CropLife Australia

April 2021

Critical Technologies Discussion Paper: Agriculture

1. INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and plant 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 patent holding and generic Australian and international companies and accordingly, CropLife advocates for policy positions that deliver whole of industry benefit. Our focus is on an Australian agricultural sector that is internationally competitive through globally leading productivity and sustainability achieved through access to the technological innovations of the plant science sector.

The plant science industry provides products to protect crops against pests, weeds and diseases, key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $20 billion annually to the Australian economy and directly employs thousands of people across the country.[1] Meeting the challenges presented by sustainably increasing food production for growing global demand will require science-based policies that support all farming production systems and the research, development and application of critical technologies. This includes chemistry and biotechnology, the opportunities of which extend far beyond the agriculture sector with applications in medicine, environmental management and industrial processing.

Recent crises, including the COVID-19 pandemic, have not only highlighted the value of technological advances, such as those that facilitated the rapid development and public access to several vaccines, but the importance of the regulatory and political environment being prepared, responsive and resilient under these circumstances. The ongoing pandemic is a prime example of the urgent and continuous need for exploration and development of agricultural innovations via both conventional systems and modern approaches.

The global pandemic caused the single greatest disruption to global food supply in generations. Throughout, the Australian agriculture sector has delivered continuity in supply of safe and nutritious food, feed and fibre to domestic and global markets, while managing the challenges associated with access of critical farm inputs, supply chain services, an agricultural workforce and border restrictions. The safe and effective technologies of crop protection products and biotechnology innovations have an increasing role in meeting and mitigating food supply challenges as the impact on global economies endures and provides an opportunity for Australian agriculture to leverage these opportunities.

[1] Deloitte Access Economics (2018). Economic activity attributable to crop protection products

Substantial regulatory barriers continue to impede investment in research and development and subsequently, the ability to commercialise critical processes and products. This limits access to and application of these advances, a loss for the Australian agriculture sector and broader society. Appropriate regulations will promote the growth of new industries across agriculture, medicine and the environment, contributions to leading global regulatory standard and the facilitation of production and export of critical technologies and their products, as well as build investor, industry and community confidence.

To harness the opportunities presented by technological innovation in agriculture, it is imperative the regulatory environment is conducive to innovation and growth. To achieve this, CropLife recommends:

1. Strengthening the regulatory environment by removing identified barriers to innovation and growth of the agricultural sector
    a. Improve access to crop protection for minor uses and specialty crops
    b. Impose acceptable timelines for review of applications by the Therapeutic Goods Administration for scheduling of chemicals
    c. Implement the recommendations from the Department of Health's Third Review of the National Gene Technology Scheme
    d. Introduce voluntary labelling requirements for approved GM crops
    e. Extend the existing patent period for agricultural chemicals and veterinary medicines.
2. Improve the efficiency and effectiveness of the globally respected, world-class Australian Pesticides and Veterinary Medicines Authority (APVMA)
    a. Complete the independent review of the agvet chemical regulatory framework and ensure sufficient funding for implementing appropriate and industry supported recommendations
    b. Replace the outdated APVMA fee and levy model with a cost recovery regime that is fit for purpose in today's dynamic environment and keeps downward pressure on costs, encourages and supports improved efficiencies, and incentivises innovation being brought into the Australian market
    c. Fund the public benefit functions of the APVMA to demonstrate both the independence of the Regulator and not unfairly impose costs onto the farming sector, noting that other regulators are provided with such funding.
3. Fund communications campaigns to counter the disruptive misinformation regarding agricultural biotechnology, as well as chemical and biological crop protection products.

These recommendations are further reinforced in CropLife's recent submissions to the following consultations:

- The Review of the National Gene Technology Regulatory Scheme – Phase 1 (*Refer Attachment A)*
- Modernising and Future-proofing the National Gene Technology Scheme (*Refer Attachment B)*
- The 2021-22 Pre-Budget; and
- The National Agricultural Workforce Strategy.

2. CRITICAL TECHNOLOGIES

Australian farmers produce almost 93 per cent of Australia's daily domestic food supply[2] with each farmer producing enough food to feed 600 people, 150 at home and 450 overseas. To continue to combat the threat of food and nutritional insecurity and the impacts of climate change and increasing production costs, while remaining internationally competitive, farmers must be able to adopt the latest safe and proven agricultural technologies and innovations. This includes access to agricultural biotechnology innovations, as well as biological and chemical crop protection products. Crop protection and biotechnology solutions can assist farmers in producing high yields with fewer natural resources by reducing water consumption, increasing nutrient uptake and reducing reliance on any single input, practice, or production tool.

CropLife submits that a truly productive, competitive and sustainable agricultural industry in Australia can only be achieved with access to innovations such as those the plant science sector delivers for Australian farmers. Chemical crop protection products and crop biotechnologies are crucial to modern farming. It is essential that government and industry work to reduce regulation that is not commensurate with risk. Creating nationally harmonised regulations and legislation will give Australian farmers timely access to the latest innovative tools in plant science. This will support Australian farmers' global competitiveness and secure a safe and nutritious food supply for both Australia and the rest of the world.

It is important that when considering technologies critical to the agriculture sector and the broader Australian economy, existing technologies – including those with cross-sectoral application prospects – are not overlooked but are supported in progression simultaneous with novel approaches.

a. Agvet Chemicals

Crop protection products are crucial to modern agronomic land and pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among target pests, diminishing the efficacy of chemical options. The economic impact of weeds alone is estimated to be in excess of $4.8 billion each year, or $13 million per day.[3]

Pesticides also play a significant role in protecting Australia's rich biodiversity. In 2006, the then NSW Department of Environment and Conservation listed weeds and pests as second only to habitat loss as a cause of biodiversity decline[4] and cautioned that weeds presented

[2] National Farmers Federation (2018). Food, Fibre and Forestry facts. A Summary of Australia's Agriculture Sector.

[3] *https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf*

[4] https://researchprofiles.canberra.edu.au/en/publications/the-impact-of-weeds-on-threatened-biodiversity-in-new-south-wales

the greatest threat to our National Parks.[5] In 2020, the Invasive Species Council's report 'Glyphosate: A Chemical to Understand' highlighted that herbicides offer the only really effective option for removing invasive weeds from Australia's bushland reserves and that, without them, most of the remaining indigenous vegetation in Australia would decline in both quantity and quality.[6]

It is imperative the Australian Government maintain the primacy of science and facts in regulatory and policy decisions. There is a need for a paradigm shift in thinking from regulating the science (as it has been proven safe) to facilitating the growth of the Australian economy by driving the plant science industry (both in the public and private domain) to its full potential.

The responsible use of crop protection products must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising costs from excessive, inappropriate and ineffective regulation. Farmers need these products because of the benefits they provide to their businesses and consumers need these products to ensure they have access to safe, affordable and nutritious food. While it is important for governments to provide for appropriate and rigorous regulation of pesticides and biotechnologies, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation, while not delivering any improvement in safety, health or environmental outcomes.

Challenges

Efficient and effective regulation is essential to support an innovative, productive and sustainable agricultural industry in Australia. Unfortunately, from an agricultural chemical perspective, innovation is undermined by a regulatory system that is inefficient and operated to discourage investment in modern crop protection technologies.

These regulatory burdens are not without consequence. In addition to raising costs and delaying introduction of innovative new products, excessive regulation increases the pre-market barrier for new products, meaning fewer tools for farmers are ultimately registered and approved for use. A company will generally not invest to register a product if the market size does not justify the necessary investment in data generation and registration costs. Exacerbating this problem in Australia is the equivalent cost of regulation for a crop protection product in the United States, despite the size of the Australian market being one-tenth that of the United States. This means that Australia is uniquely susceptible to the effects of excessive regulatory cost on the availability of chemical products for minor uses.

[5] https://www.environment.nsw.gov.au/-/media/OEH/Corporate-Site/Documents/Parks-reserves-and-protected-areas/state-of-the-parks-2004-050051.pdf

[6] https://invasives.org.au/wp-content/uploads/2020/11/Glyphosate-A-Chemical-to-Understand.pdf

A lack of available pest and weed protection products provides a significant barrier to the development of new agricultural industries. New crops are less likely to be commercially cultivated for domestic and export markets if there are no options for pest control. Horticultural crops in particular face challenges as the smaller areas under production often render the registration of new chemical products unfeasible.

Where a registered or permitted product is not available, farmers may be forced to rely on state legislation that allows 'off-label' use. Off-label uses are not risk assessed and may therefore result in unacceptable risks to users, consumers or the environment, or pose impediments to trade. For these reasons, CropLife does not support off-label use of agricultural chemical products.

The consequences of these regulatory barriers are not, however, limited to minor crops. Major commodities such as wheat and barley can still be susceptible to minor pests and diseases that are not significant enough to justify investment by registrants to extend labels or develop new control technologies. Pests may not always be a problem for a particular crop, or unusual and unexpected weather conditions in a particular season may lead to new pest and disease pressures.

These issues are addressed internationally through 'minor use' programs to coordinate and subsidise necessary research to support minor use of agricultural chemical products. An appropriately targeted and funded minor use program in Australia can safeguard Australian agriculture by increasing its productivity and diversity. Ensuring that farmers have access to adequate crop protection technologies can facilitate:

- development of new industries growing new crops for domestic and overseas markets;
- agricultural development of new regions for new crops as pest issues can be sustainably controlled;
- reduced risk to users, consumers, the environment and trade from off-label use;
- reduced reliance on APVMA-issued permits, increasing the Regulator's capacity for providing high-quality risk assessments and registrations; and
- ongoing sustainable production within existing farming systems as new tools facilitate better, more effective and long-lived resistance management strategies.

Further to regulatory barriers that impede innovation and the delivery of new and effective products to Australian consumers is intellectual property (IP), the fundamental source of protection for innovation in the plant science industry.

A pertinent issue for pioneer registrants of crop protection products is that the *IP Laws Amendment (Raising the Bar) Act 2012*[7] allows for manufacturers of generic products to obtain regulatory approval for a product containing a chemical under patent, such that regulatory approval for the generic product can be granted as soon as the patent period expires. While this practice – known as "spring-boarding" – encourages competition within the marketplace, it creates a disadvantage for the pioneer registrant that has invested considerable resources into developing the patented active constituent. As the registration process for the pioneer product generally takes many years, the pioneer registrant's patent period is considerably diminished, as are commercial returns associated with the patent period. This discourages investment in the Australian market.

Despite facing similar issues associated with patent periods and regulatory requirements to the pharmaceuticals industry, the *IP Laws Amendment (Raising the Bar) Act 2012* an extension of the current patent period[8] for up to five years to offset the impact of the registration assessment period is only available for patents covering pharmaceuticals.

A similar extension associated with agricultural technologies, particularly agricultural chemicals and veterinary medicines, would significantly improve global investment into Australia, thus alleviating a significant hurdle to innovation in Australia.

b. Biotechnology

Biotechnology is a pivotal tool for sustainable development and has become a policy priority for global policy makers. Emerging biotechnologies offer novel approaches with the potential to achieve ecologically sustainable development by transforming the way we address challenges in medicine, food production and processing, and the environment.[9]

The major strength of biotechnology is its multidisciplinary nature and broad range of scientific approaches. Recent advances in various biotechnological fields are facilitating the production of chemicals, recombinant proteins, biomaterials and pharmaceuticals. Biotechnology plays an important role, especially in the fields of medicine, food production, renewable raw materials and energy, pollution prevention and bioremediation. Resource recovery, recycling and waste disposal are other environmentally beneficial facets of biotechnology.

7 https://www.ipaustralia.gov.au/about-us/legislation/raising-bar-act
8 https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents
9 Mukhopadhyay, K., Sachan, A., & Kumar, M. (2017). Applications of Biotechnology for Sustainable Development. Springer Singapore.

A 2017 report by the National Academy of Sciences, "Preparing for Future Products of Biotechnology"[10] considered technological advances and products likely to emerge over the next 5-10 years and the risks presented by these compared to those that already existed. Given the rapid progression of technological advances, the report recommended implementing the necessary mechanisms for regulators to continuously "scan the horizon" for new processes and products that could present novel risks and to ensure their approaches to risk assessment remain robust and effective.

Genetically modified (GM) crops are an example of an application of modern biotechnology already being utilised to deliver safe and affordable food, feed and fibre to Australia and the world. GM crops represent just one of the many opportunities in breeding innovation.

GM crops are a necessary and important tool in meeting global food and nutrition security challenges. Since being first commercially cultivated in 1996, GM crops have positively contributed to global food security, environmental sustainability and helped farmers to adapt to and mitigate climate change by:

- increasing the value of crop production by US$186 billion;[11]
- improving the sustainability of pesticides by reducing usage (kg active ingredient) by 775 million kg;[12]
- reducing CO_2 emissions in 2018 alone by 27.1 billion kg[13] (equivalent to taking 16.7 million cars off the road for one year, more than all the passenger vehicles registered in Australia and 86 per cent of all vehicles registered in Australia); and
- increasing the incomes of more than 17 million small farmers and their families – some of the poorest people in the world, and thereby helping to alleviate poverty.[14]

Globally, GM technology directly increased farm income by US$18.2 billion in 2016[15], with over half the gains going to farmers in developing countries[16]. According to the metanalysis published by Klumper and Qaim, GM crops have reduced pesticide use by 37 per cent, while increasing crop yields by 22 per cent and increasing farmer profits by 68 per cent.[17]

[10] National Academies of Sciences, Engineering, and Medicine (2017). Preparing for the future products of biotechnology. Washington, DC. National Academies Press.

[11] Brookes G and Barfoot P (2020) 'Environmental impacts of genetically modified (GM) crop use 1996-2018: impacts on pesticide use and carbon emissions'. GM Crops and Food 11 (4).

[12] Brookes G and Barfoot P (2018) 'GM crops: global socio-economic and environmental impacts 1996-2016'. PG Economics, Dorchester, UK.

[13] ISAAA (2019) 'Global Status of Commercialized Biotech/GM Crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change. ISAAA Brief No. 54. ISAAA: Ithaca, NY

[14] Ibid.

[15] Brookes and Barfoot (2018) Op. Cit.

[16] ISAAA (2019) Op. Cit.

[17] Klümper, W. and Qaim, M., (2014). 'A meta-analysis of the impacts of genetically modified crops'. PloS one, 9(11), p.e111629.

Cultivation of GM crops has equally proven to be beneficial to the environment. Crop biotechnology is an important tool helping farmers become more sustainable by allowing them to produce more while using fewer natural resources and decreasing their usage of pesticides. Since GM crop cultivation started in 1996, more than 183 million hectares of land have been saved from ploughing and cultivation, leading to improved water storage, reduced soil erosion and increased availability of land for other environmental uses.

GM crops currently under research and development in Australia will help our farmers address the unprecedented challenges they are facing in a changing climate. GM traits currently investigated at the national level will be crucial tools for farmers to combat climate risks, subsoil constraints and emergent diseases. There is also considerable Australian research into GM traits that will bring health benefits to consumers, such as healthier starches and oils modified to be lower in saturated fats and with improved cooking qualities.

Challenges

The lack of clarity in Australia's regulatory framework has failed to keep pace with technological developments. The result is a disproportionate regulatory burden on some products developed using plant breeding innovations, such as genome editing where they are regulated as genetically modified organisms (GMOs) based on the use of gene technology rather than the risks presented by the characteristics of the final product. This is disproportionate because many of the resulting products are comparable to those developed using conventional methods that are not within the regulatory scope of the National Gene Technology Scheme (NGTS).

The implementation of the recommendations from the Third Review of the National Gene Technology Scheme is a crucial first step to improve the existing risk-based regulation, in order to 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.

Regulatory systems that do not keep up with scientific development limit innovation, irrespective of the size of the enterprise. Developing improved crops has a cost and the regulatory burden can make or break a project. Business decisions are made depending on regulation processes and costs. We must not limit the use of these technologies – depriving farmers and consumers of improved or innovative crops and products – because of poor regulation. Australia could miss out on opportunities if the recommendations from the NGTS review are not implemented in a timely manner.

Further to issues associated with regulatory burden, misinformation about agricultural biotechnology and crop protection products is extensive. GM crops, for example, are an ongoing target for misinformation and disinformation despite being similar to those that are currently regulated and are well-characterised commercial crops and/or traits that have a history of safe use in the environment. It is questionable why certain GM crops remain regulated despite 25 years of commercialisation with no credible evidence for adverse effects on the health and safety of people or on the environment.

Akin to governments providing information about vaccinations to counter misleading safety claims, governments have a role to play in providing facts about the benefits and risks of agricultural innovations, including crop protection products and genetically modified crops. Without this, the Australian community could forgo the benefits to productivity, food safety and nutrition provided by crop protection products and GM crops.

While the APVMA, Food Standards Australia New Zealand and the Office of the Gene Technology Regulator provide information about the roles of crop protection products and GM technologies in producing plentiful safe, nutritious food and publish clear and accessible information about their risk assessment processes, there is scope for more information and better clarification of misinformation. This would complement an adaptive future-oriented regulatory scheme informed by the accumulated knowledge and experience gained from previously assessed GMOs and applied to similar newly developed products.

3. CONCLUSION

CropLife welcomes the opportunity to provide comment on the *Critical Technologies Discussion Paper: Agriculture*. Agricultural chemicals and genetically modified crops are major contributors to the sustainability and productivity of Australia's food production systems. The benefits they generate for farmers, other users, consumers and the environment far outweigh any manageable or imagined risks associated with their adoption or use. These tools are vital to producing nutritious, healthy, affordable and disease-free food for Australian and overseas consumers. CropLife and its members are committed to supporting all farming systems in Australia by providing farmers with the innovations, technologies, tools and products they need to ensure sustainable and profitable farming practices.

The value of biotechnology is critically under-recognised by Australian governments in policy. The implementation of the recommendations from the Third Review of the National Gene Technology Scheme is a crucial first step to improve the existing risk-based regulation, in order to 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 Australia

29 November 2019

ATTACHMENT A

Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1

Introduction

As the national peak industry organisation for the plant science sector, CropLife Australia seeks to ensure that the nation's farmers have access to safe, innovative, modern agricultural tools to support the productivity and environmental sustainability of Australian farming.

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, sustainability and food security. The plant science industry is worth more than $20 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is a part of the CropLife International Federation of 91 national associations globally. Our focus is, however, specifically on an Australian agricultural sector that is internationally competitive through globally leading productivity and sustainability achieved through access to the technological innovation of the plant science sector.

CropLife welcomes the opportunity to provide comments to Phase 1 of the Implementation of the Recommendations of the Third Review of the National Gene Technology Scheme (NGTS). In particular, we welcome the focus of the Issues Paper on reviewing definitions to ensure the NGTS remains fit for purpose and streamlining processes and requirements to improve risk-proportionate regulation and reduce undue regulatory burden.

CropLife supports an implementation process that is aimed at ensuring the NGTS continues to be relevant as "gene technologies" and the products thereof evolve, whilst proportionately regulating the risks (if any) of these products to human health and the environment. The implementation of these recommendations is an opportunity to introduce the necessary changes for improving regulatory certainty and clarity, in terms of a path to market for developers, and risk-based and proportionate regulation of an increasingly broad range of innovative products. Such changes were not possible as part of the Office of the Gene Technology Regulator's (OGTR) Technical Review of the Gene Technology Regulations (Technical Review) that took place in 2016-2019, however, they would be consistent with "Option 4" presented in that Review.

CropLife's submission to the Technical Review (December 2016) and the resulting draft amendments to the Gene Technology Regulations (February 2018), to Phases 1 (September 2017), 2 (December 2017) and 3 (May 2018) of the Third Review of the NGTS, and to the Food Standards Australia New Zealand (FSANZ) Consultation Paper on Foods Derived Using New Breeding Techniques (April 2018) have all reflected our member companies' collective concerns about the lack of clarity in Australia's regulatory framework as it has failed to keep pace with technological developments. The result is a disproportionate regulatory burden on some products developed using plant breeding innovations, such as genome editing where they are regulated as genetically modified organisms (GMOs) based on the use of gene technology rather than the risks presented by the characteristics of the final product. This is disproportionate because many of the resulting products are comparable to that developed using conventional methods that are not within the regulatory scope of the NGTS.

CropLife's previous submissions to the Third Review of the NGTS highlighted additional concerns, such as the outstanding agreed recommendations from previous reviews of the NGTS that must be implemented. Had some of these recommendations been implemented in a timely manner, issues described in our (and several other) subsequent submissions would not have been necessary. One clear example of these missed opportunities to future-proof the NGTS is given by Recommendation 9 from the 2011 Review:

> **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.*"

Commentary associated with this recommendation highlighted issues that were at the centre of 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"
- That the process for introducing legislative amendment to clarify what is and what is not regulated under the Act is complex.

As stated above, CropLife welcomes the current implementation process and strongly supports efforts to introduce tangible changes in a timely manner. In this submission on the latest Issues Paper[1], CropLife will (again) be referencing its prior submissions as we have previously addressed the issues of concern to us and our message remains the same. CropLife has made substantial submissions throughout this process and we urge the Gene Technology Implementation Team to read them as they cover these issues in depth.

In this submission, we add support to our views by illustrating the impact a lack of regulation clarity and/or disproportionate regulatory requirements have on developers. This issue seems to be a missing element in this process, despite the stated priority of "reducing regulatory burden". For this reason, the expanding timeframes for the implementation phase of the current review are of increasing concern to developers with the result that confidence in the NGTS is undermined.

Regulatory systems that do not keep up with scientific development limit innovation, irrespective of the size of the enterprise. Developing improved crops has a cost and the regulatory burden can make or break a project. Business decisions are made depending on regulation processes and costs, therefore limiting the use of technology and depriving farmers and consumers of improved or innovative crops and products. Australia could miss out on opportunities if the recommendations from the NGTS review are not implemented in a timely manner. If agreed recommendations are not implemented, as was the case for previous reviews, there would be almost no point in participating in future reviews as this would appear to be a futile exercise.

[1] *Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1. Issues Paper, Department of Health, Commonwealth of Australia, September 2019.*

Part One: Definitions to support the National Gene Technology Scheme

The objectives of definitional changes described in Part One of the Issues Paper are broad and cover most, if not all of the criteria that are needed to future-proof the Scheme, while maintaining its core role of protecting human health and the environment. The Issues Paper informs that the definitions in the *Gene Technology Act 2000* (*GTA*) were drafted broadly so that they remained effective and did not become outdated as technology evolved. We agree that the *GTA* needs to retain broad definitions for these reasons, however, it cannot be expected that even broad definitions will remain relevant indefinitely, and they will require review. Also, definitions should not be the only mechanism for determining whether or not a "gene technology", or an organism developed using a gene technology, is within or outside the scope of GMO regulation.

Other mechanisms include those that are already part of the NGTS. The definitions of the *GTA* are accompanied by lists of techniques and organisms that are excluded from the scope of regulation, via the Schedules in the Gene Technology Regulations (GTR). A mechanism is in place for the review of these lists. Reviews of the GTR can be triggered by the Gene Technology Regulator (the Regulator) by advising the Legislative and Governance Forum on Gene technology about the effectiveness of the legislative framework for the regulation of GMOs. Such reviews, however, do not occur frequently enough to keep up with rapid technological developments in the field, especially in the past decade. These reviews have only occurred three times: in 2007, 2011 and more recently in 2016, with most of the outcomes of that review only recently becoming law. While this has proved somewhat "workable" as stated in the Issues Paper, it has not proved satisfactory for the regulated community. Due to this, it cannot be said that the GTR are meeting the elements of their stated purpose[2] to (emphasis added):

- Ensure that dealings with GMOs continue to be classified appropriately **according to current scientific understanding of risks** which they may pose;
- Improve the **efficiency and effectiveness** of the regulatory system; and
- Assist users to better **understand and comply** with their legislative obligations.

The most recent Technical Review resulted in amendments to the GTR that included the exclusion of organisms developed using a category of genome editing defined as site directed nuclease (SDN)-1, on the basis of the DNA repair mechanism involved being naturally occurring and that it results in the same range of nucleotide sequence changes that can occur via spontaneous mutations. However, before these amendments could even complete the requisite legislative process, genome editing technologies with similar outcomes emerged (e.g. base editing and prime editing), and these are not within the scope of the narrowly defined exclusion as they are not based on the exact same mechanism. This might not be clear to many in the regulated community, resulting in regulatory ambiguity. Further, such technologies remain within the scope of regulation as a GMO and will continue to until there is another process for making amendments at some unknown time in the future. The outcome of such amendments thus cannot be categorised as appropriate or proportionate regulation as it contradicts the scientific evidence, and it cannot be described as an efficient or clear, understandable regulatory system.

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[2] *As stated in the explanatory statement for the Gene Technology Amendment Regulations 2011: https://www.legislation.gov.au/Details/F2011L00933/Explanatory%20Statement/Text*

The issue with the SDN-1 exclusion demonstrates the limitations of technology-based definitions. The Issues Paper states that "definitions should provide legal clarity and consistency without adding complexity or compromising flexibility" and that "a definition that is valid now may not be fit for purpose in the near future". These problems will arise as long as there is a focus on technology, which does not in itself present risks requiring assessment or regulation. Technologies evolve and will continue to do so – the issue for regulatory consideration is the risk posed by the resulting organism in the context of its intended use and receiving environment. Organisms developed using very different technologies can carry the same type of change at the molecular level and present comparable risks.

Consequently, CropLife urges that reviews of the GTR occur more frequently and with timelier implementation of amendments necessary to ensure they are meeting their intended purpose. This requires, consistent with implementation of Recommendation 9 from the 2011 Review of the *GTA*, that the Regulator has greater flexibility and discretion to react to developments and the accumulation of knowledge, to initiate, conduct and complete reviews *via* a simpler, timelier process for GTR amendment. Such a process should be rooted in scientific reality through ongoing review of the scientific literature and consultation with the scientific community, rather than irregular reviews that address certain narrowly defined categories of technologies in a piecemeal way, with protracted processes for change to the GTR. That said, CropLife welcomes the SDN-1 exclusion as a first-step in the right direction towards a more proportionate NGTS.

CropLife's submission for Phase 1 of the NGTS review included a proposed amendment to the definition of "gene technology" which is reproduced below. This proposal was accompanied by additional proposals for amendments to the GTR Schedules to exclude certain technologies (e.g. cisgenesis) and organisms. These proposals were aimed at giving effect to the proposed "Option 4" of the Technical Review and demonstrated that it could be implemented with amendments to the existing NGTS. In combination, our proposed changes

are an example of how definitional change could make for a more agile, proportionate and future-proof NGTS and they are consistent with developments in other countries where regulatory processes have been introduced specifically for plants developed using genome-editing[3].

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.

[3] *Friedrichs et al (2019). An overview of regulatory approaches to genome editing in agriculture. Biotechnology Research and Innovation, **3** (2) 208-20.*

This proposed amendment is consistent with the SDN-1 exclusion and would also have the effect of excluding certain organisms developed using other types of genome editing techniques, but it would not exclude those organisms currently captured (i.e. GMOs) by the NGTS. Due to the latter, the proposed definition change above does not go far enough, and there are clear examples of where additional mechanisms are needed to ensure risk-proportionate regulation and to avoid undue regulatory burden. One of these examples is newly developed GM plants that are similar to those currently regulated and are well-characterised commercial crops and/or traits that arguably have a history of safe use in the environment. While it is questionable why certain GM crops remain regulated despite 25 years of commercialisation with no credible evidence for adverse effects on the health and safety of people or on the environment, an adaptive future-oriented regulatory scheme should be informed by the accumulated knowledge and experience gained from previously assessed GMOs and applied to similar newly developed products. Another example is plants developed using "cisgenesis". While these are captured as "GMOs" according to *process*, the *product* is comparable to plants that can be created using conventional plant breeding methods, given that the transfer of the same genetic material is possible. It is for this reason that we proposed their exclusion via the GTR.

A proportionate NGTS would not capture the examples described above, and two mechanisms enabling their exclusion, or treatment via a notification or streamlined risk assessment process rather than full regulatory assessment, have previously been proposed by CropLife. In our 2016 submission to the Technical Review, recommended exclusion of plants developed using cisgenesis and proposed specific amendments to the GTR giving effect to this in our submission to Phase One of the NGTS review. We also proposed consideration against the criteria of a "Decision Tree", which is presented again in Part Two of this submission. The Decision Tree is an example of risk-tiering for the types of products we develop; however, an expanded version or parallel versions could be developed to enable a similar approach for other types of organisms.

The use of a Decision Tree, such as the one we have proposed, would require that the Regulator has the discretion to make the necessary decisions for its effective implementation. As we have noted above and in previous submissions, implementation of Recommendation 9 from the 2011 Review could have the effect of giving the Regulator greater discretion to make such decisions.

All the mechanisms proposed by CropLife above (and previously) are consistent with maintaining a "process-based trigger as the entry point" to the NGTS (Recommendation 8). Whilst this review process is clearly demonstrating that a process-based approach does not respond effectively to technological change, it is possible to make amendments to the NGTS that enable more proportionate consideration of the products in a "hybrid" approach. There is a perception that systems that are solely product-based are better suited to technological advancements compared to process-based systems. Product-based systems, however, can also have disproportionate impacts and need to include mechanisms to allow for the exclusion of certain products. An example of this is the "novel trait" based system in Canada that captures plants developed using conventional breeding methods and disproportionately imposes a regulatory burden on plant breeders that is absent in process-based systems. Therefore, irrespective of the type of regulatory trigger, it is of the greater importance that the regulatory system is defined by appropriate protection goals and contains mechanisms allowing for proportionate treatment of technology (process) and organism (product).

Our proposals in this submission remain consistent with our fundamental position that regulation must be commensurate with the risk presented by the characteristics of the product. Regulation of plants developed using certain applications of genome editing (and cisgenesis) based on the use of gene technologies when the outcomes are comparable to that possible with conventional plant breeding methods is not proportionate, risk-based regulation and imposes undue regulatory burden.

Part Two: Risk-proportionate regulation through risk tiering and appropriate regulatory approaches

CropLife strongly supports the underlying principles of the NGTS of efficient and effective regulation that is proportionate to risk, and therefore the intent of Recommendations 9, 10 and 20. As described in Part One of this submission, CropLife considers this is possible in a NGTS that combines elements of process and product-based systems, provided that the protection goals are appropriate, and mechanisms are in place for its efficient operation.

The objectives of risk-proportionate regulation described in Part Two of the Issues Paper are broad and cover most, if not all, criteria that are needed to future-proof the Scheme, while maintaining its core role of protecting human health and the environment. We also emphasise the importance of the fundamental principle of risk assessment of a case-by-case approach. This is already an integral part of the NGTS, but this would be of elevated importance for the effective implementation of risk-tiering as a means of achieving more proportionate and streamlined regulation.

CropLife strongly agrees with the commentary in the Issues Paper that regulatory efforts need to be focussed where risk assessment and management is necessary, and not impose unjustified regulatory burden. Towards this, CropLife previously proposed a Decision Tree that was submitted for Phase 1 of the NGTS review, reproduced below. This Decision Tree illustrates how risk-tiering could be applied to the types of products we develop, and as noted previously, the concept could be expanded to include other types of organisms.

The proposed Decision Tree combines elements of process and product-based regulation: the entry point (or "trigger") is the use of gene technology, which is followed by four decision points that are based on defined criteria for different risk-tiers. These tiers incorporate mechanisms that have already been described in Part One of this submission:

i. Exclusion from regulatory scope via the GTR, e.g. as for SDN-1;
ii. Regulation via a "Streamlined Risk Assessment" (SRA) process based on existing knowledge, e.g. the biology of the organism is well-characterised in Australia, there is prior regulatory assessment of the same organism (in another country) or similar organism (in Australia);
iii. Exclusion from regulatory oversight but with a "Regulatory Notification" (RN) to the Regulator, e.g. where the organism has been developed using gene technology but is comparable to that obtainable using conventional methods excluded from regulatory scope; and
iv. Regulation as a GMO in accordance with the current Dealing Involving an Intentional Release (DIR) process.

The SRA and RN processes involve significantly reduced regulatory requirements and timeframes. A licence for a DIR currently takes 180 business days for a limited and controlled release (a field trial for a product in development) and 255 business days for a commercial release. The SRA approach would be used where it has already been established or demonstrated that a proposed licence dealing is low risk, and it would take half the time of a DIR. Regulatory Notifications would be used for plants developed using gene technologies that result in products that are similar to, or indistinguishable from those that could have been developed using conventional breeding methods. The latter would include technologies/organisms not yet excluded from regulatory scope, such as cisgenesis and certain applications of genome editing in plants.

As for definitions, a Decision Tree cannot be expected to be fit for purpose indefinitely and will likely require amendment as technologies and their resulting organisms evolve. For example, as knowledge

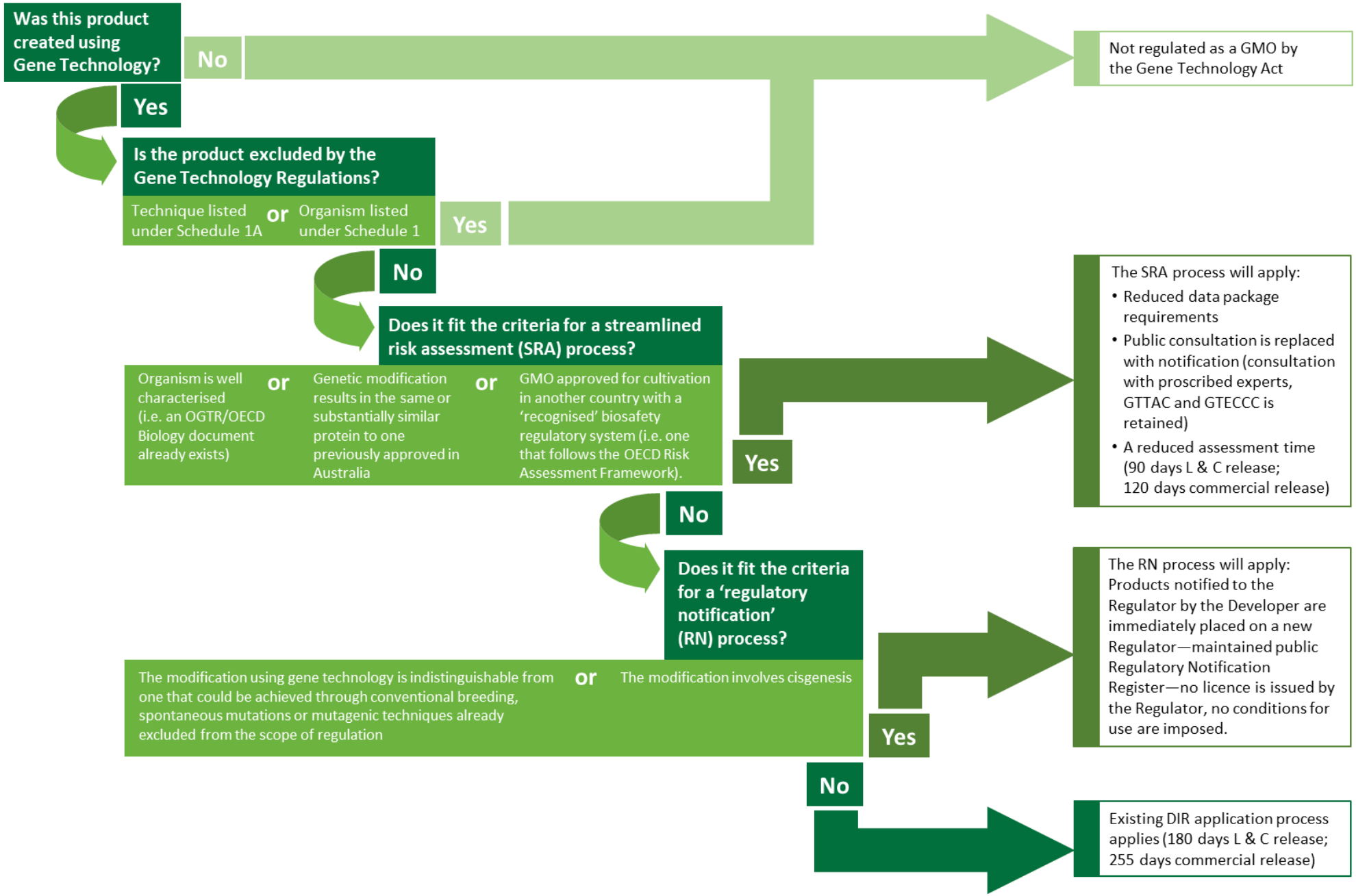
accumulates about these technologies and their resulting organisms, the criteria for the SRA and RN categories should expand, there should be cases that shift from the requirements of the SRA category to the RN category, and there should be cases identified in the RN category for exclusion from regulatory oversight via future technical reviews of the GTR. This streamlining would also be beneficial for the efficiency of the OGTR. Instead of dealing with unnecessary DIRs, resources could be redirected to other proposals made in this submission, such as the activities required for implementing more regular technical reviews of the GTR.

The Issues Paper points to the need to enable the Regulator to, in effect, implement a system such as that described above. This would require decisions to be made about the "applicability of regulation to any technological developments" (e.g. SRA or DIR; Recommendation 13(a)), and the introduction of "elements of principles-based regulation" where there is a history of safe use (Recommendation 13(b)). Recommendation 9(b) is also relevant in this respect, with the system necessitating the "flexibility to move organisms between categories". In general, CropLife supports these recommendations for the purpose of enabling a more efficient and effective NGTS that is proportionate to risk and remains so with technological advancement but contends that a broader range of defined science-based criteria should be the basis of moving organisms between categories than history of safe use. We note again that all of this is consistent with Recommendation 9 from the 2011 review of the *GTA*.

Regarding "principles-based regulation", as we have submitted previously, CropLife cautiously supports the exploration of a principles-based approach when it could lead to a more outcome-based process. Principles-based regulation could, in theory, allow a greater degree of future proofing and enable the NGTS to respond in a timelier manner to new gene technologies as they arise without having to create new rules each time. Regulatory clarity and certainty are, however, of the greatest importance to CropLife members. There are genuine concerns about the potential ambiguity of principles-based regulations. Principle-based regulation may not provide the required level of certainty or may create an unpredictable regulatory regime in which regulators can act retrospectively. Where this involves prescriptive rules, this could provide the necessary clarity, as it is easier for a regulated entity to determine what rules it must comply with and estimate the associated timelines and costs. As we have submitted previously, we welcome more specific proposals on this topic to consider.

As a final point in connection to Recommendation 13(a), as developers of products with long lead-times and requiring significant investment, CropLife supports the Regulator being able to provide formal opinions on the likely regulatory status of a proposed product, i.e. the applicable category in the above Decision Tree, even where the proposed product is "new" and does not clearly fit the existing criteria of the Decision Tree. The value of clarity regarding the path to market should not be underestimated. The ability to obtain such an opinion in the early stages of an R&D program enables estimation of the cost and timelines for complying with regulatory requirements, the economic feasibility of a program, and whether or not that program will include investment in Australia. The R&D cost to bring a GM crop to market is substantial. It was estimated at US$136 million over an average of 13.1 years for crops introduced between 2008 and 2012 and this is believed to have increased since that study was published.[4] A significant portion of this time and cost is associated with the work related to regulatory requirements – conducting the necessary studies, preparing and submitting dossiers, and obtaining regulatory approvals. The time and cost are exacerbated by regulatory ambiguity, which presents a barrier to innovation for enterprises of any size and capacity.

[4] *See: https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/*


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
No
Does it fit the criteria for a streamlined risk assessment (SRA) process?
Organism is well characterised (i.e. an OGTR/OECD 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 Risk Assessment Framework).
Yes
The SRA process will apply:
• Reduced data package requirements
• Public consultation is replaced with notification (consultation with proscribed experts, GTTAC and GTECCC is retained)
• 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 that could be achieved through conventional breeding, spontaneous mutations or mutagenic techniques already excluded from the scope of regulation
or
The modification involves cisgenesis
Yes
The RN process will apply: Products notified to the Regulator by the Developer are immediately placed on a new Regulator—maintained public Regulatory Notification Register—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)

Part Three: Streamlining regulatory requirements and processes to reduce regulatory burden

CropLife supports streamlining regulatory requirements and processes for the reasons set out in the objectives in the Issues Paper. These are consistent with the ultimate objectives of the CropLife recommendations in Parts One and Two of this submission, namely regular technical reviews of the GTR and its exclusion lists; an approach to decision-making that incorporates additional categories and criteria consistent with risk-tiering, as well as streamlining; and putting in place the mechanisms that enable the implementation of all of these recommendations by the Regulator. These recommendations are aimed at improved efficiency, effectiveness and flexibility of the NGTS, resulting in more risk-proportionate regulation, less undue regulatory burden, and improved regulatory clarity in terms of a pathway to market for developers.

There are other areas of the NGTS that also require streamlining through process improvements. CropLife's submission for Phase 1 of NGTS review sets out in detail its concerns regarding duplication of regulation between the OGTR, Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) for products regulated as GMOs. CropLife views removal of such duplication as high priority, as it imposes heavy regulatory burden, time delays and costs on applicants, with no associated benefits. To improve this situation, CropLife recommends that the APVMA accepts the risk assessments of the OGTR and FSANZ, or that APVMA regulatory responsibility for GM products with incorporated pest and/or disease control is removed. This regulatory responsibility is an outdated remnant of the pre-OGTR system, and these changes would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, businesses and community organisations.

CropLife's submission to Phase One of the Review of the National Gene Technology Scheme also raised concerns regarding the use of Section 54 of the *GTA*. Section 54 provides anyone with the ability to request a copy of applications and/or risk assessment and risk management plans, except for any confidential commercial information (CCI). While we recognise that regulatory transparency has an important role in supporting technology and product acceptance, we are concerned that s54 does not protect the data owner's rights. The documents described in s54 can already be requested under the Commonwealth *Freedom of Information Act 1982* (*FOI Act*), therefore it is an unnecessary duplication in the *GTA*.

Section 54 duplicates some of the powers under the *FOI Act* but does not provide all of its protections, and does not include the same requirements, conditions, exemptions and procedures of the *FOI Act*. Contrary to the FOI Act, there is no consultation with affected third-parties to ensure all appropriate information is protected or redacted for CCI and privacy under s54. Section 54 also lacks conditional exemptions for personal privacy, business, research or economic reasons. Compared to the FOI Act, s54 does not have review and referral procedures, or oversight from the Office of the Australian Information Commissioner. Therefore, s54 does not protect the regulated community's privacy and data.

An additional concern for the regulated community is that the OGTR is required to maintain a public FOI disclosure log that records if/when and what documents have been released under the FOI Act. There is no such requirement for the Regulator to maintain a public record of documents released under s54, leading to a process that lacks transparency. Section 54 also imposes an unnecessary burden on the OGTR as limited resources are used to repetitively deal with requests for the same information. If the documents were released *via* the FOI disclosure log, any person would be able to access the documents online without diverting OGTR resources away from core business.

Administrative processes that would benefit from improved streamlining identified in the NGTS review that we support include electronic submissions. The ability to electronically submit regulatory dossiers that could be shared between regulatory agencies would alleviate some of the application burden and potentially reduce application timeframes. Online, real-time tracking of the licensing process would equally simplify the application process for the regulated community.

We support other improvements proposed in the recommendations, including streamlining of organisation accreditation and facility certifications to reduce waiting times for the regulated community. Greater responsibility for Institutional Biosafety Committees (IBC) could be introduced in this regard, the IBC could manage facility certification and certification extensions. Ongoing training for IBC members would be a requirement and would need to take into account different levels of expertise between IBCs.

CropLife Australia

March 2021

ATTACHMENT B

Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme
Consultation Regulation Impact Statement

1 INTRODUCTION

CropLife Australia 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 patent-holding and generic, Australian and international and small to large companies. Accordingly, CropLife only advocates for policy positions that deliver whole of industry benefits.

The plant science industry provides products to protect crops against pests, weeds and diseases, key to the nation's agricultural productivity, sustainability and food security. The industry is worth more than $20 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is a part of the CropLife International Federation of 91 national associations globally. Our focus is, however, specifically on an Australian agricultural sector that is internationally competitive through globally leading productivity and sustainability achieved through access to the technological innovation of the plant science sector. CropLife seeks to ensure that the nation's farmers have access to safe, innovative, modern agricultural tools to support productivity and environmental sustainability.

CropLife actively participated in the consultations throughout the Third Review (Review) of the National Gene Technology Scheme (NGTS) and provides the following comments on the Consultation Regulation Impact Statement (CRIS). We support efforts to implement the four identified key recommendations arising from the Review to modernise and futureproof the NGTS. We especially welcome the focus on potential pathways that would improve risk-proportionate regulation and reduce undue regulatory burden. In principle, CropLife supports the concept of a proportionate regulatory model and the described aim of providing flexibility to respond to scientific advances in a timely manner.

That stated, we do have concerns that plant breeding approaches generally referred to as "new breeding techniques" have not been considered in the papers published as part of this consultation. We wish to emphasise that the current Scheme responds very slowly to biotechnological advances. Option A of maintaining the status quo is therefore not feasible. Option C is not feasible either as it is too rigid in its structure and would be an inhibitor to innovation. Changes proposed as part of Option B offer some flexibility, particularly for established technologies. Changes linked to Option B are, however, not clear as to if or how they address current issues that are already frustratingly outdated. In its current form, Option B represents what would have been a preferred solution 10 years ago, in the early days of discussions on new breeding techniques. If adopted as presented, Option B would lead to a Scheme that would become obsolete before even coming into force. This is not tenable and would profoundly impact innovation in Australia.

The tone of the Explanatory Paper and the CRIS suggests that the NGTS is currently up-to-date and needs to prepare for what may come in the future. Unfortunately, this is not the case. The Technical Review of the Gene Technology Regulations (Technical Review) that took place in 2016-2019[1] resulted in some updates to clarify the regulatory scope of certain genome-editing approaches. The outcome only partially addressed the needs of our industry, which were presented with detailed supporting scientific literature and evidence. This outcome was understood to be an interim solution pending the Review of the NGTS.

The CRIS specifically refers to *gene-editing* and *synthetic biology* in the context of futureproofing. Yet it is not clear how the proposed authorisation pathways in Option B, or the proposed amendments to three definitions will address this. We remain concerned that areas we have repeatedly emphasised as needing more immediate consideration throughout the Review, namely genome-editing and other "new" plant breeding approaches, are not directly addressed. These approaches can barely be considered new as they have been under discussion for more than a decade. Nonetheless, the regulatory approach in Australia remains unclear and updates so far are disproportionate. When concerns have been raised by CropLife members, they have been told to send in applications, as a means of testing the system. This is neither a considered way to ensure a streamlined system, nor will these applications eventuate while we have unclear or disproportionate regulatory requirements in Australia.

The aims of the proposed proportionate regulatory model should be twofold, with the implementation of the key recommendations an opportunity to introduce the necessary changes to:

(i) Provide mechanisms that enable the Regulator to provide timely regulatory certainty and clarity for "new" and "emerging" technologies that are not (yet) expressly addressed by the NGTS; and

(ii) Improve the regulatory approach – in terms of risk and science-based proportionality and regulatory burden – for new and established technologies and organisms that are currently within the scope of regulation.

Both aspects are critically important as they enable developers to determine a path to market, thus making investment in R&D in Australia feasible. They also give developers the confidence that the regulatory system remains risk-based and proportionate while dealing with an increasingly broad range of innovative approaches.

A proportionate regulatory model would reflect "Option 4" presented in the Technical Review of 2016-2019[2]. It was claimed this option could not be realised due to the limitations imposed by the underlying process-based policy setting. Alternative reform options – including elements proposed in the current CRIS – could contribute to providing a similar outcome, namely, regulatory oversight primarily based on the risk presented by the final product, rather than the tools used to develop it. Text in the CRIS (e.g., p21) indicates risk being determined based on the type of gene technology

[1] See Office of the Gene Technology Regulator, Technical Review of the Gene Technology Regulations 2001, Discussion Paper: Options for Regulating New Technologies, October 2016

[2] See: Office of the Gene Technology Regulator, Technical Review of the Gene Technology Regulations 2001, Discussion Paper: Options for Regulating New Technologies, October 2016.

used. This is not consistent with a proportionate approach (or the original intend of the NGTS) as it is possible for different technologies to produce comparable outcomes. A regulatory approach primarily directed by the risk presented by the product remains possible even where a process-based regulatory trigger is retained.

The evolution of biotechnology has been continuous since the development of the NGTS over 20 years ago and this progress has not been accompanied by sufficient adaptation of the regulatory framework. Despite several reviews over the years, there has only been minor tweaking of the NGTS, with most recommendations never implemented. This lag of over a decade has resulted in a damaging lack of clarity for certain technologies/applications and/or in a regulatory burden that is excessive due to its inconsistency with several decades of accumulated scientific evidence and understanding.

We have detailed the impact on R&D in numerous submissions over recent years, but this remains generally poorly understood and underestimated. A good example is provided by the disproportionate regulatory burden on certain plant breeding approaches involving genome-editing where the genetic changes in the resulting organism are comparable to that achievable using conventional breeding, but the organism is regulated to the same extent as a GMO (e.g., the organisms listed in the new Schedule 1B that was added to the Gene Technology Regulations in 2019 following the Technical Review). This cost – with now-dated figures (from 2012) – was estimated at USD136 million, with a 13.1-year timeline from discovery to commercialisation[3]. Such costs and timelines can only be commercially justified where a high return can be guaranteed, which means that many highly innovative applications do not proceed and their potential benefits for agriculture is never realised. This is the negative consequence of a technology/process-based regulatory approach. Such precautionary approaches have become outdated over the past decade as technologies and products have moved beyond "traditional" recombinant DNA methods and transgenics. CropLife has previously made proposals throughout the multiple consultations in since 2016 to improve this situation in Australia:

- the Technical Review (December 2016)
- the resulting draft amendments to the Gene Technology Regulations (February 2018)
- Phases 1 (September 2017), 2 (December 2017) and 3 (May 2018) of the Third Review of the NGTS
- Phase 1 (December 2019) of the implementation of the recommendations of the Third Review of the NGTS
- the Food Standards Australia New Zealand (FSANZ) Consultation Paper on Foods Derived Using New Breeding Techniques (April 2018)
- the Review of the Food Standards Australia New Zealand Act 1991 (November 2020)

[3] See: Cost of bringing a biotech crop to market.

CropLife is fully supportive of appropriate and rigorous regulation of gene technology but we emphasise that it is equally important to recognise of the effects of poorly considered, duplicated and excessive regulation has on R&D, with increased costs and timelines, reduced investment in innovation, all the while not delivering any improvement in safety, health, or environmental outcomes.

Consultation is a core part of regulatory reform and CropLife supports rigorous and transparent processes for evaluating proposed changes and options. This must, though, be followed by action and not by more, prolonged and seemingly never-ending series of consultative rounds. Such prolonged processes require the investment of considerable resources by all involved and falsely adds to perceptions that the issue is insurmountably complex and risky.

Australia is missing out on opportunities in plant breeding due to its lack of action to enable a clear and proportionate regulatory pathway for contemporary technologies and approaches and will continue to if the recommendations from the NGTS review are not implemented in an effective and timely manner. The impacts of this are being felt, with research projects moved from Australia to North America due to the current regulatory burden: research that can be conducted under a US permit currently requires a Dealing Involving Intentional Release (DIR) in Australia, even where the species and traits are already well characterised. This impacts timeframes and imposes an unnecessary regulatory burden on applicants. Under a more proportionate regime that would recognise history of safe use and previous risk assessments, this research could have been conducted here. Another example of regulatory burden is the impact of the current regulatory system on stacked traits: even though the single traits have been assessed, any stacking of related or unrelated traits need to undergo a full assessment as part of a new DIR. Again, this proves costly and not proportionate to potential risk. We welcome the streamlining proposed under Option B, as it could potentially address these issues.

If agreed recommendations, including streamlining and the adoption of a more proportionate regulatory system, are not implemented, as was the case for previous reviews, there would be almost no point in participating in future reviews as this would appear to be a futile exercise.

2 PROPOSED DEFINITIONS

The Issues Paper released in 2019 for Phase One of the implementation of the recommendations of the Review explained that definitions in the *Gene Technology Act 2000* (GTA) were intended to be broad so that they remained effective and did not become outdated as technology evolved. These definitions were drafted in the 1990s and an unsurprising outcome of the Review was that these needed to be updated to clarify their scope (Recommendation 4). In CropLife's previous submissions, we have made detailed proposals for amendments that were consistent with implementing our preferred regulatory model ("Option 4" per the Technical Review). We also pointed out that even broad definitions could not be expected to remain relevant indefinitely and that reviews would continue to be required.

The amendments to the definitions proposed in the CRIS do not provide any additional clarity or futureproofing, or address the issues identified in the case studies presented in the Explanatory Paper.

2.1 Definition of *gene technology*

There are two changes proposed for this definition, the first being the addition of the word "creation". We strongly oppose the addition of this word to the definition of *gene technology*. The case study presented on page 11 of the Explanatory Paper refers to creating new organisms. This is misleading and speculative: while it is currently possible to chemically synthesise DNA and assemble it into larger fragments to ultimately obtain a chromosome[4] and introduce it to an *existing* host organism, it is not currently possible to create a *new* organism or create new life – as this term implies. Further, this is not even a realistically foreseeable possibility[5]. Furthermore, it is evident that such work would be captured by "modification of genes or other genetic material", with the term "modification" sufficiently broad. "Genetic modification" is internationally understood as referring to a novel combination of genetic material[6]. Conversely, "creation" is defined as bringing something into existence[7], which in this context is ambiguous, unnecessarily provocative and scientifically unsound.

The explanatory text on page 9 of the CRIS refers to "gene-editing" and "synthetic biology" in the justification for needing to amend the definition of *gene technology* to provide certainty. Gene (or genome) editing is not actually addressed at all with this proposed amendment, so no clarity is provided and synthetic biology is not even defined. There is no generally agreed definition of the term "synthetic biology", with it generally synonymous with "biotechnology" (and *gene technology* as currently defined - without amendment) and it is unnecessarily provocative and scientifically unsound to use it in an abstract way here in connection to "creation". We also find it highly questionable to provide for "creation" in a legislative definition based on speculation of what is to come in the "new scientific field of synthetic biology", especially considering that other technologies and applications (including genome-editing) that do in fact exist today are not addressed.

4 See e.g.: https://www.onlinelibrary.wiley.com/doi/full/10.1111/pbi.12466.
5 See: Future Trends in Synthetic Biology – A Report
6 See e.g., Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
7 E.g., Oxford Dictionary; Collins English Dictionary; Webster Dictionary.

The second change to the definition of *gene technology* that is proposed is to allow for techniques to be included via specification in the Gene Technology Regulations (GTR). We do not see what value this adds considering that the definition is already broad and that this change does not appear to allow for something that is not already possible through the ability to declare an organism a genetically modified organism (GMO) (or otherwise) in the GTR. For example, the most recent Technical Review resulted in the addition of Schedule 1B to the GTR in 2019, which specifically states that organisms resulting from certain specific genome-editing technologies are GMOs and hence those technologies are by default within regulatory scope. This would also be inconsistent with a proportionate regulatory model, which in principle should not be focussed on listing specific technologies for regulation.

The GTR example above illustrates that there is already a mechanism in place enabling review and amendment, but as we have stated previously, these reviews do not occur frequently enough. Technical reviews have only occurred three times: 2007, 2011 and 2016, with most of the outcomes of the latest review becoming law in 2019. This example also demonstrates that such reviews do not necessarily have proportionate and scientifically justifiable outcomes. These outcomes included listing defined organisms developed using genome-editing approaches (generally known as site-directed nuclease category 1, or SDN-1) in Item 4 of Schedule 1 (organisms that are not GMOs) and organisms developed using other certain genome-editing approaches were listed in a newly created Schedule 1B (organisms that are GMOs). During the period of the Technical Review, other genome-editing technologies with comparable outcomes to SDN-1 were reported (e.g., base-editing and prime editing), but it is unclear if the resulting organisms are currently within the scope of the exclusion as these technologies are not based on the exact same repair mechanism. Thus, regulatory ambiguity remains for more recently developed plant breeding tools.

We note that it is not clear from the Explanatory Paper or the CRIS how the existing (and proposed) mechanisms for technical reviews and inclusion/exclusion via the GTR would operate coherently alongside proposed/suggested new additional mechanisms, such as:

- non-notifiable dealings determination;
- other legally binding determinations issued by the Regulator;
- interpretive guidance issued by the Regulator; and
- enhanced use of the GMO Register.

We welcome further explanation of this, as this appears to increase complexity and makes it more difficult to determine the regulatory status of new innovations. We recommend that these mechanisms are an interim step before express inclusion/exclusion in the GTR.

As we have submitted previously, greater clarity is needed in the definition of *gene technology* that reflects contemporary needs and current scientific evidence and understanding, in combination with other existing mechanisms including more timely technical reviews of the GTR. CropLife's submission for Phase 1 of the Review included the following proposed amendment to the GTA definition of *gene technology*:

Proposed amendment to the definition of "gene technology" in the Gene Technology Act

Gene technology means any technique

(a) for the modification of genes or other genetic material; or

(b) specified in the regulations for the purpose of this paragraph

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.

This proposal is consistent with developments in other countries where regulatory processes have been introduced specifically for plants developed using genome editing[8]. This is also consistent with the SDN-1 exclusion resulting from the most recent Technical Review of the GTR (Schedule 1, Item 4), but it would necessitate a change to the organisms in the scope of the added Schedule 1B (Items 1 and 2). This proposal does not impact transgenic organisms that were already captured by the NGTS prior to the 2019 amendments to the GTR.

An additional mechanism that we have proposed previously is reflected in the suggestion on page 12 of the Explanatory Paper, whereby the Regulator can provide legally binding determinations. This is of potential utility, however, the more important determination is whether the resulting organism is a GMO within regulatory scope, rather than whether the technology used is *gene technology*. We have advocated for the Regulator to have the ability to provide legally binding determinations on this question in previous submissions, for the purpose of providing regulatory certainty to developers where this is not yet provided in the NGTS. It is critical that such determinations are transparent, based on current sound scientific evidence and understanding and be subject to review.

The Explanatory Paper (page 12) also suggests that the Regulator could provide interpretive guidance regarding *gene technology* and this may be of utility, but again in regard to whether the resulting organism is a GMO within regulatory scope. For example, this would be useful to ensure consistency of advice regarding what is in or out of scope of the genome-editing examples discussed above: Item 4 of Schedule 1 (organisms that are not GMOs) and Items 1 and 2 of Schedule 1B (organisms that are GMOs). With the continued development of new genome-editing approaches, clarity may be required regarding the scope of terms such as "site-directed nuclease", "nucleic acid template" and "homology-directed repair".

[8] Friedrichs et al (2019). An overview of regulatory approaches to genome-editing in agriculture. Biotechnology Research and Innovation, 3 (2) 208-20.

These additional mechanisms must be rooted in scientific reality, requiring the Office of the Gene Technology Regulator (OGTR) to keep abreast of scientific literature on technological developments and their outcomes. The determination process could be run on a case-by-case basis or scheduled to take place every year. Both options present their own advantages and issues, including reactivity or cost. We would welcome more specific proposals on these topics.

2.2 Definition of *genetically modified organism* (GMO)

As for *gene technology*, we strongly oppose the addition of the words "or created" to the definition of *genetically modified organism* (GMO). The Explanatory Paper again justifies this based on what "may become possible" in synthetic biology (still undefined) and a case study (page 14) that in our view clearly presents a *modified* organism, not one that has been *created*. Cell chassis are typically microbial cells (i.e., an *existing* host organism) with a *modified* genome, e.g., a chemically synthesised minimal or reduced genome.

The Explanatory Paper also mentions the interrelated defined term *organism* but does not propose amendments. We also do not propose any changes to this but note that some of the issues raised in the case studies in the Explanatory Paper may be more relevant to the scope of *organism* rather than *gene technology* and GMO. Amendments should not be made to the definition of GMO (or *gene technology*) as a way of expanding the scope of *organism.*

2.3 Definition of *deal with*

The proposed definition of *deal with* removes potential ambiguities and the breakdown in "make/supply/use" is a welcome way to ensure the definition remains futureproof. We note that the word "create" is not used in this definition of *deal with* and would strongly oppose its later addition, for the reasons explained above.

Our views on the proposed definitions remain consistent with our fundamental position that regulation must be commensurate with the risk presented by the characteristics of the product. We acknowledge that the NGTS will retain a process-based trigger but maintaining an emphasis on a process-based approach to define its regulatory scope will only result in it becoming increasing outdated and disproportionate. A case in point is the continued regulation of plants developed using certain applications of genome-editing (and cisgenesis) as GMOs based on the use of gene technologies when the outcomes are comparable to what is possible with conventional plant breeding methods. This is not proportionate, risk-based regulation and it imposes undue regulatory burden.

3 PROPOSED OPTIONS TO FUTUREPROOF THE NGTS

3.1 Options

Of the three options presented:

a. Option A of maintaining the status quo is clearly not a feasible option. This does not address any of the issues identified or implement any of the recommendations resulting from the Review. The result will be an outdated NGTS that provides a disincentive for R&D in Australia.

b. Option B is potentially the most aligned with the proposed best practice regulatory decision tree (the Decision Tree) submitted previously by CropLife[9]. The objective of that Decision Tree is to introduce streamlining of the regulatory approach based on risk-tiering, in a manner that is consistent with the overarching objectives of the NGTS of protecting human health and the environment. Further, Option B appears to be based on existing structures that the regulated community is familiar with, which will limit disruptions. Option B however, in its current form, falls slightly short of what would be a current, modern, world best regulatory system. Indeed, Option B does not clearly address "new" breeding techniques, particularly genome-editing and therefore does not address the main concerns of our industry in terms of bringing it up to date and providing some degree of future proofing.

   CropLife supports in principle the adoption of the three overarching authorisation pathways in Option B based on the indicative risk of a dealing. We welcome the proposal to consider matters such as the characteristics of the GMO, the type of dealings and whether effective risk management measures are known. This is consistent with the Decision Tree, would contribute to more proportionate regulation and remove some of the current regulatory burden. The case study provided in the CRIS about field trials with constructs/GMOs that have already been assessed is a textbook example of the issues CropLife has been raising for several years. A streamlined assessment for dealings that have a history of safe use/management would be a very welcome change and would lead to gain of time and efforts both for the regulated community and the OGTR.

   An enhanced Option B could also provide a specific regulatory pathway for clinical trials involving GMOs, without the need for any additional complications. It would give Australia a world best regulatory system and would provide a more efficient and streamlined approach than what is proposed as part of Option C. An enhanced Option B would work for all regulated communities and sectors in Australia and ensure the NGTS remains flexible, fit for purpose and futureproof. Moreover, an enhanced Option B would align Australia with its major trade competitors. This would prove critical for both agricultural and medical research and for Australia in general, as this would ensure the benefits from new innovations reach the Australian community.

[9] See: CropLife's submission to Phase 1 of the Review of the NGTS

In terms of risk criteria, those that are relevant to our industry are included in the Decision Tree and some are listed in the Explanatory Paper; the parent organism, the introduced trait (if any), the type of dealing and experience in risk management. We do not agree with two criteria suggested on page 17 of the Explanatory Paper: "the genetic modification responsible for the trait" and "the technology used to make the genetic modification". These are not appropriate risk criteria, considering that comparable outcomes are possible in plant breeding using gene technology and conventional tools. We also note that gene technology is not always aimed at traits; for example, in plant breeding genome-editing tools are also important for the acceleration of breeding programs to guide genetic recombination and facilitate efficient development of hybrid crop seeds.

As also evident in the Decision Tree, we welcome the recognition of assessments and approvals by other countries with comparable or recognised regulatory frameworks. This promotes more efficient use of resources and reduces duplication of efforts. An encouraging example is the current joint initiative between Health Canada and FSANZ to improve the efficiency and synchronisation of GM food safety assessments. The initiative has now moved to a pilot phase. Once the pilot is completed, the safety assessment sharing system will need to be finalised, including guidelines for applicants. This initiative can then be used as an example of good practices other regulatory agencies (and other countries) could adopt.

As we have noted at length above, CropLife deplores the lack of clarity on what Option B means for "new" technological developments in use or development in our industry: the CRIS and related Explanatory Paper do not explain how this Option (or Option C for that matter) provide the agility to respond to scientific advances and new applications of gene technology in a timely manner (CRIS page 7). No clarity is either given on how these options improve the current situation of disproportionate regulation of certain gene-editing approaches in the same manner as GMOs. Therefore, Options B and C, as presented, continue to be outdated and not fit for purpose. As stated earlier in this submission, such lack of clarity and disproportionality leads to research projects not being considered or being moved from Australia to other countries.

c. Option C appears to be largely the same as option B, with an additional initial categorisation step. This option seems to have been developed as an intermediate between Options A and B but adds a layer of complexity that appears unnecessary. The potential need for a double licence, as highlighted in the case study provided in the CRIS (page 30), would be a concern for the regulated community as it adds more regulatory burden and duplication. This option would also prove more difficult and burdensome for Institutional Biosafety Committees (IBCs). The matrix model adds complexity to the system and it could prove difficult to decipher which first category an application belongs to.

Another concern is the lack of flexibility of the three categories proposed as part of Option C. Relying on legislative changes to amend categories could prove long and frustrating for the entire regulated community and would further worsen the regulatory burden.

3.2 Non-notifiable dealings

The Explanatory Paper poses the question (pages 23 and 27) of what types of dealings would be appropriate to include in the non-notifiable pathway. CropLife strongly recommends that this pathway is applied to "new" technological developments to provide more proportionate regulation. This would include applications of gene technology in plants that are intended for release into the environment. For example, this pathway would be appropriate for certain genome-editing approaches used in plant breeding, including those that would currently fall within the scope of Schedule 1B of the GTR (site-directed nuclease applications involving template-guided repair, such as SDN-2, cisgenic SDN-3 and Oligonucleotide-directed mutagenesis, ODM). As we have presented at length in previous submissions, supported by ample scientific literature, these approaches can be used in plant breeding to achieve outcomes that could also be achieved using conventional tools, but in a more precise and efficient manner. Therefore, the resulting organisms do not present risks that would justify a licenced authorisation pathway. As also mentioned previously, regulatory clarity is lacking for more recently emerged genome-editing approaches, such as base-editing, which is expected to become widely adopted in plant breeding – such approaches should also fall within the scope of the non-notifiable pathway, if they are not within the GTR Schedule 1 exclusion.

Stacked traits would also be appropriate dealings to include in the non-notifiable pathway, as they are the result of conventional breeding, once single traits have been assessed, As mentioned earlier in our submission, stacked traits are currently disproportionately regulated.

We emphasise that the non-notifiable dealing pathway can only be an interim solution pending future (and timely) amendments of the GTR to provide broader exclusions. If the NGTS is to be agile and respond appropriately to developments, such review (and exclusions) should be conducted on a more regular basis. We suggest that this could be triggered by requests from applicants and/or from organisations, such as CropLife, representing developers. We also request that developers are able to apply to the Regulator for certain dealings or classes of dealings to be categorised as non-notifiable.

The non-notifiable dealing pathway is not entirely satisfactory since it presents an unnecessary step and therefore unnecessary complexity, as opposed to express and timely exclusions via the GTR. It could lead to issues further along the value chain and with trade since dealings listed as non-notifiable are still regulated in some way and would be considered GMO. A better, more proportionate option would be to provide for exclusions in the GTR, as part of the current implementation process, of applications of gene technology for the development of plant varieties that are similar or indistinguishable from varieties that could have been produced using conventional plant breeding methods, such as, for example, SDN-2 and ODM. The scientific basis for such exclusions is already provided in our previous submissions and is recognised in the reforms made in other countries. For example, recent reforms to the regulatory oversight of the United States Department of Agriculture (USDA) are specifically aimed at excluding genetic modifications in crops that are achievable using conventional breeding. These reforms have been made based on an extensive analysis of available scientific evidence. The variation we are proposing for Option B could pave the way for a more proportionate, futureproof NGTS and eliminate the need for further unnecessary, lengthy steps of regulatory reform.

We welcome more clarity and consultation regarding what a non-notifiable dealing could be, or a non-notifiable class of dealings, how these would be determined and what evidence (if any) would be required from a developer. The Explanatory Paper asks for risk indicators to guide the Regulator and we welcome further consultation on this. We support transparency on this topic but would caution against lengthy, broad public consultation to provide this information, given the highly technical nature of the topic. We wish to reiterate that for our purposes, the primary consideration should be whether the modification is indistinguishable from that achievable with conventional breeding tools.

CropLife supports the publication of the determinations to provide transparency, accountability and certainty for the regulated community and other stakeholders. It is not clear if such determinations would be additional to, or be of the same status as, legally binding determinations (as suggested on page 12 of the Explanatory Paper). We strongly emphasise that there is a need for regulatory clarity and that all these potential mechanisms need to operate in a coherent manner. Therefore, these mechanisms only provide interim solutions pending review and amendment of the legislative framework.

3.3 Licensed dealings

CropLife supports in principle the proposal to have three different types of licenced dealings, based on risk, history of safe use and management. Permits would be a very welcome option for GM crops, such as cotton or canola that have been assessed multiple times previously and therefore do not require case by case assessment and are amenable to a standard set of conditions. We also suggest that, consistent with the Decision Tree, permits should be applicable to GM crops that have been approved for cultivation in another country with a "recognised" biosafety regulatory system (i.e., one that follows the Organisation for Economic Co-operation and Development (OECD) and Codex Risk Assessment Guidelines). Obtaining a permit for such dealings would prove a gain of time for applicants and the Regulator and would ease some of the current regulatory burden. We welcome more clarity regarding standard licence conditions that would be associated with the obtention of a permit.

As set out in the Explanatory Paper (pages 31-32), we welcome the proposal for "expedited assessments" for dealings such as:

- A variation on dealings that would otherwise be eligible for a permit,
- Dealings for which the Regulator has extensive regulatory experience with the parent organism but requires a case-by-case risk analysis due to unfamiliarity with the introduced trait,
- Dealings previously licenced and with a risk assessment that could inform assessment of the new application,
- Dealings with the GMO that have been assessed and authorised by reputable regulatory agencies overseas.

These are examples relevant to our industry that improve streamlining of regulatory processes, with a gain of time and decreased regulatory burden. We add that the use (and update, if needed) of pre-existing risk assessments could help streamline processes. Also, as we proposed for permits, expedited assessments could also be considered for dealings that can be informed by risk assessments conducted by regulatory agencies in other countries.

We note that "expedited assessment" may not be the most appropriate term for the proposed pathway. While it may be expedited compared to a full assessment, it is not a partial or rushed assessment. A more fitting term may be "streamlined assessment", which is consistent with the recommendation to streamline processes (and the process recommended in the Decision Tree).

In principle, CropLife supports the proposal for full assessment to apply to dealings for which regulatory experience is limited or absent. More clarity is needed, however, regarding what would be considered high indicative risk and substantial uncertainty as to risk. We also seek clarity regarding timeframes, especially consultation timeframes. Varied consultation lengths could falsely lead to the perception that these dealings present more risk. The current consultation system for limited and controlled/commercial applications is clear. Similar clarity would be needed for full assessments.

CropLife supports in principle the Regulator having the ability to move dealings between authorisation pathways based on accrued scientific knowledge and understanding, as well as regulatory experience. This must be based on transparent and sound criteria set out in delegated legislation. We urge the timely development of this necessary detail and argue that such technical matters should involve consultation with the regulated community and relevant stakeholders but not the general public.

3.4 Delegated legislation

The CRIS explains that Options B and C rely on the elaboration of delegated legislation to provide much of the detail regarding the "eligibility criteria" for the proposed authorisation pathways. We recognise that this could potentially provide more flexibility to respond to the types of "new" developments of interest to our industry, but we require some clarity regarding the types/forms of delegated legislation that would be necessary or are envisioned. We welcome more explanation of what this could entail, the likely timeframes involved and which mechanisms would be put in place. Consultation with the regulated community and other relevant stakeholders would be needed to ensure the proposed options would indeed provide the necessary flexibility and regulatory clarity. Yet more rounds of consultations (as mentioned in passing in the CRIS) and prolonged processes are of concern for the regulated community.

4 ENABLERS AND TECHNICAL CHANGES

CropLife supports streamlining regulatory requirements and processes that are aimed at improved efficiency, effectiveness and flexibility of the NGTS, resulting in more risk-proportionate regulation, less undue regulatory burden and improved regulatory clarity in terms of a pathway to market for developers.

There are other areas of the NGTS that also require streamlining through process improvements. CropLife's submissions to the different Phases of the NGTS review and implementation have set out in detail its concerns regarding duplication of regulation between the OGTR, Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) for products regulated as GMOs. CropLife views removal of such duplication as a high priority, as it imposes heavy regulatory burden, time delays and costs on applicants, with no associated benefits. To improve this situation, CropLife recommends that the APVMA accepts the risk assessments of the OGTR and FSANZ, or that APVMA regulatory responsibility for GM products with incorporated pest and/or disease control is removed. This regulatory responsibility is an outdated remnant of the pre-OGTR system and these changes would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, businesses and community organisations. Therefore, we cautiously welcome Recommendation 80 from the Draft Report of the Independent Review of the Agvet Chemicals Regulatory System, recognising the importance of one regulator (here the Gene Technology Regulator) becoming the primary assessor and decision-maker, with the other regulator (here the APVMA) only playing the role of an advice-giver. As part of this model, efficacy and trade could be covered by industry stewardship practices.

CropLife supports the removal of some of the burden linked to confidential commercial information (CCI) as part of the futureproofing of the Scheme. Topics such as CCI transfer in case of, for example, company acquisition or CCI revocation as requested by an applicant should be streamlined and simplified. This would provide a significant gain of time for both the regulated community and the Regulator. CCI is a necessary part of the application process but the mechanisms described above would significantly ease the process.

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) Transpacific 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. We have advocated for data protection throughout the consultation process and still support initiatives that would ensure more solid and longer protection.

CropLife's previous submissions to the Review of the NGTS raised concerns regarding the use of Section 54 of the *GTA*. Section 54 provides anyone with the ability to request a copy of applications, except for any CCI. While we recognise that regulatory transparency has an important role in supporting technology and product acceptance, we are concerned that s54 does not protect the data owner's rights. The documents described in s54 can already be requested under the Commonwealth *Freedom of Information Act 1982* (*FOI Act*), therefore it is an unnecessary duplication in the *GTA*.

Section 54 duplicates some of the powers under the *FOI Act* but does not provide all its protections and does not include the same requirements, conditions, exemptions and procedures of the *FOI Act*. Contrary to the *FOI Act*, there is no consultation with affected third-parties to ensure all appropriate information is protected or redacted for CCI and privacy under s54. Section 54 also lacks conditional exemptions for personal privacy, business, research or economic reasons. Compared to the *FOI Act*, s54 does not have review and referral procedures, or oversight from the Office of the Australian Information Commissioner. Therefore, s54 does not protect the regulated community's privacy and data.

An additional concern for the regulated community is that the OGTR is required to maintain a public FOI disclosure log that records if/when and what documents have been released under the *FOI Act*. There is no such requirement for the Regulator to maintain a public record of documents released under s54, thus the process lacks transparency. Section 54 also imposes an unnecessary burden on the OGTR as limited resources are used to repetitively deal with requests for the same information. If the documents were released *via* the FOI disclosure log, any person would be able to access the documents online without diverting OGTR resources away from core business.

The adoption of an automated database, together with electronic submissions, that could be shared between regulatory agencies and an improved interface would prove a simple way to streamline processes and would alleviate some of the burden both for the OGTR and for applicants. Furthermore, such measures could potentially help reduce application timeframes. Online, real-time tracking of the assessment and licensing process would equally simplify the application process for the regulated community.

Ongoing training for IBC members would be a requirement and would need to consider different levels of expertise between IBCs. Both administrative and legislative changes will impact the way the regulated community interacts with the Scheme and education and training is a key part of ensuring a smooth transition.

5 OTHER CONSIDERATIONS

Under Options B and C, it is proposed that the process for listing on the (existing) GMO Register would be streamlined. CropLife has expressed its support for increased use of the GMO Register in previous submissions (Phase One, NGTS Review) and we support the two proposals on page 24 of the CRIS, namely that:

1. The eligibility criteria be changed so that there is no longer a requirement for the dealing to have been previously authorised under a license; and
2. A determination by the Regulator to include a dealing on the GMO Register be an administrative decision made by written instrument, instead of being made by legislative instrument.

CropLife still supports the use of the GMO Register to address low level presence (LLP) concerns by listing GM crops that are no longer commercially produced in Australia (also known as discontinued products). If a licence-holder decides to discontinue the sale of a licenced GMO, said GMO should be added to the Register, to address any risks of LLP in the environment. If a third-party was then to decide to make, supply, use or sell the GMO (following patent expiry), they would have to apply for a new commercial licence.

6 CONCLUSION

CropLife and our members have constructively engaged in all previous consultations and proposed specific initiatives to improve the system, both in its effectiveness and its efficiency. Despite our frustration with the slow process and lack of proper implementation of most of these reforms, we remain committed to continuing to work constructively with the Federal Government to ensure Australia has a world-leading biotechnology regulatory system.

CropLife welcomes this consultation as a sign of progress towards implementation of key recommendations resulting from the Review of the NGTS. We especially welcome that efforts are being directed to amendments providing a more proportionate regulatory system. We have expressed our concerns at length, here and previously, regarding the urgent need for a proportionate regulatory approach and clarity on a path to market for plant breeding tools used by or in development in our industry.

Our main concern is that the NGTS will remain outdated and unfit for purpose following the implementation of either option presented. The proposals made in this consultation have the potential to contribute to a more streamlined approach to the regulation of gene technologies that have long been in use in our industry (i.e., GM crops). Regarding "new" technologies, we strongly advocate for a regulatory model consistent with "Option 4" in the Technical Review as this provided the most proportionate and scientifically justifiable approach. The proposals we have supported in this consultation are aimed at achieving the next best outcome within the current process-based policy constraint. We emphasise that continued reliance on this outdated constraint as an obstacle will eventually have to be addressed if the NGTS is to remain relevant and have the necessary futureproof agility. We argue that the NGTS should exclude from its scope applications of gene technology resulting in plant varieties that are similar or indistinguishable from varieties that could have been developed through conventional plant breeding methods. This would be an important step in the implementation process to remove disproportionate regulation.

None of the options proposed in this consultation are optimal but we remain hopeful that they may contribute to a vast improvement on the current situation. We have concerns about the complexity of what is proposed, with many mechanisms potentially operating in tandem and that there is still much to be done – the criteria to be devised in delegated legislation is what will have the greatest impact on gene technology innovation in Australia.