Regulations, the Gene Technology Regulator stated her intention to clarify that null (or negative) segregants are not GMOs and not subject to regulation. CropLife and some of our member company submissions support this initiative, however, proposals to change the Act to achieve this were out of the scope of the technical review. For this Review, CropLife proposes that this clarification can be achieved with the following minor amendment to the definition of “genetically modified organism” in the Act, as proposed in Box 3 below.

Box 3: Proposed amendment to the definition of "genetically modified organism" in the *Gene Technology Act*

genetically modified organism means:

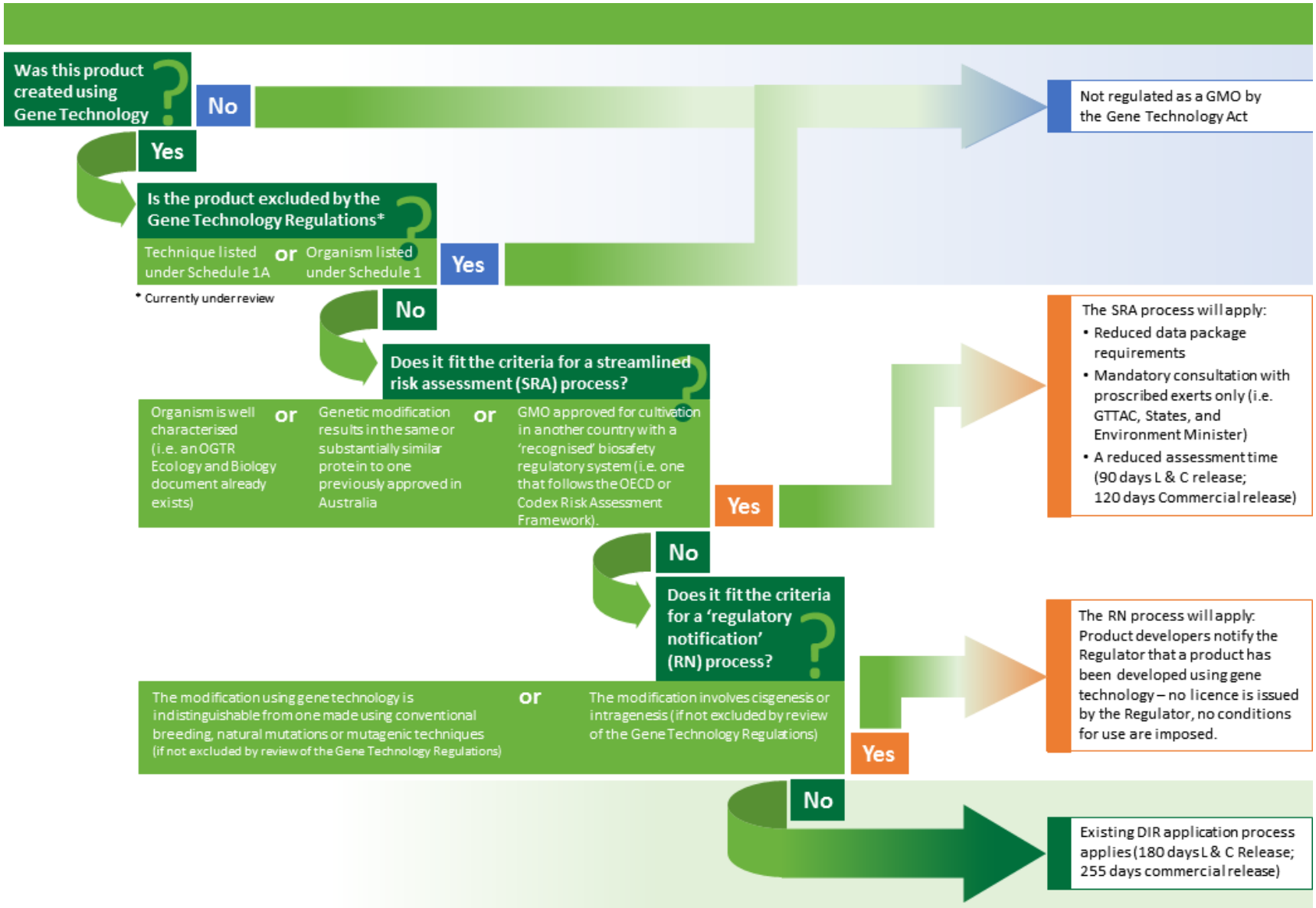
(a) an organism that has been modified by gene technology; or
(b) an organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology; or
(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
(e) an organism that has not inherited genes or other genetic material from an organism (the initial organism) that occurred in the initial organism because of gene technology;
(f) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

The inserted text (underlined) in Box 3 above is intended to exclude null segregants derived from regulated transgenic organisms, as well as organisms developed from techniques such as SDN-1 or SDN-2 where their development has involved an intermediate transgenic step.

CropLife has developed and included in this submission, a Decision Tree (Figure 1) to illustrate what a future Scheme that improves risk based regulation could look like. This approach seeks to tailor the degree of regulatory oversight to identification and management of risks posed by an end-product. We encourage the Independent Panel for the 2017 review of the Scheme to contact us to further discuss the practicality and implementation of this proposal.


Was this product created using Gene Technology
No
Not regulated as a GMO by the Gene Technology Act
Yes
Is the product excluded by the Gene Technology Regulations*
Technique listed under Schedule 1A
or
Organism listed under Schedule 1
Yes
* Currently under review
No
Does it fit the criteria for a streamlined risk assessment (SRA) process?
Organism is well characterised (i.e. an OGTR Ecology and Biology document already exists)
or
Genetic modification results in the same or substantially similar protein to one previously approved in Australia
or
GMO approved for cultivation in another country with a 'recognised' biosafety regulatory system (i.e. one that follows the OECD or Codex Risk Assessment Framework).
Yes
The SRA process will apply:
• Reduced data package requirements
• Mandatory consultation with proscribed exerts only (i.e. GTTAC, States, and Environment Minister)
• A reduced assessment time (90 days L & C release; 120 days Commercial release)
No
Does it fit the criteria for a 'regulatory notification' (RN) process?
The modification using gene technology is indistinguishable from one made using conventional breeding, natural mutations or mutagenic techniques (if not excluded by review of the Gene Technology Regulations)
or
The modification involves cisgenesis or intragenesis (if not excluded by review of the Gene Technology Regulations)
Yes
The RN process will apply: Product developers notify the Regulator that a product has been developed using gene technology – no licence is issued by the Regulator, no conditions for use are imposed.
No
Existing DIR application process applies (180 days L & C Release; 255 days commercial release)

The Decision Tree illustrated in Figure 1 above contains four decision points necessary to determine firstly, if a product has been created using gene technology and therefore, if it is subject to regulatory oversight as a genetically modified organism (GMO).

Decision Point 1: Was the product created using 'gene technology'?

Product developers already consider this question when deciding if a product is captured by the regulatory scheme. CropLife has suggested amendments to the definition of 'gene technology' in Box 1 above for consideration by the reviewers. Implementation of the proposed amendment would give effect to Option 4 from the Technical Review of the Gene Technology Regulations.

Decision Point 2: Is the product excluded by the Gene Technology Regulations?

Product developers also already consider this question when deciding if a product is captured by the regulatory scheme. The response to this question could change depending on the outcome of the Technical Review of the Gene Technology Regulations, which may result in the exclusion of additional techniques in Schedule 1A of the Regulations. CropLife has also suggested amendments to Schedule 1A in Box 2 above for consideration by the reviewers.

Currently, if a product is created using gene technology, and not excluded by the Gene Technology Regulations, and the intention is to release the product into the environment, it must enter the existing regulatory pathway for Dealings Involving an Intentional Release (DIR). This process currently takes 180 business days to obtain a limited and controlled release (i.e. field trial) licence and 255 business days to obtain a commercial release licence.

Decision Points 3 and 4: Does the product fit the new criteria for a 'streamlined risk assessment' or 'regulatory notification' process?

Decision Points 3 and 4 are new decision points proposed by CropLife. The purpose of inserting these decision points into the gene technology regulatory framework is two-fold, firstly, where it has been established or demonstrated that proposed licensed dealings are low risk, the requirements and timeframes for assessment could be substantially reduced. Secondly, to give effect to CropLife's view, as expressed in our submission to the 2016 Review, that plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to or indistinguishable from varieties that could have been produced through conventional breeding methods.

Decision Points 3 and 4 propose two new processes in the regulatory pathway: a 'Streamlined Risk Assessment' and if Option 4 is not adopted by the Review of the Regulations, a 'Regulatory Notification' process.

A Streamlined Risk Assessment (SRA) process would apply when the following criteria are met:

a) The genetically modified organism (GMO) is well characterised (i.e. an OGTR Ecology and Biology document already exists); OR
b) The genetic modification results in the same or a substantially similar protein to one previously approved in Australia; OR

c) The GMO has been approved for cultivation in another country with a 'recognised' biosafety regulatory system (i.e. one that follows the OECD and Codex Risk Assessment Guidelines).

If one or more of those criteria are met, the SRA process features:

a) Reduced data package requirements, with a focus on environmental risk assessment; AND
b) Mandatory consultation only with the states, the Gene Technology Technical Advisory Committee and the Federal Environment Minister; AND
c) A reduced assessment timeframe commensurate with acknowledgement of lower risk (90 days for a Limited and Controlled Release licence and 120 days for a Commercial Release licence).

If Option 4 is not adopted following the Review of the Regulations and specific techniques such as one or more of SDN-1, 2, ODM and cisgenesis are not excluded by Regulation, CropLife proposes a Regulatory Notification (RN) process that could apply to products that meet the following criteria:

a) The modification using gene technology is indistinguishable to one made using conventional breeding, natural mutations or mutagenic techniques; OR
b) The modification involves cisgenesis or intragenesis (if not already excluded pending the outcome of the Review of the Gene Technology Regulations).

If one of those criteria is met, the RN process would involve product developers notifying the Regulator that a product had been developed using gene technology. No licence would be issued by the Regulator for these products, and no conditions for use would be imposed. The RN process may be unnecessary if the amendments previously proposed in Boxes 1, 2 and 3 are preferred by the Reviewers.

2.2 Existing and potential mechanisms to facilitate an agile and effective Scheme which ensures continued protection of health and safety of people and the environment

2.2.1 Duplication of regulation of gene technologies

Unnecessary duplication of regulation is undesirable because it increases the regulatory burden for applicants with no associated benefit.

In 1996, in the absence of other regulation, a policy decision was made to treat biologically active genetically modified (GM) genes/proteins as agricultural chemicals, even though they remained *in planta*. This policy decision allowed the Australian Pesticides and Veterinary Medicines Authority (APVMA) to regulate GM insect-resistant cotton prior to the establishment of the Gene Technology Regulator as the arbiter of dealings involving GMOs in Australia.

Section 14 of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code) establishes that the APVMA is required to register an agricultural chemical product when it is *'satisfied'* that a range of issues have been addressed. Prior to granting registration of an agricultural product, the APVMA must be satisfied that a product will:

- Be effective for all the uses claimed; AND
- Be safe to humans, target and non-target species; AND
- Not pose unacceptable risks to the environment or trade with other nations.

A comparison undertaken by CropLife of the data requirements for assessment of GM products with incorporated pest and/or disease control by the APVMA, the OGTR and Food Standards Australia New Zealand (FSANZ) shows a high level of concordance. Product efficacy and resistance management considerations stand out as differentiators of the APVMA.

CropLife notes that the APVMA have traditionally outsourced risk assessments for some modules to other government entities such as the Office of Chemical Safety (OCS, i.e. toxicology), and the Department of Environment (DoE, i.e. environmental risk).

Outsourcing of risk assessments to other government agencies has led to significant time delays in the evaluation of some applications, with issues having included, for example:

- Disagreement between agency assessments (i.e. OGTR and DoE)
- Knock-back in the assessment of modules due to a lack of relevant expertise.

Section 6 of the Code provides opportunities for the APVMA to accept the risk assessments of the OGTR and FSANZ as part of their assessment. Further, the Code allows for certain products to be classified partially or completely exempt from APVMA regulation.

Acceptance by the APVMA of OGTR and FSANZ risk assessments, or the removal of APVMA regulatory responsibility for GM products with incorporated pest and/or disease control would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, business and community organisations.

2.2.2 Managing incidents of Low Level Presence

Low level presence (LLP) refers to the unintended presence, at low levels, of minute amounts of GM plant material that has been approved in at least one country but not necessarily in the importing country.

Global approvals and acceptance for GM crops are varied. Even between countries with well-established regulatory systems for gene technology, approval timelines and duration of approvals may differ. These differences can lead to approvals among key trading countries occurring at different times, with potentially unnecessary negative impacts on trade.

CropLife supports global adoption of science-based risk assessment approaches to LLP policy to avoid unnecessary economic costs (caused by, for example, recall of grain shipments due to co-mingling of GM grains that may be unapproved in the destination jurisdiction) and improve consumer confidence in our food supply chain and regulatory framework.

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. The Australian Government needs to examine the impact of its current legislation in relation to LLP and develop specific policies to recognise its trading partners' systems for risk assessment and management, particularly in relation to import of GM-derived plant materials (grain or seed).

Enhanced communication, data sharing and recognition of regulatory equivalence between and among global regulators could minimise the differences in approach and timing of approval, and reduce the time required to conduct risk assessments and make management decisions in countries where LLP situations may occur.

CropLife encourages the Departments of Agriculture and Water Resources, Health, Foreign Affairs and Trade, together with the regulatory agencies FSANZ and the OGTR to coordinate and articulate a comprehensive and systematic LLP assessment and management process to reduce the trade impacts of instances where LLP may occur. CropLife supports LLP policies that are proportionate to risk to provide continued food, human health and environmental safety for consumers, farmers, processors and grain handlers.

CropLife notes that Inadvertent Dealing licenses are one mechanism by which the Regulator can deal retrospectively with incidents of LLP. Inadvertent dealing licenses, however, currently only allow for the 'disposal' of a GMO. The agreed **Recommendation 10** from the 2011 Review of the Act called for the Act to be amended so that the Regulator can authorise other appropriate dealings, such as storing and testing (that relate to disposal of inadvertently obtained GMOs). CropLife supports the permitted dealing options for the Regulator under an inadvertent dealing licence being broadened beyond solely disposal, to include testing, storing, use in the course of manufacture, import and transport.

CropLife supports the Australian Government's continued active participation in coordinated discussions related to LLP and global trade efforts, including the Global LLP Initiative.

2.3 The appropriate legislative arrangements to meet the needs of the Scheme now and into the future, including the Gene Technology Agreement

2.3.1 Lack of a nationally consistent regulatory scheme for gene technology

The *Gene Technology Act 2000* (Cth) was intended to establish a national system of regulating GMOs. Despite this intention, most states implemented legislation to address 'marketing concerns' that are neither consistent nor transparent. This unclear path to market was well demonstrated in 2003 when the Gene Technology Regulator approved GM canola for commercial release and all the canola growing states immediately implemented politically motivated moratoria on commercial cultivation of this crop. This led to years of delays, which reduced the management options for Australian farmers and created real uncertainty about the future of GM crops in Australia.

The map below (Figure 2) illustrates the fragmented nature of the National Regulatory Scheme for Gene Technology.

Figure 2: *Current regulatory position of each State and Territory on GM crops.* Source: Licensed from the Agricultural Biotechnology Council of Australia (ABCA) under a Creative Commons Attribution 3.0 Australia.

GM crops are intensively studied and rigorously regulated in Australia. All regulation should be commensurate with the associated risk, cost and benefit to the community. CropLife supports the continued use of science-based risk assessment as the basis for sensible decision making. It is a key principle of good governance that governments should only intervene in a market where there is demonstrated market failure. State government moratoria on commercial production of GM crops have, however, never identified any such failings.

In 2005, the then Australian Bureau of Agricultural Resource Economics (ABARE) reported that Australia's canola growers were suffering an economic loss because of the state moratoria on the commercial cultivation of GM canola. The report concluded that if the moratoria were to continue, it could result in a loss of $3 billion, in net present value terms, in the period to 2015[1].

A more recent ABARE report in 2008 indicated that the estimated economic benefit to Western Australia from adopting GM canola from 2008-09 for the following ten years would be $180 million in 2006-07 dollars. Over the same period, the benefit to New South Wales farmers (excluding those in the Murray Catchment Area) was estimated to be $273 million and South Australian farmers would receive a benefit of $115 million.

New South Wales, Victoria and Western Australia now allow the commercial production of GM canola; however, this was only allowed after at least a five year delay following federal regulatory approval. It is not clear if such a delay will be repeated if future GM crops are introduced in Australia. Several states still have legislative bans on GM technology, maintaining vague 'market considerations' legislation, even in states where GM canola is now commercially produced. CropLife notes that the New South Wales Government announced on 1 June 2011 that it would be extending its *Gene Technology (GM Crops Moratorium) Act* until 2021, 25 years after GM cotton was first commercially grown in that state.

South Australia introduced the *Genetically Modified Crops Management Act 2004* (SA) to ensure that the cultivation of GM crops was regulated in that state. On 8 February 2008, against the advice of its own scientific advisory committee, the South Australian Government decided to extend its moratorium on growing GM canola in South Australia beyond the end of April 2008 when the regulations were due to expire. The South Australian Government has even gone beyond marketing concerns and banned the transport through their state of sealed bags containing GM seed. This intervention means there is no clear path to market for the developers of GM crops in South Australia, even when licence applicants have satisfied the requirements of the Commonwealth *Gene Technology Act 2000*. In 2015, the *Adelaide Advertiser* reported that South Australian Agriculture Minister, the Hon Leon Bignell MP, admitted that the South Australian State Government did not have solid economic data to support its decision to maintain the South Australian GM moratorium[2].

1 Apted S., McDonald D., Rodgers H., 2005, *'Transgenic Crops: Welfare implications for Australia'* Australian Commodities, vol. 12, no. 3

2 Adelaide Advertiser, 24 July 2015.

Independent market analysis by Mecardo in 2016 and 2017 showed there is little evidence to determine that South Australia has achieved a premium for its non-GM canola crop due to the moratorium on GM technology. Comparing the difference between non-GM canola in Adelaide (SA) and Kwinana (WA) demonstrated a clear premium for non-GM in Kwinana throughout the entire season. There is even evidence of GM canola in Kwinana achieving a premium over Adelaide non-GM.[3]

In January 2014, the Tasmanian Government also extended its moratorium on GM crops in direct contradiction to two consultants' reports commissioned by the Government on the issue of market benefit from GM-free status[4,5]. With both reports concluding there was little to no indication of a price premium generated by a GM free status, the decision was clearly political and not based on actual scientific and economic evidence[6]. Without access to the latest technologies, Tasmanian farmers will miss out on the environmental and economic benefits GM crops are already bringing to mainland states and farmers across the globe. The Government's own commissioned report states that over the past decade, Tasmania's agricultural sector has suffered a $40 million net farm-gate loss due to this moratorium[7]. The situation in Tasmania is a prime example of how important decisions that affect the competitive future of an entire sector, with far-reaching implications for the environment and the state economy, should not be made on political and ideological grounds, but rather that on data and facts.

Recommendations from both the 2006 and 2011 reviews of the Act have called on all jurisdictions to reconfirm their commitment to a national regulatory scheme for gene technology.

The failure to implement a consistent national regulatory scheme has created crippling uncertainty in the agricultural biotechnology industry in Australia and completely undermined the effective regulation of GM crops. Both of these issues need to be addressed if Australia is to continue to have a competitive and productive food industry with safe and affordable food choices available to everyone.

The Australian Government should recognise that evidence to date has demonstrated that GM crops do not pose any risks to human health and the environment that cannot be identified and managed, and consequently the state and territory moratoria on these crops is anti-competitive and in no way commensurate with the risk.

The Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture in November 2016 recommended that "the New South Wales, South Australian, Tasmanian and ACT Governments should remove their moratoria on GM crops. All states and

3 Whitelaw A (2016) *'Is the GM ban in South Australia providing a premium?'.* Mercado Expert Market Analysis: 25 July 2016; and Whitelaw A (2017) *'Controversial canola'.* Mercado Expert Analysis: May 25 2017.

4 FreshLogic 2013, An attitudinal assessment of key domestic market gatekeepers to gauge perception of and attitudes towards Tasmania, GM crops and food grown in areas that allow the cultivation of GM food and non-food crops, Hawthorn VIC.

5 Macquarie Franklin 2012, Market Advantage of Tasmania's GMO-free Status, Devonport TAS.

6 http://dpipwe.tas.gov.au/Documents/Final%20Report_v.final_16-12-13.pdf

7 Macquarie Franklin, Op. Cit.

territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs by 2018".[8] The state moratoria on GM crops were also identified in the March 2015 Harper *Competition Policy Review* as a significant example of a regulatory restriction on competition[9].

2.3.2 Repeal of s21(1)(aa) of the *Gene Technology Act 2000*

As noted in the previous section, the decision to regulate GM crops at a state level completely undermines the National Regulatory Scheme for Gene Technology. This circumvention of the national scheme is facilitated by section 21(1)(aa) of the *Gene Technology Act 2000,* which states that:

> The Ministerial Council may issue policy principles in relation to the following:
>
> recognising areas, if any, designated under State law, for the purpose of preserving the identity of one or both of the following
>
> (i) GM crops;
> (ii) Non-GM crops;
>
> for marketing purposes.

Section 21(1)(aa) facilitated the making of the Gene Technology (Recognition of Designated Areas) Principle 2003 by the then Gene Technology Ministerial Council on 31 July 2003.

The making of this policy principle gave the states and territories the power to recognise areas (if any) designated under a State law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

Western Australia, South Australia, Tasmania, Victoria, New South Wales and the ACT immediately used this policy principle to legislate for moratoria on the commercial cultivation of GMOs, leading to the situation described at length previously.

Section 21(1)(aa) is a costly disincentive for private investment in Australian agriculture. It has been demonstrated to be unnecessary for the purpose of preserving the identity of GM and non-GM crops, and it removes farmer choice. **CropLife strongly recommends** the repeal of s21(1)(aa) in the Commonwealth *Gene Technology Act 2000*, the repeal of the corresponding Section in State and Territory Acts, and the immediate disallowance by the responsible Minister of the Gene Technology (Recognition of Designated Areas) Principle 2003.

8 Productivity Commission 2016, Regulation of Australian Agriculture, Report no. 79, Canberra.

9 Harper I, Anderson P, McCluskey S and O'Bryan M 2015, The Australian Government Competition Policy Review, pp116.

2.3.3 Repeal of Section 54 – Person may request copies of certain documents

The object of s54 of the Act is to provide anyone with the ability to request a copy of the non-confidential commercial information (CCI) parts of an application, or risk assessment or a risk management plan. Regulatory transparency is crucially important and can help support public acceptance of plant biotechnology products, however, s54 of the Act is entirely duplicative and unnecessary. It is essential to maintain a balance between transparency and protecting regulatory data from misuse, thereby protecting the data owner's rights. CropLife is supportive of public access to regulatory information, however, we recommend this section be repealed.

The documents described under this section can already be requested under the Commonwealth *Freedom of Information Act 1982* (FOI Act). The FOI Act is intended to 'cover the field' regarding access to information held by Australian Government agencies. Section 54 duplicates some of the powers under the FOI Act, but provides only some of the protections. It obfuscates the requirements, conditions, exemptions and procedures of the FOI Act.

The OGTR is already required to maintain an FOI disclosure log, which is a public record of if/when and what documents have been released under the FOI Act. There is, however, no requirement for the Regulator to maintain a public record of documents released under s54, hence voiding the transparency provided by the FOI disclosure logs maintained by the OGTR. This facilitates the repetitive use of limited OGTR resources in dealing with additional or further requests under s54 for the same information. If the documents were released via the FOI disclosure logs, any person would be able to access the documents online without diverting further OGTR resources away from core business.

The FOI Act provides for consultation with affected third-parties to ensure all appropriate information is protected or redacted for CCI and privacy, whereas s54 lacks this third-party review protection. The FOI Act also provides for conditional exemptions for personal privacy, business, research or economic reasons, amongst others, all of which are missing from the s54 provision. Most importantly, the FOI Act has established review and referral procedures and oversight from the Office of the Australian Information Commissioner that is not available under s54.

2.3.4 Clarifying the approval status of outcrosses to closely related species

When undertaking a risk assessment for a GM event, the OGTR assesses the risk of outcrossing to sexually compatible species. The OGTR acknowledges in the Risk Assessment and Risk Management Plan for certain crops, e.g. canola, that hybridisation can and does occur, albeit at very low frequencies. CropLife proposes that for those species for which a Biology and Ecology document exists, any hybrid resulting from an outcross between a GM event and a sexually compatible species also be covered under a commercial licence issued for said GM event. The genetic modification will only give an advantage to a GM hybrid in managed environments, where selective measures are implemented. For example, where a selective herbicide is used.

GM plants with tolerance to specific herbicides can easily be controlled by alternative herbicides or by mechanical cultivation and pose no greater risk to the environment than volunteers of the commercial GM event.

Alternatively, CropLife would **support** a FSANZ-like system whereby when the OGTR approves a GM event, any plant 'line' bred conventionally that inherits that GM event is also covered as a dealing under the licence.

The Australia New Zealand Food Standards Code Schedule 26 defines 'line' and 'transformation event' as follows:

> ***line*** means:
>
> (a) a plant, the genetic material of which includes a transformation event or events; or
> (b) any plant, descended from the plant referred to in paragraph (a), that is the result of conventional breeding of that plant with:
> (i) any other plant that does not contain a transformation event or events; or
> (ii) any other plant that contains a transformation event or events, whether expressed as a line or event, that is listed in the table to section S26—3;
> (iii) but shall not be taken to mean any plant derived solely as a result of conventional breeding.
>
> ***transformation event*** means a unique genetic modification arising from the use of gene technology.

This could potentially be implemented by the existing **s40(4)** of the *Gene Technology Act* that permits a person to apply for a licence for dealings with "a specified class of GMOs". To CropLife's knowledge, the interpretation of what constitutes a 'specified class of GMOs' has never been tested. This is a concept worth exploring further by the Review Panel.

2.3.5 GMO Register, discontinued products and patent expiry

As discussed previously in this submission, there is the opportunity for the Australian Government to identify applications of gene technology where there is negligible risk to human health and safety and the environment and streamline the regulation of these applications accordingly. One way to achieve this is to increase the list of well characterised and understood GM crops that are listed on the GMO Register. Currently, the only GMOs that are listed on the Register are the different varieties of GM carnations that have been developed by Florigene.

2.3.5.1 Discontinued products

The Register could also be used to address LLP concerns by listing GM crops that are no longer being commercially produced in Australia (i.e. discontinued products). A previously licensed GM crop could be placed on the Register at the point a company decides to surrender its licence. This would help to address reporting implications if the licence for such crops is surrendered because the crop has been discontinued by the original licence holder.

2.3.5.2 Patent expiry

Currently, the licence holder for a GMO is responsible for reporting on several aspects of the risk management plan and is also responsible for providing annual reports to the OGTR. As these crops become generic (i.e. the patents expire) the number of providers could potentially increase dramatically. When this happens, it will be impossible for one company to provide reports on all the uses of that crop.

CropLife **recommends** that there needs to be a specific requirement that a further licence needs to be obtained if someone other than the original licence-holder wants to 'deal' (within the definition the Act) with a GM crop once it goes off-patent. Going off-patent does not necessarily mean risk is completely reduced to a GMO Register-type level, and even if it is reduced, the reporting of volumes produced will still be important to meet international reporting obligations (i.e. OECD).

To summarise, if the original licence-holder decides to discontinue the sale of a licenced GMO, then the GMO Register should be used to address the low level presence of the GMO in the environment. If a third party wants to then sell the GMO (for example following patent expiry), it should have to apply for a new commercial release licence in order to do so.

2.3.6 Data Protection

A major disincentive to investment in developing agricultural biotechnology tools is that data that is generated for assessment by the OGTR is not protected in the same way as regulatory data that is submitted to the APVMA. Until recently, this has not been of huge consequence because the GM traits were protected by a patent on the technology. However, the first patents on GM crops are expiring shortly.

There is potential to now combine GM traits that are out of patent in crops. The regulatory costs of doing this are large and there is a real possibility that competitors will be able to utilise the approval of non-patented traits without having to bear the development and regulatory costs. CropLife believes that the Government should consider introducing data protection provisions for regulatory data that is submitted to regulators. This would prevent free-riding as competitors would not have the advantage of having a free-ride on the investment made by the originating company. Free-riders are considered poor economic policy because they discourage private investment by reducing the competitive advantage that is given to the company that originally invests in the technology. This reduces research that is necessary to bring about new innovative products that are necessary to meet new challenges and support competitiveness.

CropLife believes that data that is submitted for regulatory purposes should be protected for a minimum of ten years from unauthorised use from competitors, commensurate with APVMA data protection, and as was agreed to by the Australian Government during the (now defunct) Trans Pacific Partnership negotiations. The company that generates the data can choose to sell this data to competitors who wish to use it, or alternatively the competitor may choose to generate its own data for regulatory purposes.

2.3.7 Strict Liability, Mandatory Insurance and Compensation

The 2005-06 Statutory Review of the *Gene Technology Act 2000* and Gene Technology Agreement considered issues raised in submissions relating to strict liability, mandatory insurance and compensation under the Act for any damage caused by GMOs. The Independent Panel that led this review, systemically explained why such matters were not relevant for inclusion in the Act. A summary of the key findings of the Independent Review Panel follows.

Strict liability for 'contamination'

In considering this issue, the Independent Panel noted that:

> "there is no other product in Australia which has attracted a strict liability presumption under the common law. In the past, and also in overseas jurisdictions, courts have imposed a strict liability regime in relation to 'superhazardous goods'. Given the object of the Act is to manage risks to human health and safety and the environment, it is contradictory to categorise any GMO assessed by the Regulator and licensed for intentional release as a superhazardous good."[10]

On balance, the Independent Panel concluded that a strict liability regime should not be introduced into the Act. CropLife supports the findings of the Independent Panel and recommends to the 2017 Reviewers that Strict Liability is not an issue that requires re-visiting in the current Review as the common law of torts continues to provide effective remedies for persons claiming to have incurred damage from GMOs.

Compensation fund

In 2006, the Independent Panel concluded that:

> "the need for a compensation scheme rested on the presumption that the common law and consumer protection legislation would not prove adequate for dealing with losses…"
>
> "Having considered these issues as well as the operation of the common law and consumer protection legislation in Australia, the Review concluded that a mandatory compensation scheme such as the Danish scheme should not be introduced."[11]

CropLife supports the 2006 findings of the Independent Panel and recommends to the 2017 Reviewers that a Compensation Fund is not an issue that requires re-visiting in the current Review as the common law and consumer protection legislation continue to provide adequate protection. There have been no incidences or situations since the Independent Panel's last assessment of this matter that would justify a change in this position.

10 *Statutory Review of the Gene Technology Act and the Gene Technology Agreement (2006), Commonwealth of Australia, p39.*

11 *Ibid., p41.*

Mandatory Insurance for GMOs

The 2006 Review concluded that:

> "[In Australia] there are no products covered by statutory insurance requirements."
>
> "The Review sought comment from the Insurance Council of Australia (ICA) and noted that the ICA was not in favour of imposing mandatory insurance because of practical limitations."
>
> "On balance, the Review concluded that mandatory product insurance for GMOS should not be required."[12]

CropLife supports the conclusion of the Independent Panel in 2006, and **recommends** to the 2017 Reviewers that Mandatory Insurance for GMOs is not an issue that requires re-visiting in the current review as the Regulator has existing power under sub-section 62(3) of the Act to impose licence conditions for the release of GMOs into the environment that may:

> "include conditions requiring the licence holder to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing."

In the 17 years the Act has been in operation, no Regulator has found it necessary to impose any conditions of this sort on a licence holder.

2.4 Funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the scheme

2.4.1 Cost recovery

CropLife supports regulatory cost recovery where it is justifiable, appropriate and proportionate to undertaking core business, and not used to subsidise a regulator's non-cost recovered budget shortfalls.

Unfortunately, all too often we have seen attempts by regulatory agencies to use regulatory cost recovery to balance budgets or make applicants pay for work not related to the regulatory risk assessment of a product.

For example, in June 2012 (and again in December 2016), Food Standards Australia New Zealand (FSANZ) released an industry consultation paper indicating they intended to increase their existing cost recovery fee for assessment of applications by an average of 57 per cent (a cost increase that would have amounted to twenty-five times inflation). Such an exorbitant and unprecedented increase, should it have proceeded, would have had an immediate negative effect on the competitiveness and productivity of Australia's food sector. This proposal would

[12] *Ibid., p42.*

have made the regulatory cost in Australia, on a per capita basis, over five times more expensive than any other country in the world to seek regulatory approval for a GM food or food ingredient.

On both occasions FSANZ had not considered the serious and significant impact that such increases in regulatory cost recovery fees would have had on both private and public sector applicants and the concomitant significant disincentive to innovation.

As a further example, in the 2013 Budget, the former government announced the assessment and development of a cost recovery model for services provided by the Office of the Gene Technology Regulator (OGTR). On behalf of the sector, CropLife provided very clear and detailed feedback to the consultants undertaking the process outlining very serious concerns for significant negative impact on the plant science industry, public research and development, Australian agriculture and the operations of the OGTR itself.

Australia is already one of the most expensive markets in the world to bring a regulated GM crop product to market. The plant biotechnology industry is already subject to regulatory cost recovery via FSANZ, and by the Australian Pesticides and Veterinary Medicines Authority (APVMA) (if there is an agricultural chemical registration required). As outlined previously in this submission, there is significant regulatory duplication for certain gene technology products between the OGTR and the APVMA. To avoid 'double charging' this overlap would need to be removed. If the OGTR were to also adopt cost-recovery mechanisms, a similar regulatory overlap between OGTR and FSANZ would need to be very closely examined to ensure double charging of applicants did not occur.

The cost of establishing, managing and signing-off on large scale, multi-year, multi-jurisdiction field trials to generate data for the OGTR is a significant cost already borne by the applicant. The cost of managing an Institutional Biosafety Committee is also already a significant cost borne by the applicant. The regulated gene technology sector in Australia remains a fledgling industry, with a very limited number of companies in the commercial agricultural biotechnology market. A user pays model would only increase inefficiencies as the bulk of the gene technology research carried out is within Government funded research and teaching institutions so would only result in a cost shifting exercise.

Other cost recovery schemes entitle the applicant, once successful, to access the market. Due to ongoing state moratoria (discussed previously) on commercial GM products, this is not the case for products approved by the OGTR, where a successful application can still be denied commercialisation by state governments. It is important to note that imposing such costs on registrants of the system simply imposes additional costs on end users and (for agricultural applications) on the farm gate.

Greater government resources (both monetary and human capital) being made available to the OGTR to undertake regional regulatory outreach and training activities would be strongly supported by CropLife.

3 CONCLUSION

Australia's *National Regulatory Scheme for Gene Technology* is efficient, effective, robust and most importantly science-based. It is, however, showing its age, technology has advanced and there are aspects of the *Gene Technology Act 2000* and the Gene Technology Regulations 2001 that are no longer fit-for-purpose and require revision.

This Review is timely to reassess the policy framework that sits behind the National Gene Technology Regulatory Scheme, and to ensure the Scheme, and the Act, can improve the existing risk-based regulation to achieve a better future balance between regulating the process involved in creating products of gene technology, and regulating the risks (if any) to human health and safety and the environment associated with the final products.

The continuing moratoria on commercial production of GM crops in some Australian states and territories also serve as reminder that a truly national scheme for regulation of gene technology has never been fully realised.

Up to 18 million farmers in 26 countries planted over 457 million acres of GM crops in 2016, contributing to food security, sustainability and mitigating the effects of a changing climate by **increasing crop productivity** (US$168 billion in farm income gains 1996-2015); **conserving biodiversity** (saved 174 million hectares of land from cultivation 1996-2015); **reducing CO_2 emissions** (26.7 billion kgs CO_2 saved in 2015, equivalent to removing 12 million cars off the road for one year) and **helping alleviate poverty and hunger** (GM crops benefited 18 million farmers and their families totalling >65 million people in 2015).[13]

Crops developed using gene technology (regardless of the technique used to develop them) will continue to deliver agronomic, environmental and socio-economic benefits to farmers and consumers globally in the years to come. Australia's gene technology regulatory system is already recognised as one of the best in the world and with some structural adjustments it can remain a global leader into the future.

By implementing the specific recommendations made by CropLife in this submission along with the outstanding agreed recommendations from the 2011 Review, the Government would effectively and successfully improve the National Gene Technology Regulatory Scheme, ensuring it is fit-for-purpose, flexible enough to deal with oversight of new technologies, and continues to provide a science-based regulatory system for the Australian community while allowing access to gene technology innovations by Australia's farming sector.

[13] ISAAA (2016), *'Global Status of Commercialized Biotech/GM Crops: 2016'*. ISAAA Brief No. 52. ISAAA: Ithaca, NY.