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Gene Technology Implementation Team
Office of Health Protection Division
Department of Health
CANBERRA ACT 2600

Via email: Gene.Technology.implementation@health.gov.au

17 March 2021

Dear Gene Technology Implementation Team

Re: Consultation Regulation Impact Statement – Modernising and Futureproofing the National Gene Technology Scheme

As the national peak industry organisation representing the agricultural chemical and plant biotechnology sector in Australia, CropLife Australia provides the attached submission in response to the *Consultation Regulation Impact Statement – Modernising and Futureproofing the National Gene Technology Scheme*.

The National Gene Technology Scheme is science-based and has so far proven effective and robust. The Scheme is, however, currently falling well behind of what Australia requires to ensure it has a world best practice regulatory system. Parts of the Scheme are no longer fit for purpose, leading to unnecessary regulatory burden for applicants and uncertainty that is detrimental to investment in research and development in Australia.

The Consultation Regulation Impact Statement proposes options to futureproof the Scheme. CropLife supports the concept of a proportionate regulatory model with more flexibility to respond to scientific advances to ensure Australia can reap the benefits of such innovations. All options as they stand would lead to the new system becoming obsolete before it is even implemented.

CropLife's submission proposes options to properly futureproof the Scheme, based on our previous submissions to both the Review of the National Gene Technology Scheme and to the Technical Review of the Gene Technology Regulations. We include proposals to moderately enhance one of the options presented by the Department, making best use of the implementation process to address issues of appropriate regulation of new breeding techniques. These proposals are practical, feasible and consistent with the core principles of the Scheme.

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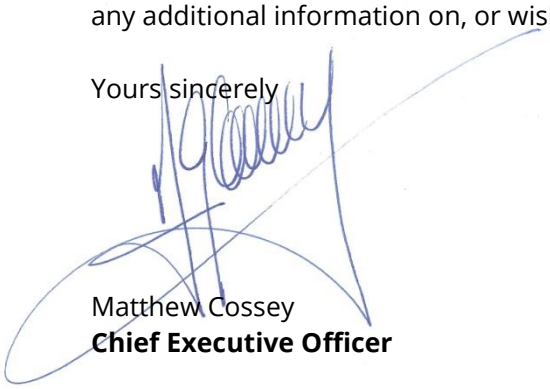
Please do not hesitate to contact me, or have your team contact CropLife's Director of Crop Biotechnology Policy, Dr Anne-Sophie Dielen, on 02 6273 2733 or annesophie.dielen@croplife.org.au should you require any additional information on, or wish to discuss any aspect of this submission.

Yours sincerely



Matthew Cossey
Chief Executive Officer

CropLife Australia

March 2021

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.