BASF Australia Ltd submission on the National Gene Technology Scheme, Consultation Regulatory Impact Statement

17 March 2021

BASF Australia Ltd (BASF) is a large and diverse business with a broad portfolio of fungicides, herbicides, insecticides and biological crop protection products, as well as seeds, traits, seed treatment products and digital solutions. Our scientific expertise extends much further than agriculture. We also provide innovative solutions for human nutrition, professional pest control, ornamentals, turf and landscape management.

BASF welcomes the opportunity to comment on the Consultation Regulatory Impact Statement (CRIS[1]), and the accompanying Explanatory Paper,[2] to support implementation of key recommendations from the third review of the National Gene Technology Scheme (NGTS). We particularly welcome efforts aimed at implementing a more proportionate regulatory model that better incorporates the vast body of scientific evidence, accumulated knowledge, and regulatory experience that exists today.

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 (GM) crops in Australia goes back to the inception of work in this area in canola in the mid-1990s. Our experience is in agricultural biotechnology and the comments we make in this submission are mainly related to this area.

BASF wishes to reinforce messaging delivered by plant biotechnology developers and plant breeders through the multiple reviews and phases in recent years, via CropLife Australia (CropLife) and the Australian Seeds Federation, respectively. This has included contributions to the 2016 technical review of the Gene Technology Regulations (GTR), the three phases of the third review of the NGTS (2017-2018), and Phase 1 of the implementation of recommendations of the third review of the NGTS (2019). In this latest round of consultation, BASF highlights the following points:

1. Amendments to definitions in the *Gene Technology Act 2000* (Cth) must be aimed at providing regulatory clarity for existing and future developments in gene technologies and the resulting organisms. There is currently a lack of clarity regarding their application to certain technologies in development and use in our sector (that continue to be described as "new"), or their scope is unjustifiably broad. Consequently, regulatory oversight is not commensurate with risk, and inconsistent with the aim of a more proportionate regulatory model. The proposed amendments to the definitions of *gene technology* and *genetically modified organism* do not address current needs, nor future needs. This ongoing situation presents disincentives for investment in innovation in our sector in Australia.

[1] Consultation Regulation Impact Statement: Modernising and future-proofing the National Gene Technology Scheme - Proposed regulatory framework to support implementation of the Third Review of the Scheme. Department of Health, Commonwealth of Australia, December 2020.

[2] Explanatory Paper: Modernising and future-proofing the National Gene Technology Scheme - Proposed regulatory framework to support implementation of the Third Review of the Scheme. Department of Health, Commonwealth of Australia, December 2020.

2. Of the "options" presented, Option B appears to be most consistent with a more effective, efficient and proportionate regulatory scheme for **established** (i.e. transgenic) gene technologies/GMOs. It also appears to generally be consistent with the "Decision Tree" proposed previously by CropLife (2017[3]), which aimed to introduce risk-tiering and streamlined regulatory processes for established technologies as well as "new" technologies.

3. None of the "options" presented clearly address the concerns of the plant science industry which have been submitted several times previously, most notably that there is a lack of clarity regarding the scope of regulatory oversight for technologies in development and use in the agricultural plant science industry, and it remains disproportionate in that certain gene technologies/organisms are within the scope of regulatory oversight where there is no scientifically sound justification. There are several examples of this in plant breeding where "gene technologies" can be used to develop plant varieties with the same modifications (and risk profiles) as varieties developed using conventional tools. We maintain our position that such plants should be excluded from the scope of GMO regulation.

4. We recognise that multiple mechanisms are proposed or suggested in this consultation that are aimed at complementing the proposed options to provide agility for responding to new developments. We can also envisage how some of these could provide a pathway for products that we believe should be excluded from the scope of GMO regulation. We can therefore support some of these mechanisms in principle, however much of the necessary detail still needs to be developed. It also remains unclear how these can operate together in a coherent and transparent way and not create excessive complexity.

5. There is currently no provision under the *Gene Technology Act* for data protection such as that afforded by equivalent Acts such as the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth). It is our preference that the *Gene Technology Act* incorporates data protection provisions for information and data submitted to the Office of the Gene Technology Regulator (OGTR). We recommend that the *Gene Technology Act* also incorporates the ability for the OGTR to deal with confidential information in a more simplified and less cumbersome way than is currently practiced.

6. We once again emphasise that a consistent and harmonised regulatory approach must be applied by the OGTR with other agencies such as Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

We strongly urge the Gene Technology Implementation Team to push for an effective resolution to what has been an extraordinarily prolonged period with repeated rounds of consultation on largely the same subject matter. The lack of timely and meaningful reform means that what was once one of the world's most robust science-based regulatory frameworks is now lagging behind. With the current consultation we remain concerned that there is still no clear path forward for implementing many of the recommendations of the

[3] CropLife Australia (2017) Submission to the 2017 Review of the National Gene Technology Regulatory Scheme. Canberra, Australia. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/C28DC671DFEB6FDBCA2581CF00775388/$File/CropLife%20Australia.pdf.

third review of the NGTS, or the shortcomings of the 2016 technical review of the GTR in relation to "new" technologies which were understood to be an interim solution.

Proposed amendments to definitions in the *Gene Technology Act*

The 2019 Issues Paper[4] regarding implementing the recommendations of the third review of the NGTS explains that the definitions in the *Gene Technology Act* were intentionally broad so that they did not quickly become outdated as technology evolved. The CRIS and Explanatory Paper make proposals for changes to the definitions of *gene technology*, *genetically modified organism* and *deal with*, each of which we comment on in detail below.

Definition of *gene technology*

Two changes are proposed to the definition of *gene technology*. The first change is the proposed addition of the word "creation". BASF strongly opposes this addition, primarily because it is unnecessary, there is no sound scientific explanation for its adoption, it is misleading due to the connotation that may be attached to it, and the potential breadth of its application.

We believe, the addition of "creation" to the definition of *gene technology* is confusing as it is not clear if it is referring to the creation of DNA or the creation of an organism, and this is not clarified by the example provided in the case study on page 11 of the Explanatory Paper. In the context of the *gene technology* definition, it should be refering to DNA, for which "creation" is more correctly described as synthesis, or synthesis and assembly, which have long been enabling tools used in biotechnology. Their outcomes remain sufficiently captured by "modification of genes or other genetic material" in the existing definition, with "genetic modification" internationally understood as referring to a novel combination of genetic material.[5] In our view, the example provided in the case study on page 11 of the Explanatory Paper is clearly captured by the existing definition.

In regard to the creation of organisms, while not relevant to this definition, it should be made clear that current and foreseeable scientific capability is the introduction of chemically synthesised and assembled DNA into an *existing* host cell. It is not currently possible, or foreseeable, that an entirely *new* organism or new life can be created, which this term implies and/or may be perceived as suggesting is possible.

The justification for use of the addition of "creation" in the CRIS refers to "gene editing" and "synthetic biology". However, gene editing is not addressed at all by this proposed amendment, and it is already captured by "modification of genes or other genetic material". Further, the term synthetic biology is not even defined, nor is there a generally agreed or internationally adopted definition of it. The proposed changes,

[4] Issue Paper: Implementing recommendations of the third review of the National Gene Technology Scheme: Phase 1 - Modernising and future-proofing the National Gene Technology Scheme. Department of Health, Commonwealth of Australia, September 2019.

[5] See e.g., Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

therefore, do not address anything of substance, and such a proposal appears based on speculation of what may come in the future whilst current real needs remain unaddressed.

For Phase 1 of the third review of the NGTS in 2017, CropLife proposed an amendment to the definition of *gene technology* which is supported by BASF and provided again in the box below. This proposed amendment is compatible with maintaining a "process-based trigger as the entry point" to the NGTS (Recommendation 8 of the third review of the NGTS), however we maintain that such an approach will never be completely "future-proof". This proposed amendment is also consistent with the original intention of maintaining a broad definition, which is workable provided that mechanisms remain in place enabling certain gene technologies and/or the resulting organisms to be excluded from regulatory scope via the GTR.

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 2019 amendments to the GTR (following the 2016 technical review), and maintaining the applicability of the NGTS to established (transgenic) technologies/GMOs. However, the proposed amendment would also have the effect of excluding certain organisms developed using other types of genome editing approaches that were explicity included in the scope of the NGTS by the 2019 amendments to the GTR, and for which we maintain should not be regulated in the same manner (i.e. GTR Schedule 1B). The "policy settings" that did not allow the exclusion of gene editing approaches (e.g. SDN-2, ODM) for developing products that could have also been developed using conventional breeding have not been addressed in the proposed amendments. We view this as a significant shortcoming of the current proposals.

The SDN-1 exclusion was based on the changes being "no different to natural mutations, [and] they do not give rise to any different risks to natural mutations"[6]. This is consistent with the scientific evidence, however, the scientific evidence also supports broader exclusions for changes that could have also been achieved using conventional tools. Our proposals are intended to give effect to such exclusions, and are

[6] Office of the Gene Technology Regulator (2017) Updating Gene Technology Regulation in Australia. Regulatory Impact Statement for Consultation. Available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/39DB72B3BB9AA790CA25823B00812B73/$File/Regulation%20Impact%20Statement%20for%20consultation.doc.

aligned with our fundamental position that plants developed using "new" technologies, including genome editing, should **not** be within the regulatory scope of the NGTS if:

(a) There is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a defined genetic construct), or;

(b) The final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;

(c) The genetic variation is the result of spontaneous or induced mutagenesis.

In the 2017 technical review of the GTR,[7] "Option 4" was preferred by our industry due to its consistency with our fundamental position, with its focus on the risks presented by the product. Supporting scientific rationale for such an approach was elaborated at length in CropLife's submission.[8] In addition to the proposed amendment to the *gene technology* definition, CropLife also recommended exclusion of the use of cisgenesis in plants (via addition to Schedule 1A in the GTR), again on the basis of the resulting product being comparable to that which could be developed using conventional breeding tools.

In combination, the changes proposed by CropLife (and supported by BASF) are an example of how definitional changes could give effect to a more proportionate NGTS that is consistent with developments in other countries where regulatory processes have been introduced specifically for plants developed using "new" technologies such as genome editing and cisgenesis.[9] These proposals support 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 comparable outcomes can be achieved with conventional breeding tools is not proportionate, risk-based regulation, and imposes undue regulatory burden.

The second change to the definition of *gene technology* that is proposed is to allow for techniques to be included via specification in the GTR. We do not see what value this adds considering that the definition is already broad, and that it is already possible to declare an organism a genetically modified organism (GMO) (or otherwise) in the GTR. For example, the 2017 technical review of the GTR 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.

[7] Discussion Paper: Options for Regulating New Technologies - Technical Review of the Gene Technology Regulations 2001, Office of the Gene Technology Regulator, October 2016.
[8] CropLife Australia (2016) CropLife Submission to the Discussion Paper on Options for Regulating New Technologies. Canberra, Australia. Available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/$File/CropLife%20Australia.pdf.
[9] Friedrichs *et al* (2019) An overview of regulatory approaches to genome editing in agriculture. *Biotechnology Research and Innovation*, **3**(2) 208-20.

Definition of *genetically modified organism*

In line with our strong opinion against the use of the word "creation" in the definition of *gene technology*, we also oppose addition of the words "or created" to the definition of *genetically modified organism* (GMO). The case study on page 14 of the Explanatory Paper and discussion on what may become possible in the science of "synthetic biology" (for which no definition is offered in the paper) represent a *modified* organism, not one which has been "created". To remove doubt, if such an organism is in fact created in the future, it could be declared to be a GMO in the GTR as provided for in the current definition.

Definition of *deal with*

We support the proposed change to the definition of *deal with* as it simplifies the definition, making it less complex in its interpretation, and it also succeeds in future-proofing the definition.

Legally binding determinations and interpretive guidance

BASF supports CropLife's previously suggested mechanism whereby the Regulator can provide legally binding determinations to potential applicants. Page 12 of the Explanatory Paper captures this proposal by suggesting a process by which the Regulator may provide a legally binding determination on whether a specific technique is *gene technology*. We emphasise that the more important question that often needs clarification is whether or not the resulting organism is a GMO within the scope of the NGTS, not whether or not the technology used is *gene technology*.

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 the scope of the NGTS.

We are of the strong view that these additional mechanisms must be based on scientific evidence and reality, and would therefore require policy changes which are consistent with the relevant scientific literature. We welcome more specific proposals on these mechanisms, and emphasise that such determinations must be transparent and subject to review.

Proposed Options & Authorization Pathways

BASF's preference among those presented is Option B. Option A represents maintenance of the status quo which is clearly untenable as it fails to address any of the issues identified by us and others throughout the many consultations in the NGTS reviews.

Option B would result in modifications to the structure of the NGTS that appear to be consistent, at least in principle, with the "Decision Tree" proposed by CropLife (and supported by BASF), which set out risk tiering and streamlined pathways applicable to both established and "new" technologies.

A potential refinement to Option B may be to establish a separate pathway for assessment of medical applications as proposed in Option C. This may have advantages in assessment as some of the issues specific to medical applications will not need to be addressed for other types of applications.

Option C is similar to Option B, except for the additional categorisation step for the dealing. This additional step creates a more complicated decision matrix and appears to offer less flexibility in administration of the NGTS.

We note with concern that the "eligibility criteria" for the pathways in Option B include "the technology used to make the genetic modification" (Explanatory Paper, page 19), and that the consultation documents generally convey the message that risk may be determined based on the technology used. This is a contention we have long challenged, as presenting a technology as being inherently risky is misleading and perpetuates misunderstanding. After more than four decades of experience with gene technologies we now have sufficient knowledge to show that uses of such technologies need less regulation rather than more.

Licensed dealings

In line with CropLife, BASF supports the the proposal to have three different types of licenced pathways. We welcome the "permit" pathway for GM crops such as 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 CropLife Decision Tree, permits should be applicable to GM crops that have been approved for cultivation in another country with a "recognised" biosafety regulatory system (as proposed for the "expedited assessment"). We welcome more clarity and constructive dialogue regarding applicable standard licence conditions.

We also welcome the "expedited assessment" pathway for dealings relevant to our activities, including: 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; and dealings previously licenced and with a risk assessment that could inform assessment of the new application (as set out on pages 31-32 of the Explanatory Paper). This would provide a more streamlined and risk-proportionate approach for established technologies. We would caution however against using the term "expedited assessment", as this could be misunderstood to be an incomplete or rushed assessment.

In principle, we also support the proposal for "full assessment" to apply to dealings for which regulatory experience is limited or absent, but request more clarity regarding what would be considered high indicative risk, and substantial uncertainty as to risk.

We also support in principle the Regulator having the ability to move dealings between these categories, but emphasise that the criteria enabling this must be transparent. The consultation documents indicate that these criteria need to be elaborated in delegated legislation and we welcome consultation on these important details, and urge their timely development.

Non-notifiable dealings

BASF and CropLife have previously submitted extensive information to show that certain genome editing approaches and cisgenesis in plants warrant exclusion from the regulatory scope of the NGTS. The CRIS and Explanatory Paper describe "non-notifiable dealings" as having an indicative risk which is very low. BASF strongly recommends that the "non-notifiable dealing" authorisation pathway is utilised to address the issues we have identified regarding such "new" technological developments to provide more proportionate regulation. 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), and those for which regulatory clarity is currently lacking (e.g. base editing). We have submitted scientific evidence at length previously to support our assertion that these approaches can be used in plant breeding to achieve comparable outcomes to conventional tools, and therefore the resulting organisms do not present risks that would justify a licenced authorisation pathway. Stacked traits would also be appropriate dealings to include in the non-notifiable pathway where they are the result of conventional breeding where the single traits have been assessed.

BASF maintain that a more appropriate approach for the genome editing examples we list above would be **express exclusion from regulatory scope**, and view this authorisation pathway as an intermediate step pending technical review and amendment of the GTR. Again, we are concerned how this and other existing/proposed/suggested mechanisms will operate alongside one another in a coherent manner and welcome clarity. We also welcome more clarity on 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, and are committed to constructive dialogue on this.

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 innovation is that it was developed 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 with 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 on a product to APVMA that has already been received by FSANZ and the OGTR. The current 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. We believe the involvement of the APVMA in the approval process for gene technology products is duplicative and unnecessary.

We are pleased that the CRIS and Explanatory paper discusses a proposal to eliminate this regulatory duplication, such that an organism may be either excluded from, or approved by a single regulatory authority, with other regulatory authorities acting as advisors to the principle authority. In this case, a GMO would require approval only by OGTR, with FSANZ and the APVMA acting as advisory agencies.

Technical change to CCI provisions

BASF wish to support applicants to the OGTR and the OGTR itself in removal of some of the heavy administrative burden linked to management of Confidential Commercial Information (CCI) under the Scheme. We see this as a necessary part of futureproofing the administration of the Scheme. Recently, the topic of CCI transfer in the case of company divestment/acquisition, or CCI revocation as requested by an applicant has presented significant difficulties to BASF, and no doubt other companies who have been involved in similar acquisitions and/or divestments. Purchasers of intellectual property (IP), such as BASF, under divestments/acquisitions currently have no recourse under the CCI provisions of the *Gene Technology Act* to flag a change of, or transfer of, IP ownership so that the new owner of the IP has full control over their data in the OGTR's system. This is an unacceptable situation which must be addressed.

Making changes to the CCI provisions would provide for significant improvements in handling data, relieving the OGTR and the regulated community of administrative burden that currently consumes a great deal of time.

BASF also emphasises that there is a need for data protection processes in handling ours and other applicants' data and information as part of regulatory applications to the OGTR. Data protection provisions currently do not exist under the *Gene Technology Act* and would be a strong requirement for when the patent life of many current events expire. Under a data protection scheme similar to the one developed for the APVMA as part of the (now defunct) Transpacific Partnership negotiations, data that is submitted for regulatory purposes are given a minimum of 10 years protection from unauthorised use by competitors. A company that generates the data can choose to sell this data to (or otherwise reach an agreement with) competitors who wish to use it, or alternatively if the company who is the "pioneer innovator" of the product does not wish to sell the data, the competitor may choose to generate their own data for regulatory purposes. It is understood that when the data is purchased under a divestment/acquisition under a data protection scheme, transfer of IP ownership of that data is also recognised and registered with the Regulator. BASF, as part of CropLife, have advocated for data protection in the third review of the NGTS, and we continue to call for initiatives that would provide protection for the data of the "pioneer innovator".

Conclusion

BASF appreciates the opportunity to contribute to this consultation and welcomes any sign of progress towards implementation of key recommendations and a "proportionate regulatory model" as a result of the third review of the NGTS. Our views are aligned with those of CropLife, including sharing their concerns that this review process has been extremely drawn out, and timeframes for change that have a meaningful impact on our activities remain uncertain. We are also concerned that no clear or proportionate pathway is described for "new" technologies in development or use in our sector such as genome editing. We recognise that this may be addressed in part by the many mechanisms proposed or suggested in the consultation documents, but consider this a complex and sub-optimal approach, with much of the necessary detail still to be developed. Nevertheless, we remain committed to continuing to work constructively and welcome further discussion to progress reforms towards a regulatory environment that supports innovation in plant breeding.