BASF Australia Ltd
ABN 62 008 437 867
Level 23, 40 City Road
MELBOURNE 3006
Telephone: +61 3 8855 6600
www.basf.com.au

**BASF Australia Ltd. submission to Consultation Paper:**

**Gene Technology Amendment Regulations**

**27 February 2026**

## Introduction

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 has a strong history in both the development of gene technology products and of plant varieties using conventional breeding techniques. In Australia, we are involved in commercial seed sales and trait licensing, and our experience with the cultivation of genetically modified crops dates to the inception of work in this area in canola in the mid-1990s.

Commencing with the 2016 Technical Review of the Gene Technology Regulations, BASF has actively engaged throughout the multiple phases of the 2017 Third Review of the NGTS, advocating for outcomes that are science-based, risk-proportionate and 'future-proof'. We welcome the opportunity to comment on the January 2026 Consultation Paper on the Gene Technology Amendment Regulations, seeking to implement recommendations of the 2017 Third Review of the National Gene Technology Scheme (NGTS). We particularly welcome those proposed amendments aimed at implementing a more proportionate regulatory framework that better incorporates the vast body of scientific evidence, accumulated knowledge and regulatory experience that exists today.

In drafting our submission, we have worked closely with peak industry bodies, and we support the submissions from CropLife Australia and the Australian Seed Federation. We have framed our submission to respond to the Consultation Paper[1] that explains the proposed amendments to the Gene Technology Regulations. As we commented in our November 2024 submission to the Consultation on the Draft Gene Technology Bill[2], there remains uncertainty in addressing the capture of modern gene technologies, such as plant genome editing, within the scheme. We note the new proposal in the 2026 Consultation Paper to utilise the GMO Register as an authorisation pathway for certain genome edited plants. We believe that this approach is not consistent with the intended purpose of the GMO Register, and our concerns are detailed in this submission. We also note that the 2024 Consultation Paper on the Draft Gene Technology Amendment Bill stated that separate consultation would be undertaken regarding genome editing but to our knowledge this has not occurred.

[1] Consultation Paper: Gene Technology Amendment Regulations https://www.genetechnology.gov.au/news/consultation-proposed-amendments-gene-technology-regulations-2001, accessed 5 January, 2026.
[2] BASF submission to the Consultation Paper on the Draft Gene Technology Amendment Bill, November 2024. https://www.genetechnology.gov.au/reviews-and-consultations/past/proposed-amendments-gene-technology-act-2000 accessed 23 February, 2026.

In our submission we have not responded to every question in the Consultation Paper but rather we have focussed our remarks on the following elements of the proposed amendments to the Regulations:

i) the absence of a clear and operational definition of 'novel' as a regulatory trigger;

ii) the increased complexity in GMO regulatory pathways; and

iii) the proposed use of the GMO Register as a mechanism for the authorisation of genome edited plants.

## Responses to the Consultation Paper

### Question 1 – Do you have any comments or concerns with regards to the proposed changes to the structure of the Regulations generally?

***Recommendation 20 of the Third Review:*** *The Review recommends that the Scheme ensures regulation remains commensurate with the level of risk posed by a dealing so that no unnecessary regulatory burdens are imposed*.[3]

BASF supports the objective of the Third Review to modernise and future-proof the National Gene Technology Scheme; however, as they relate to plant science sector, aspects of the proposed amendments are inconsistent with this goal. The Consultation Paper states that "[t]he regulatory model endorsed by ministers proposes a framework where dealings with GMOs would be classified into a system of authorisation pathways that are fit for purpose for **current and future GMO applications**".[4] In our view, the amendments, as they relate to new gene technologies, do not align with this ministerial proposal, nor with Recommendation 20 (cited above) of the Third Review that that the Scheme "ensures regulation remains commensurate with the level of risk". The proposed amendments to the Regulations do not account for the evolution of modern gene technologies and their applications. A specific example is the issue of products developed using genome editing, where the outcome of using gene technology may be identical to that which could have been achieved through mutagenesis or other conventional breeding methods.

The proposed amendments to the Regulations go towards modernising Australia's regulatory approach for GMOs; however, they remain 'process-focussed' and lack the appropriate level of responsiveness and risk-proportionality that is needed for cases where the outcome of using gene technology does not result in a transgenic organism. Our main concern, as expressed previously in our submission to the Consultation Paper on the Draft Gene Technology Amendment Bill, is that the intended 'future-proofing' of the Scheme has not been achieved, particularly for genome edited plants.

The proposed amendments to the Regulations do not address our concerns about ongoing disproportionate regulatory scope regarding newer gene technologies that are used for breeding purposes in the plant science industry. A particular example, discussed in more detail later, is the proposal to authorise certain types of genome edited plants as GMOs via the GMO Register. Whilst we acknowledge that this would effectively put them in a category with a very low regulatory burden, our concern arises from the GMO "label" that comes with the name of the Register. A different approach is preferable, and we suggest our preferred alternative later in this submission.

3 Third Review of the National Gene Technology Scheme: Final Report (Report, October 2018) [Recommendation 20, p 11].

4 Consultation Paper: Gene Technology Amendment Regulations, *Op. cit.* p2.

**Question 2 – Do you consider that any other terms are unclear and require definition?**

While the Consultation Paper proposes a formulation for 'novel dealing', this is not well defined, which results in ambiguity and a lack of clarity. The absence of a clear and operational definition of the word 'novel' itself remains a significant issue, particularly as the concept of 'novel' is now used as a regulatory trigger both in Australia (e.g. ANZ Food Standards Code, definition of 'novel DNA'[5]), and overseas, for example: Canada – 'plants with novel traits'[6]; or Argentina – 'novel combination of genetic material'[7].

Where it is appropriate and makes sense to do so, BASF supports harmonising definitions in the National Gene Technology Scheme with those in the Australia New Zealand Food Standards Code ('the Code'); for example the recently approved definition of 'novel DNA'.[8] The definition of 'novel DNA' in the Code focuses on the origin and nature of the inserted genetic material thereby providing certainty to Regulators, the regulated community and the general public.

'*Novel DNA*' is defined in the Code as DNA that:

*(a) a person has inserted into the genome of an organism, cell or cells; and*
*(b) is:*
*(i) from a species that has not previously been crossed or hybridised with the species of the organism, cell or cells; or*
*(ii) from a species that has previously been crossed or hybridised with the species of the organism, cell or cells, where the sequence or arrangement of the inserted DNA was changed prior to its insertion; or*
*(iii) not from an existing species* [9]

We understand that the two agencies (OGTR and FSANZ) have different areas of regulatory responsibility, and we agree that not all definitions are automatically transferable between them, but this definition is not specifically about food (or food safety). The absence of a definition of 'novel' in the Gene Technology Regulations that aligns with the FSANZ definition of 'novel DNA' is a lost opportunity to promote regulatory consistency across Commonwealth frameworks. BASF aligns with the CropLife Australia proposal that adopting a clear, objective and outcomes-based definition of 'novel' within the Gene Technology Regulations, that aligns closely with the definition of 'novel DNA' in the Code would improve regulatory certainty and support a more harmonised regulatory framework. This would provide a scientifically defensible threshold for what constitutes a regulated organism.

During the Department of Health Information Session[10] on the proposed amendments, in response to a question on this topic, some clarity was provided in the context that 'novel dealings' is intended to exclude GMOs and traits with which the Regulator has established familiarity. BASF supports codification of this emerging best practice in GMO regulation and agrees that it is consistent with the stated goals of the Review of regulatory streamlining and risk tiering. Our interpretation of the purpose of 'familiarity' (and the way that 'novel dealing' is proposed in this Consultation) is to allow for a reduced regulatory burden for certain dealings with GMOs. We understand and agree that those proposed dealings which are familiar to the Regulator should require less time to assess and have standard conditions applied to them.

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[5] ANZ Food Standards code, https://www.legislation.gov.au/F2015L00385/latest/text. Standard 1.1.2 Definitions at s1.1.2-17. Accessed 17 February 2026.
[6] Government of Canada, https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits. Accessed 17 February 2026.
[7] Republic of Argentina, https://www.boletinoficial.gob.ar/detalleAviso/primera/240529/20210208. Accessed 17 February 2026.
[8] ANZ Food Standards Code, *Op. Cit*
[9] *Ibid.*
[10] Department of Health, Disability and Ageing, 'National Gene Technology Scheme – Proposed amendments to the Gene Technology Regulations – Information Session'. (Webinar, 6 February 2026).

For this reason, we support CropLife Australia's position that the word 'novel' should not be used when describing regulatory familiarity, as it conflates two separate concepts: novelty (a characteristic of genetic composition) and familiarity (a reflection of prior risk assessment and regulatory experience).

**Question 4 – Do you consider the concept of designated dealing clear?**

BASF's understanding is that the concept of 'designated dealings' broadly refers to dealings with GMOs that are, or could give rise to, pathogenic or infectious agents as a result of the genetic modification; or dealings with genetically modified gene drives. However, despite referencing the current Part 3 of Schedule 3 to the Regulations, it is not clear from the Consultation Paper what the specific criteria will be to trigger this regulatory pathway, nor what the regulatory requirements will be for this type of dealing. Based on the types of dealings referenced in the Consultation, it is assumed that these dealings will trigger the highest risk regulatory pathway, even if it is proposed that they be carried out in contained facilities for research purposes.

**Question 6 – Do you have any concerns with revised timeframes?**

BASF supports reductions in consideration periods / timeframes where this reduces regulatory burden and is proportionate to risk. The majority of the proposed alternative licence consideration periods in the Consultation Paper meet these criteria, however we have concerns with lack of a statutory timeframe for listing a new dealing on the GMO Register. The provided 'Summary of Authorisation pathways'[11] lists 'NIL' for the statutory approval timeframe for the GMO Register. The lack of a statutory clock for listing a new dealing on the GMO Register could lead to commercial uncertainty and make it exceedingly difficult to plan product launches in instances where this regulatory pathway is followed.

**Question 7 – Do you have any concerns around the proposed range of dealings that will be required to be licenced?**

The proposed use of the GMO Register to authorise certain genome edited plants may result in the continued regulatory capture as GMOs of organisms that are comparable to those that result from conventional breeding approaches (that are not regulated under the Scheme). While the intention of the proposed amendments is to introduce risk-tiering, this has not been achieved with the current proposal. To reiterate, our concern does not arise from the relatively low level of regulatory burden association with the GMO Register, but rather with the 'GMO' label that the name of the GMO Register applies.

In our 2024 submission to the Draft Gene Technology Amendment Bill, we noted that those countries which have regulatory policies in place for genome editing have (mostly) implemented an overarching principle that applications of genome editing resulting in genetic changes comparable to the outcomes that could occur spontaneously or via conventional breeding should be excluded from current GMO/biotechnology regulatory oversight. On a more technical level, criteria such as the presence/absence of a new or novel combination of genetic material, absence of foreign DNA/genes in the final product, or similarity to conventional/traditional breeding have been used as determinants of regulatory scope. While we recognise that the aim of the amended Regulations is to incorporate flexibility and future proofing into the Act, this is missing insofar as it

[11] Summary of Authorisation Pathways https://consultations.health.gov.au/best-practice-regulation/draft-amendments-to-the-gene-technology-regulation/supporting_documents/information-sheet-summary-of-authorisation-pathwayspdf. Accessed 24 February 2026.

applies to genome edited plants. One of the objectives of the Third Review was to be informed by regulatory developments internationally, it remains unclear that this has happened.

There are several examples in plant breeding, where gene technology can be used to develop plant varieties with the same modifications (and therefore risk profile) as varieties developed using conventional tools. The point here is that some of these genome edited plants would currently fall within the scope of the *Gene Technology Act 2000* and, in our opinion, need to be considered in a better way than the proposal to authorise some of them via the GMO Register. The intention is to future-proof the regulation of these types of organisms by developing regulation that is commensurate with risk, and this has been a missed opportunity to do so.

Contemporary breeding programs may incorporate genome editing tools as one component of the overall breeding workflow. These tools can be applied iteratively and at scale, for example to hundreds of plant lines during early-stage research and selection. Many edits produced by these methods are molecularly indistinguishable from variants that can occur naturally or that can be generated through conventional breeding or traditional mutagenesis. A regulatory approach that evaluates each individual edit independently ("one edit = one trait") risks creating disproportionate burdens. A more practical approach would use a reference framework based on the range of sequence variations that can be achieved through conventional breeding and mutagenesis methods, rather than treating every edit as requiring a unique regulatory pathway.

The proposal to authorise some genome edited plants through inclusion in the GMO Register, is not the most risk-proportionate way of reducing regulation for those organisms already captured by the Scheme that are genetically identical to conventionally bred organisms.

BASF aligns with CropLife's position that a more coherent approach would be to address conditions of regulatory capture or exclusion of genome-edited plants more explicitly within the Regulations, with the GMO Register reserved for its intended purpose of managing dealings with GMOs that have a demonstrated history of regulatory familiarity. Such approach will be fully in alignment with the concept or risk-tiering and will ensure the desired level of proportionality.

A two-step process that reflects this could include:

1) Has the organism been developed using gene technology? If yes, then it is captured by the scheme.

2) Does the end-product contain 'novel DNA' as a result of gene technology? Whereby the definition of 'novel DNA' is aligned with the ANZ Food Standards Code. If yes, then the product is captured by the Scheme and falls into one of the risk tiered pathways. If no, the product is exempted by the Scheme and subject to the same pathway to market requirements as conventional products.

**Question 8 – Do you have any concerns with dealings that are proposed to be authorised by a GMO permit?**

We acknowledge that the GMO Permit framework is designed to support more predictable oversight for GMOs with established regulatory familiarity. Of particular utility to BASF could be the proposed Class P1 permit for GMO field trials, as this may result in reduced regulatory burden in a manner that is proportionate to risk. However, without more clarity on which species and characteristics will be specified in the Rules, or the specific conditions that might be included on a Class P1 permit, it is difficult for us to comment further.

**Question 9 – Do you have any concerns in relation to the proposed notifiable dealings classes?**

In implementing risk-tiering, the proposed amendments have also increased the complexity of the Scheme. For example, the distinction between 'pre-notified notifiable dealings' (PNNDs) and 'post-notifiable dealings' (also PNNDs) is confusing. *Prima facie* 'pre-notifiable notifiable dealings' appear intended to operate as simplified GMO licences with a set of standard conditions attached to them. However, if this is the case, it is not immediately clear how they differ from the proposed GMO permit class, with the exception that they will not be assessed by the Regulator and there is therefore no statutory approval timeframe associated with either PNND class of dealing. The statement in the Consultation Paper that an IBC Record of Assessment is not required for 'pre-notified notifiable dealings' is also confusing as in the Summary of Authorisation Pathways document it states that these dealings are assessed by a regulated entity's IBC.

While the implementation of risk-tiering classes within Notifiable Dealings should reduce the overall regulatory burden, it is not yet clear whether the increased complexity (and time spent navigating the system) that comes with this will deliver commensurate benefits to product developers. For example, it is not clear how the import of plant germplasm that is regulated by the Scheme would be treated under the proposed notifiable dealing pathway.

**Question 10 – Do you have any concerns in relation to the proposed non-notifiable dealings classes?**

From the consultation paper, it is not clear, other than a name change, what the differences are between current 'exempt dealings' and the proposed 'non-notifiable dealings' (NNDs – not to be confused with NDs, (Pre-)NNDs or (Post-)NNDs). With the proliferation of different regulatory pathways to introduce risk tiering, it creates uncertainty for proponents in distinguishing between exempt (non-notifiable), notifiable and licensed dealings. We align with CropLife's position that risk, rather than containment, should remain the primary determinant of whether a dealing is appropriately exempt (or a NND), with containment being one factor relevant to risk assessment rather than one of the main criterion.

**Question 11 – Do you consider the language 'not involving intentional release into the environment' appropriate for NNDs?**

The use of the phrase 'not involving intentional release into the environment' for NNDs could create confusion within the Scheme, as currently 'dealings not involving intentional release' (DNIRs) are a distinct class of licensed GMO dealings where activities do not meet the criteria for exempt dealings or notifiable low risk dealings (NLRDs). The DNIR concept is conceptually distinct from the exempt dealings pathway that is intended to be replicated by NNDs. The use of this similar language risks blurring the distinction between exempt, notifiable and licensed dealings. To address this, we suggest the adoption of alternative language that clearly distinguishes NNDs from the current DNIR licence pathway. This would better support regulatory clarity, certainty and predictability and assist to reduce the overall regulatory burden.

**Conclusion**

After nine years of consultation, BASF appreciates that progress is being made towards modernising Australia's National Gene Technology Regulatory Scheme, and we support the initiative and the resulting amendments to the Regulations that will result in regulatory streamlining and risk-tiering.

However, we believe this is yet to be is fully achieved in relation to plant breeding innovations where the principle is that "like products should be treated in like ways"[12] . We also note the growing number of countries that exclude certain genome editing outcomes from the scope of GMO regulatory oversight.

Whilst the draft amendments to the Regulations will, in some instances, improve the regulation of traditional GMOs, they do not succeed in future-proofing the Scheme as it applies to newer gene technologies. As we reach the end of the first decade of this review process, we remain committed to continuing to contribute to further discussion on regulatory policies that support innovations in plant breeding.

[12] Jenkins D, Dobert R, Atanassova A, Pavely C. (2021) Impacts of the regulatory environment for gene editing on delivering beneficial products. In Vitro Cell Dev Biol Plant.;57(4):609-626.