BASF Australia Ltd submission to Phase 1 of the Implementation of the Recommendations of the Third Review of the National Gene Technology Scheme

BASF Australia Ltd (BASF) is a diverse chemical, biological product, nutritional and seed business supported by an extensive global research and development framework. The research and development framework in plant breeding and trait development has a strong history in the area of development of products of gene technology and also in the development of plants bred using conventional breeding techniques.

As a company we welcome the opportunity to provide comment to the Issues Paper (September 2019) on the Implementation Phase of the review of the National Gene Technology Scheme (NGTS).

In Australia, BASF is involved in commercial seed sales and trait licensing, with activities including breeding and seed multiplication. Our historical experience with genetically modified crops in Australia goes back to the inception of work in this area in canola in the mid-1990s. Similarly, experience gathered over the years with the evolving National Gene Technology Scheme can be dated from its commencement to now. Our experience is in agricultural biotechnology and the comments we make are mainly related to this area.

In making this submission on the Issues Paper[1], we wish to reinforce messaging delivered by the plant biotechnology industry through the multiple stages of public consultation that we have participated in in recent years. This has included contributions to the 2016 technical review of the Gene Technology Regulations (GTR) (Technical Review), and contributions to the three phases of the third review of the NGTS. BASF wishes to highlight the following positions as having relevance to the current Issues Paper –

1. That the definition of "gene technology" and any associated exclusions to that definition must be reassessed in order to future proof the NGTS, provide regulatory clarity, and remove the disincentives to innovation in Australia that currently exist. We propose ways in which this could be achieved for the types of products we develop, in combination with several other streamlining mechanisms aimed at providing greater flexibility in assessment and decision making.
2. That an effective and efficient regulatory scheme requires removal of duplicative regulatory processes involving the assessment of the same information by multiple agencies.
3. That an effective, efficient and proportionate regulatory scheme requires more streamlined regulatory processes and requirements that allow for taking into account the accumulated knowledge and experience gained regarding regulation of "gene technologies" and the resulting organisms, and decision-making based on a risk-tiered approach.
4. Consistency of the regulatory approach applied by the Office of the Gene Technology Regulator (OGTR) with other agencies such as Food Standards Australia New Zealand (FSANZ)

Within this submission we address these points more extensively. Previous submissions by CropLife Australia (CropLife), to which we have contributed, have provided our stance on topics raised in the Issues Paper at earlier points in the consultation processes associated with the NGTS review.

[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.

We appreciate that elements of proposed change may not be able to be quickly implemented. However, certainly in the area of defining "gene technology" and any exclusions from this definition in the *Gene Technology Act 2000* (*GTA*) and subordinate legislation or guidelines managed by the Gene Technology Regulator ("the Regulator"), we see implementation of proposed changes as of highest priority in allowing stakeholders of the Scheme to move forward with development of innovations in plant breeding and provision of products thereof to the Australian farming community.

Definitions to support the NGTS

During the Technical Review, four Options for regulating certain "new" technologies were proposed.[2] BASF's preferred Option was Option 4, and this position, along with the scientific rationale, was clearly stated in CropLife's submission. It was understood at the time that implementation of Option 4 as a result of the Technical Review was limited by the underpinning process-based policy principles of the NGTS.

Upon the commencement of the third review of the NGTS in 2017, CropLife's submission to Phase 1 of the NGTS review provided a proposed revision to the definition of "gene technology" that is supported by BASF and is provided in the box below. The proposed amendment is consistent with the intention to develop a broad definition of "gene technology" within the *GTA*, provided that certain gene technologies can be excluded from its scope in Schedule 1A of the GTR, and certain organisms resulting from gene technologies are excluded from regulatory scope via Schedule 1 of the GTR. The proposed amendment is also consistent with international developments in regulatory processes with respect to 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.

This proposed amendment is consistent with the SDN-1 exclusion resulting from the Technical Review, and it 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. The SDN-1 exclusion was based on the changes it results in being "no different to natural mutations, [and]

[2] Office of the Gene Technology Regulator (2016). Technical Review of the Gene Technology Regulations 2001. Discussion Paper: Options for Regulating New Technologies. http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf

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

they do not give rise to any different risks to natural mutations."[4] This is consistent with the scientific evidence, however the scientific evidence also shows that a proportionate scheme would not capture all other types of genome editing techniques and resulting organisms.

Enactment of the proposed amendment to the definition of "gene technology" would contribute to giving effect to Option 4, originally proposed in the Technical Review of the GTR, and a Scheme which is more risk-proportionate when considering the risk of the resultant product.[5] In addition to the proposed amendment to the definition, CropLife proposed that the use of cisgenesis in plants is excluded via its addition to Schedule 1A of the GTR, on the basis that the resulting products are equivalent to that which could be developed using conventional breeding techniques. These proposals are consistent with maintaining a "process-based trigger as the entry point" to the NGTS (Recommendation 8).

In combination, the CropLife proposed changes (supported by BASF) are an example of how definitional change could make for a more agile, proportionate and future-proof NGTS that are consistent with developments in other countries where regulatory processes have been introduced specifically for plants developed using genome-editing. These proposals support the fundamental position of BASF and other CropLife member companies 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. In addition to these changes, we urge that that reviews of the GTR occur more frequently, and with timelier implementation of amendments necessary to ensure they are meeting their intended purpose. In the following sections of this submission we propose additional mechanisms that could also contribute to a more streamlined, risk-based NGTS.

Removal of regulatory duplication

Addressing duplication of activities by regulators in the approval of dealings with products of gene technology is an important issue that should also be addressed as a matter of priority in the implementation of the outcomes of the NGTS review.

The history of the current NGTS as it relates to plant breeding innovations is that the *GTA* and its subordinate regulations were developed as a Scheme with many interfaces to existing regulatory Schemes, e.g. *Food Standards Australia New Zealand Act 1991*, *Agricultural and Veterinary Chemicals Code Act 1994*, etc. These interfaces to other Schemes have resulted in significant complexity for applicants when it comes to ensuring that all required approvals are in place. For example, addressing the requirements of the APVMA for insect resistant and pathogen resistant crops typically involves delivery of the same information

[4] Office of the Gene Technology Regulator (2017). Updating Gene Technology Regulation in Australia. Regulatory Impact Statement for Consultation. p.10.
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/39DB72B3BB9AA790CA25823B00812B73/$File/Regulation%20Impact%20Statement%20for%20consultation.doc
[6] CropLife Australia (2017) Submission to the 2017 Review of the National Gene Technology Regulatory Scheme. Canberra, Australia. p. 7

on a product to APVMA that has already been received by FSANZ and the OGTR. This regulatory process is extremely time-consuming and costly for the applicant and necessitates duplicative and redundant effort from the regulators. This provides no additional value in terms of risk assessment and risk management and is wasteful of resources, both for the applicant and government regulators.

An example of the above is the APVMA's consideration of insect resistant crops that have been developed to express pesticidal proteins. These are treated as "active ingredients" by the APVMA who currently lacks the necessary in-house expertise to evaluate such crops. The OGTR and FSANZ have the appropriate expertise for evaluation of gene technology products and vesting them with responsibility for evaluation of risks to human health and the environment, as currently happens, is appropriate. Involvement of the APVMA in the approval process for gene technology products is duplicative and unnecessary.

Streamlining the Gene Technology Scheme

CropLife proposed a Decision Tree for streamlining regulatory requirements in their submission to Phase 1 of the NGTS review.[6] BASF continues to support the Decision Tree and the approach proposed for its use in streamlining the NGTS.[7]

With regard to Recommendation 13(a), BASF Australia Ltd as a developer of products with long lead-times and requiring significant investment, 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 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 and predictability regarding the path to market should not be underestimated. Developers of new products need to understand well in advance (many years) whether to invest in the research and commercialization of a new product. If the scope of regulation for these products is not well understood, no reliable business decision can be made. Costs to generate extensive packages of regulatory data are substantial and can be a deciding factor on whether to advance a project.

BASF supports the underlying principles of the NGTS of efficient and effective regulation that is proportionate to risk Therefore we support the intent of Recommendations 9, 10 and 20.[8]

BASF strongly agrees with the idea in the Issues Paper that regulatory efforts need to be focussed where risk assessment and management is necessary, rather than in imposing unjustified regulatory burden. The CropLife Decision Tree (supported by BASF) illustrates how risk-tiering could be applied to the types of products we develop, and also be expanded to include other types of organisms.

We reiterate below the CropLife proposed Decision Tree, which combines elements of process and product-based regulations: the entry point (or "trigger") is the use of gene technology, which is followed by four

[6] CropLife Australia (2017) Submission to the 2017 Review of the National Gene Technology Regulatory Scheme. Canberra, Australia. p. 7
[7] CropLife Australia (2019) CropLife submission to Phase 1 of the Implementation of Recommendations of the Third Review of the National Gene Technology Scheme. Canberra, Australia.
[8] Department of Health (2019). *Op. cit.*

decision points that are based on defined criteria for different risk-tiers and mechanisms discussed when this Decision Tree was originally proposed[9]:

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 the products we develop) 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 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, we support these recommendations for the purpose of enabling more efficient and effective NGTS that is proportionate to risk and remains so with technological advancement, but contend that a broader range of defined science-based criteria should be the basis of moving organisms between

[9] CropLife Australia (2017). *Op. Cit*.

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*.

Principles-based regulation

BASF Australia Ltd is willing to explore the utility of principles-based regulation and its applicability to the NGTS. However, we do so with a desire to understand further the detail associated with effecting this style of regulation for the NGTS.

Should the path to develop the NGTS using principles-based regulations be taken, it is important to understand the nature of the proposed changes in structure to the scheme and the intended outcomes. BASF is unable to comment further on this issue without a clear proposal on principles-based regulation. However, the implementation of amendments and mechanisms such as we have proposed to improve the current NGTS should not be held back by consideration of the applicability of principles-based regulation to the NGTS.

Consistency of the regulatory approach applied by the OGTR with other agencies such as FSANZ

Food Standards Australia New Zealand (FSANZ) commenced examination and discussions on the "new plant breeding techniques" a significant time before these two review processes – in 2012/2013 . Eight years later developers of food crops utilizing new plant breeding methodologies are still seeking clarity and commitment to reform that provides proportionate and harmonized approaches from both FSANZ and OGTR. It is imperative that FSANZ , OGTR and the Department of Health work closely as part of the implementation phase of the NGTS review to ensure some measure of uniformity in approaches taken.

Conclusion

BASF appreciates the opportunity to contribute to the stakeholder consultation process for the Issues Paper on Implementation of the Review of the NGTS. Our positions are aligned with those of the CropLife submissions that have been made throughout this process since 2017. We share the concerns of CropLife that the process of review of the NGTS and implementation of the review outcomes has been drawn out and the ongoing lack of regulatory certainty for products derived from certain new technologies presents an obstacle to investment in R&D. As a result, farmers and Australian consumers are being denied access to innovative products that other countries already have access to. We urgently need a NGTS that is more responsive, effective, efficient and risk-proportionate and we request that the many proposals we have made throughout this process are given thorough consideration.