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

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

29 November 2019

Dear Secretariat

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

As the national peak industry organisation representing the agricultural chemical and plant biotechnology sector in Australia, CropLife Australia welcomes the opportunity to provide a submission to *Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1*.

While the Scheme is efficient, effective, robust and most importantly science-based, it needs modernisation. Technology is advancing at a rapid pace and parts of the National Gene Technology Scheme are no longer fit-for-purpose.

The implementation of the recommendations from the Third Review of the National Gene Technology Scheme is crucial 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's submission proposes options to future-proof 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 consider these options to be practical, feasible and consistent with the core principles of the Scheme.

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

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CropLife Australia

29 November 2019

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

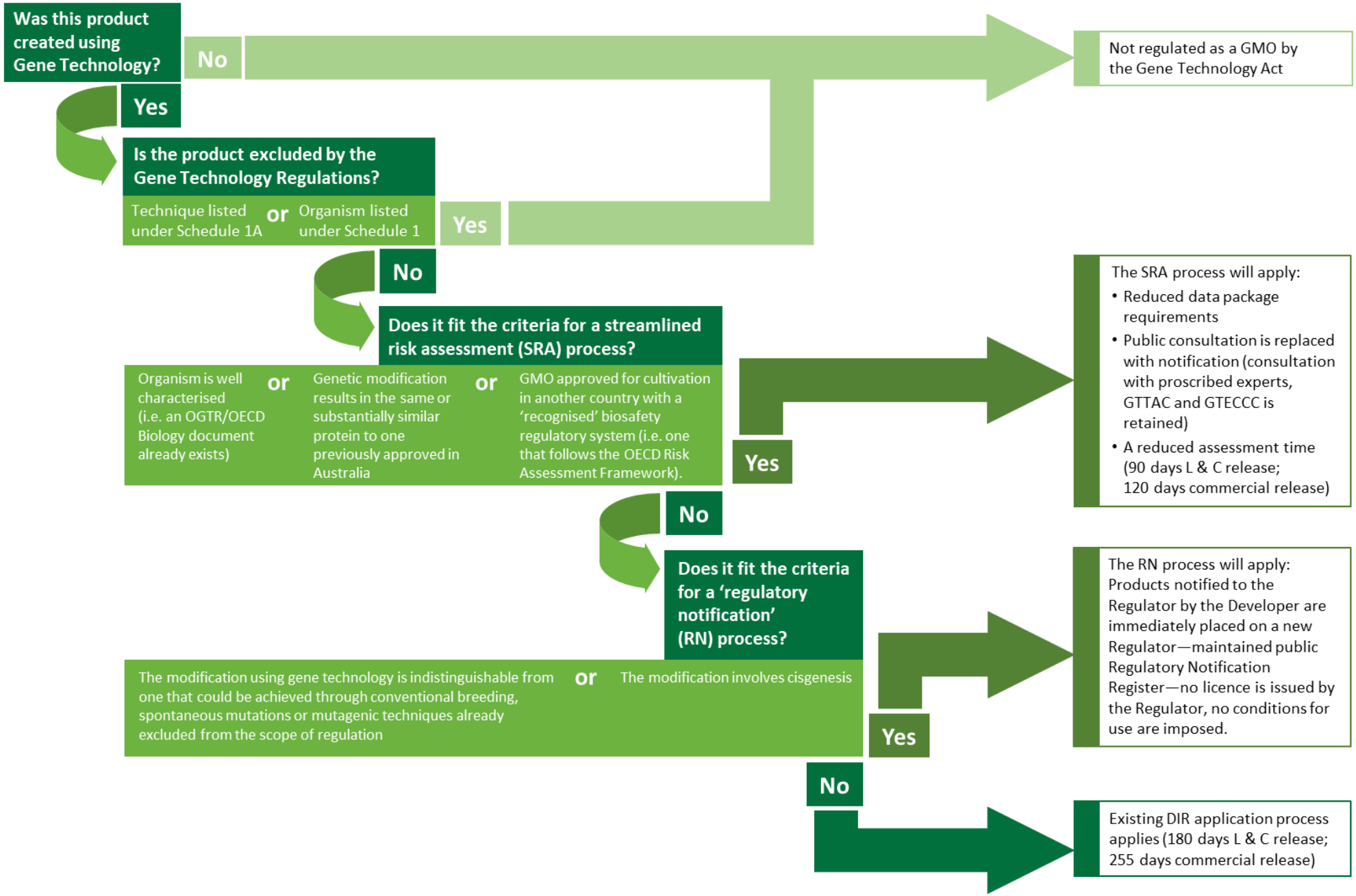
accumulates about these technologies and their resulting organisms, the criteria for the SRA and RN categories should expand, there should be cases that shift from the requirements of the SRA category to the RN category, and there should be cases identified in the RN category for exclusion from regulatory 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.