Australian Seed Federation
SOWING SEEDS

17 March 2021

Gene Technology Implementation Secretariat
Department of Health
GPO Box 9848
CANBERRA ACT 2601

By email: Gene.Technology.Implementation@health.gov.au

Dear Gene Technology Implementation Secretariat

RE: CONSULTATION REGULATION IMPACT STATEMENT ON MODERNISING AND FUTURE-PROOFING THE NATIONAL GENE TECHNOLOGY SCHEME

The Australian Seed Federation (ASF) is the peak national body representing the interests of Australia's sowing seed industry, worth over $1 billion annually to the Australian economy and providing hundreds of jobs in rural and regional Australia. The membership of ASF comprises stakeholders from all sectors of the seed supply chain including plant breeders, seed growers, seed processors and seed marketers.

The ASF welcomes the opportunity to provide a response to the Consultation Regulatory Impact Statement (CRIS) on Modernising and future-proofing the National Gene Technology Scheme. Of the three Options presented in the CRIS, the ASF supports Option B, despite this option only partially meeting the objectives of modernising and future-proofing the National Gene Technology Scheme. The ASF believes Option B is a good option to streamline the regulation of now long-established 'traditional' gene technology in a way that is more proportionate to the risk profile of well understood and characterized organisms and traits. However, Option B fails to satisfactorily address the different risk indicators presented by innovations in gene technology, particularly those innovations which present a risk profile comparable to that of conventional breeding.

We look forward to working with the reviewers as this consultation progresses.

Yours sincerely

Mr Osman Mewett

Chief Executive Officer

Australian Seed Federation
SOWING SEEDS

AUSTRALIAN SEED FEDERATION SUBMISSION

TO THE

CONSULTATION REGULATION IMPACT STATEMENT ON MODERNISING AND FUTURE-PROOFING THE NATIONAL GENE TECHNOLOGY SCHEME

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Introduction

The Australian Seed Federation (ASF) is the peak national body representing the interests of Australia's sowing seed industry, worth over $1 billion annually to the Australian economy and providing hundreds of jobs in rural and regional Australia. The membership of ASF comprises stakeholders from all sectors of the seed supply chain including plant breeders, seed growers, seed processors and seed marketers.

ASF welcomes the opportunity to provide a response to the Consultation Regulatory Impact Statement (CRIS) on Modernising and future-proofing the National Gene Technology Scheme. The ASF has previously provided submissions to the 2016 Technical Review of the Gene Technology Regulations; Phase 1, Phase 2 and Phase 3 of the 2017 Third Review of the National Gene Technology Scheme; the 2018 FSANZ Review of Food Derived from New Breeding Techniques; and the Phase 1 Discussion Paper on *Implementing Recommendations of the Third Review of the National Gene Technology Scheme*.

In Australia, the seed industry is a vital link in the development of crops that are critical to the nation's agricultural productivity, sustainability, and food security. The ASF is providing this submission in the interest of developing a nationally and internationally consistent approach towards the regulation of gene technology, and to future-proof ASF members' ability to deliver the best seed and technology to farmers.

Since the commercial introduction of genetically-modified (GM) plants in Australia a quarter of a century ago, technology developers and regulatory authorities have gained significant experience in evaluating their safety based on identifying and assessing risks to human health and safety, and the environment. Over 3,500 independent regulatory agency reviews have reached positive conclusions on the safety of GM plants for food and feed[1]. The approvals have unanimously found in each case that the GM plant in question was as safe as its conventional counterpart.

Of the three Options presented in the CRIS, the ASF supports Option B, despite this option only partially meeting the objectives of modernizing and future-proofing the National Gene Technology Scheme. The ASF believes Option B is a good option to streamline the regulation of now long-established 'traditional' gene technology in a way that is more proportionate to the risk profile of well understood and characterized organisms and traits. However, Option B fails to satisfactorily address the different risk indicators presented by innovations in gene technology, particularly those innovations which present a risk profile comparable to that of conventional breeding.

[1] Waters, Stephen, et al. "Recommendations for science-based safety assessment of genetically modified (GM) plants for food and feed uses." *Journal of Regulatory Science* 9.1 (2021): 16-21.

The ASF supports the adoption of an *enhanced* Option B, which in addition to what is proposed, specifically and immediately excludes products developed using SDN-2 and ODM from regulation as GMOs in Australia, and provides a pathway for the exclusion of new gene technologies in the future. An enhanced Option B could also provide a specific regulatory pathway for clinical trials involving GMOs, without the need for the additional complications introduced by Option C. This is what real future-proofing of a regulatory scheme looks like.

Innovations enabled by gene technology, as opposed to genetically modified organisms (GMOs) *per se*, are the future of Australian agriculture. It is therefore imperative that Australia has a supportive regulatory environment, and that reform efforts result in a regulatory paradigm based on risk indicators that do not automatically treat all products of gene technology as a GMO, as this results in real world negative outcomes for innovation, trade and commerce. Risk indicators must have a basis in the vast body of accumulated scientific evidence and knowledge.

Case Study

Company A has developed a new herbicide tolerant trait in canola using a gene editing technique that relies on the use of a site-directed nuclease and template guided repair (e.g. "SDN-2"). The trait is conferred by a single targeted base-pair edit.

Company B has developed the same herbicide tolerant trait in canola as Company A using a gene editing technique that relies on the use of a site-directed nuclease but not template guided repair (e.g. "SDN-1"). The trait is conferred by a single targeted base-pair edit.

Company C has developed the same herbicide tolerant trait in canola as Company A and B using a gene editing technique that relies on the use of oligo-directed mutagenesis (e.g. "ODM"). The trait is conferred by a single target base-pair edit.

Company D has developed the same herbicide tolerant trait in canola as Company's A, B and C using conventional breeding techniques, with the trait conferred by a single base change (random mutation).

Despite Company A, B, C and D's products being identical, under the current regulatory system, and under Option B, Company A and C's products would be regulated as a GMO in Australia whereas Company B and D's products would be treated as a conventionally bred product and have a clear path to market in Australia.

When the outcome of different breeding programs is the same, it makes no sense to regulate one product as a GMO, and not regulate the other as the risk to human health and safety and the environment are the same, regardless of the breeding technique used. Nearly every other country with a functioning regulatory system uses the presence or absence of recombinant DNA or a functional coding region as the trigger for regulation.

By treating products developed using techniques such "SDN-2" and "ODM" as GMOs, the Australian approach has created, and will continue to create international barriers to trade as a direct result of the non-alignment of our regulatory system with those of our trading partners.

The ASF submits that genetic variation in a final plant product should not be regulated under the Scheme 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.

Definition of 'gene technology'

The ASF does not support and has strong concerns regarding the inclusion of the word 'creation' in the example definition of 'gene technology' on page 12 of the CRIS Explanatory Paper. There is no internationally accepted definition of synthetic biology, and the attempt to create a 'catch-all' is both unnecessarily provocative and scientifically unsound. The proposed definition is not based on science or global consensus, but rather on speculation of what gene technology may or may not deliver.

The ASF notes that CropLife Australia's submission for Phase 1 of the National Gene Technology Scheme review included a proposed amendment to the definition of 'gene technology' which is reproduced below. This is consistent with criteria (a) above, and would make for a more agile, proportionate, and future-proof Scheme that is consistent with developments in other countries where regulatory processes have been introduced specifically for plants developed using genome-editing.

Proposed amendment to the definition of "gene technology" in the Gene Technology Act

Gene technology means any technique

(a) for the modification of genes or other genetic material; OR

(b) specified in the Regulations for the purpose of this paragraph

But does not include:

(a) sexual reproduction; OR

(b) homologous recombination; OR

(c) techniques that do not result in the integration of one or more genes in a defined genetic construct into the genome; OR

(d) any other technique specified in the regulations for the purposes of this paragraph.

This proposed amendment is consistent with the existing SDN-1 exclusion (resulting from the 2019 amendments to the Gene Technology Regulations), and it would also have the effect of excluding certain organisms developed using other types of genome editing approaches (e.g. base editing, prime editing, SDN-2 and ODM) for which there is currently a lack of clarity (e.g. base editing, prime editing) or express inclusion (e.g. SDN-2, ODM) in regulatory scope. The proposed amendment would not exclude transgenic organisms captured (e.g. GMOs) by the Scheme. However, to ensure risk-proportionate regulation and to avoid undue regulatory burden for some products developed using gene technology (e.g. cisgenesis), additional mechanisms are needed.

The ASF's view is that the word 'modified' is sufficient to capture the modification of epigenetic marks within an organism. Although the question must be asked again whether such epigenetic marks create a risk to human health and safety and the environment given such epigenetic changes are an everyday occurrence as part of natural breeding processes.

While there is some value in the Regulator providing interpretive guidance on the definition of *gene technology*, the more important determination is whether the resulting organism is a GMO within regulatory scope, rather than whether the technology used is *gene technology* per se. The ability to provide legally binding determinations for the purpose of providing regulatory certainty is desirable for developers where this is not provided already in the Scheme. It is critical, however, that such determinations are transparent, based on current sound scientific evidence and understanding, and be subject to review by developers affected by the determination.

Definition of 'genetically modified organism'

As for the proposed definition of 'gene technology', the ASF strongly opposes the insertion of the words 'or created' in the proposed definition of 'genetically modified organism'. The Explanatory Paper itself on page 13 states that this is an attempt to capture techniques that 'may become possible' as opposed to those techniques grounded in scientific reality. In the ASF's view, the word 'modified' is broad enough to capture the example provided in the Case Study on page 14 of the Explanatory Paper.

Definition of 'to deal with'

The ASF is broadly supportive of the proposed changes to the definition of 'deal with' as they remove ambiguity and will assist to futureproof the *Gene Technology Act*. The ASF would caution the reviewers to ensure the proposed changes do not have an unintended effect in state jurisdictions that maintain moratorium legislation, as some state gene technology legislation may still rely on the definition of 'deal with' in the Commonwealth Act.

Authorisation Pathways

As stated in the Introduction above, of the Options presented in the CRIS, the ASF believes that Option B will modernise the Scheme as it relates to 'traditional' GMOs, and this represents a good outcome and in line with the risk-tiering and regulatory streamlining approach advocated for by agricultural peak bodies since 2017.

However, as good as Option B is for modernising the Scheme's approach to traditional GMOs, it fails entirely to adequately address or provide a clear path to market and freedom to operate for developers using innovative applications of gene technology in their breeding programs. As such, the ASF strongly supports the adoption of an *enhanced* Option B, that immediately excludes SDN-2 and ODM from regulation as GMOs in Australia and provides a clear pathway for the exclusion of future gene technologies.

The exclusion of SDN-1 from regulation as a GMO in Australia in the 2016-2019 review of the Regulations was only ever intended as an interim step by the Regulator. The CRIS, and Option B more broadly, fail to either consider or demonstrate a pathway for exclusion from regulation for gene-editing techniques such as SDN-2 and ODM, particularly where these techniques are used in plants.

To facilitate risk-proportionate regulation, gene technology regulation needs to be more outcome-focussed and less technology specific. For example, regardless of the technology used, if there is no integration of one or more genes in a defined genetic construct into the genome, or if there is integration of genetic material but it is derived from the same or a sexually compatible plant species, these products should be excluded from regulation. These exclusions should apply regardless of whether the technology used was SDN-1, -2, cisgenic SDN-3, ODM, prime editing, base editing, or whatever the next technology may be. The use of a technology classed as a "gene technology" does not automatically result in risk that is greater than that which may arise through spontaneous or induced mutagenesis, or the use of other conventional breeding tools. Therefore, from a risk-perspective, it makes no sense to regulate based on the breeding process used.

Non-notifiable dealings

The creation of a new authorisation pathway 'non-notifiable dealings' is broadly supported by the ASF as it recognizes that some dealings with GMOs are well understood and of very low risk to human health and safety and the environment. This pathway will potentially reduce the current disproportionate regulation of these GMOs.

However, organisms that fall into this pathway will still be considered GMOs for regulatory purposes, and this could lead to issues further down the supply chain, such as the requirement for mandatory labelling as a GM food by FSANZ (pending the outcome of their ongoing review), or trade issues where there is a lack of regulatory harmonization between trading partners. This is why the ASF is strongly advocating for the express exclusion of techniques such as SDN-2 and ODM as opposed to having them fall into this pathway whereby although the regulatory touch will be lighter, they will still be considered GMO.

It is not clear from the Explanatory Paper whether dealings that fall into this pathway will be contained dealings only, or if they will also include dealings permitted for release into the environment. The ASF agrees with the CropLife submission that the non-notifiable dealing categorisation should be considered as an interim solution pending future (and timely) amendments of the Regulations to provide broader exclusions. Such review (and exclusions) should be conducted on a more regular basis. The last review of the Regulations commenced in 2016, and the original intention of the Scheme was for them to be reviewed on a 5-year basis, so they should be due for further review in 2021 with the aim to exclude techniques such as SDN-2 and ODM from regulation as a GMO.

The ASF agrees with CropLife that this pathway is not entirely satisfactory since it presents an unnecessary step, and therefore unnecessary complexity, as opposed to express and timely exclusions via the Regulations. The ASF welcomes further discussion regarding what the relevant risk indicators could look like for a product to fall into this pathway; the primary consideration of course should be whether the modification is indistinguishable from that achievable with conventional breeding tools. As previously discussed, this pathway could lead to issues further along the value chain since dealings listed as non-notifiable are still considered GMO for regulatory purposes.

Licensed dealings

The ASF is broadly supportive of the proposal to have three different tiers of licensed dealings based on risk, history of safe use and management of the regulated GMO. In particular, the ASF views utility of this proposal for dealings involving species such as cotton and canola, and traits such as herbicide tolerance and insect resistance, with which the Regulator has extensive regulatory experience.

For those parts of the risk assessment that relate to human health, the ASF would encourage the OGTR to look at risk assessments undertaken by overseas regulatory agencies, in order to further streamline the assessment timeframe. For example, for GM foods, FSANZ has entered into a Safety Assessment Sharing initiative with Health Canada, and the OGTR could look to invoke similar arrangements.

The ASF supports the proposal for "expedited assessments" for dealings such as:

- A variation on dealings that would otherwise be eligible for a permit,
- Dealings for which the Regulator has extensive regulatory experience with the parent organism but requires a case-by-case risk analysis due to unfamiliarity with the introduced trait,
- Dealings previously licenced and with a risk assessment that could inform assessment of the new application.

These are examples relevant to the seed industry that could improve streamlining of regulatory processes, with a gain of time and decreased regulatory burden. The use (and update, if needed) of pre-existing risk assessments could help streamline processes. Expedited assessments could also be considered for dealings that can be informed by risk assessments conducted by regulatory agencies in other countries (as discussed above).

The ASF agrees with the suggestion made by CropLife that the reviewers reconsider the use of the word 'expedited' as this carries potential negative connotations that the assessment has been rushed or shortcuts taken. The ASF supports the use of the phrase 'streamlined assessments' as this more accurately reflects the intent of the process.

International Regulatory Harmonisation

The ASF notes that the European Food Safety Authority (EFSA) concluded in 2020 that genome editing techniques that modify the DNA of plants do not pose more hazards than conventional breeding or techniques that introduce new DNA into a plant.[2]

In 2018, the Australian Government endorsed the WTO 'International Statement on Agricultural Applications of Precision Biotechnology'. Included in this statement was a commitment that '*…due consideration should be given by governments to avoid arbitrary and unjustifiable distinctions between end-products derived from precision biotechnology and similar end-products that are obtained through other production methods.*'[3] This statement encouraged nations to adopt regulatory approaches for gene editing that are '*scientifically based and internationally harmonized*' in order to '*…prevent regulatory asymmetries and, in turn, potential trade disruption*.' It was unfortunate that the Australian authorities were unable to fully achieve this objective in the 2016-2019 review of the Regulations and the ASF is disappointed that the CRIS fails to either consider or demonstrate a pathway to address this objective in 2021.

In the meantime, it is notable that thirteen countries[4] have introduced regulatory policies clarifying that crop varieties developed using gene-edited techniques including SDN1, SDN2 and ODM, and containing no foreign DNA, would not be regulated as GMO. Seven of these countries stood alongside Australia in support of the 2018 WTO Statement. The scientific basis for such exclusions is already provided in the evidence provided in previous industry submissions, and is recognised in the reforms made in other countries. For example, recent reforms to the regulatory oversight of the United States Department of Agriculture (USDA) are specifically aimed at excluding genetic modifications in crops that are achievable using conventional breeding – reforms made based on an extensive analysis of the scientific evidence. Multiple additional countries are known to be developing policies broadly aligned with the first thirteen and, to the best of our knowledge, there are no countries planning to introduce new policy that would regulate SDN2 or ODM in the same way as GMOs.

The WTO Statement is essentially the crux of where Modernising and Future-Proofing the National Gene Technology Scheme needs to land. Gene technology in and of itself does not pose a risk to human health and safety or the environment. Therefore, regulation of gene technology should be based on the risk (if any) posed by the outcome of using that technology, and not simply on the fact that gene technology was used.

[2] https://www.efsa.europa.eu/en/news/existing-guidance-appropriate-assessment-genome-editing-plants
[3] https://www.agriculture.gov.au/ag-farm-food/biotechnology/international-statement-agricultural-applications-precision-biotechnology
[4] Argentina, Brazil, Chile, Colombia, Ecuador, Guatemala, Honduras, Paraguay, Israel, Nigeria, Japan, US, Canada.

What's in the Pipeline?

Industry is often asked by regulators what products developed using gene technology are in the development pipeline? For understandable commercial reasons, many product developers choose not to share this information to protect their intellectual property rights. For several years, CropLife International published a plant biotechnology product pipeline for traditional GMOs.[5] They have also published a report on the public sector biotech pipeline.[6] Several companies also publish information on their product pipeline on their websites[7]. Below is an illustrative product pipeline from an ASF member company. What is interesting about this pipeline is every pre-commercial trait is being developed using the company's proprietary non-transgenic *Rapid Trait Development System* for gene-editing using a template for targeted-repair.

Figure 1: Source - https://www.cibus.com/pipeline.php

It is possible that under Australia's current regulatory system, and under the system proposed in the CRIS, that all the pre-commercial crop and trait combinations in Figure 1 would be regulated as a GMO in Australia, even if genetically they are identical to gene knockouts developed either using SDN-1, somaclonal mutation or conventional breeding. This makes no sense from a risk perspective and is certainly not representative of risk proportionate regulation.

[5] https://croplife.org/wp-content/uploads/2017/09/CropLifePlantBiotechPipeline2017_V5.pdf
[6] https://croplife.org/news/public-sector-biotech-products-in-the-pipeline-around-the-world/
[7] https://www.cropscience.bayer.com/innovations/seeds-traits; https://agriculture.basf.com/global/en/innovations-for-agriculture/innovation-at-a-glance.html; https://www.syngenta.com/en/seeds

If, from a risk perspective an end product is comparable to a conventionally bred product, there needs to be a pathway through the regulatory system for it to be treated as such.

It is also interesting to look at what products are going to through the regulatory system in other countries. Until recently, the USDA had in place an 'Am I regulated?' (AIR) process, recently replaced by the SECURE rule. As of August 2020, 59 different crops (and 1 fungus) had completed the AIR process from both private and public sector companies (Table 1).

Table 1: The landscape of potential US crop products enabled by genome editing – Products completing USDA 'Am I regulated' progress as of 25 August 2020 (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated)

Crops (59 total, 1 fungus)	Traits	Developers
Soybean – 10	Product Quality (Composition/Flavour) – 27	Simplot – 9
Potato – 8	Longer shelf life – 7	Calyxt – 7
Tomato – 6	Pest resistant – 6	Yield10 Bioscience – 4
Corn – 5	Growth habit – 5	Cibus – 4
Pennycress – 5	Yield improvement – 3	Inari – 3
Camelina – 3	Herbicide tolerance – 2	Corteva – 2
Canola – 3	Stress tolerance – 1	ToolGen – 2
Rice – 2	Modified colour – 1	Benson Hill – 2
Wheat – 2	Research purposes – 2	Covercress – 2
Avocado – 2	Confidential trait/other - 4	Evogene – 2
Other (1 each) – Alfalfa (lucerne), Seteria, Lettuce, Tobacco, Citrus, Petunia, Flax, Barley, Pea, Strawberry, Indian mustard		Illinois State Uni – 3
		Uni of Minnesota – 2
		Uni of Florida – 2
		Iowa State Uni – 2
		Other developers - 14

Table 1 illustrates that the R&D into products utilising gene editing in the US is considerable and there is huge potential for Australia agriculture if, and only if, there is a clear path to market and freedom to operate in Australia for the developers of these products. The ASF does note that the USDA has a unique regulatory system that relies on the presence/absence of plant pest-derived sequences in the final plant, and the 'AIR' decisions are not clear indicators of the decisions other US regulators such as the EPA or FDA. Depending on the decisions of other regulators the products in Table 1 may have varying degrees of difficulty making it to the market outside of the scope of GM regulation in the US.

By contrast, in the EU the 25 July 2018 ECJ ruling on targeted mutagenesis has had a significant impact on innovation and development pathways for products using gene technology. Research by Jorasch (2020) demonstrated that "Around 40% of the SMEs and 33% of the large companies stopped or reduced their NBT-related R&D activities after the ECJ ruling. Those companies who have major markets outside the EU moved the focus of their product development with NBTs to markets outside the EU (100% of the large and ~20% of the SMEs)."[8] This dis-investment and market exit from innovation in gene technology may also become a reality in Australia in the absence of risk proportionate regulation and the exclusion from regulation of certain gene technologies, such as SDN-2 and ODM, as GMOs.

[8] Jorasch, Petra. "Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU." *Frontiers in Plant Science* 11 (2020): 1463.

CONCLUSION

Australia has gone from a leader (in 2016) to a laggard (in 2021) regarding keeping pace with the global trends of gene technology regulation. We are as out-of-step (just in a different way) with risk proportionate regulation of new gene technologies as New Zealand and the EU, and risk falling further behind the US, Latin America, and Japan in our approach to regulating new gene technologies.

With some further information and discussion to determine the risk indicators for the proposed tiered regulatory pathways, the ASF supports Option B as a good option towards modernising the regulatory approach to traditional GMOs. However, this Option provides no clarity or pathway for the exclusion of gene technologies from the regulatory scheme when the outcome of using these technologies is identical to that which could be achieved using conventional breeding tools.

To truly modernise the Scheme, the reviewers need to consider risk proportionate regulation of "new" technologies, including those that have been under discussion for more than a decade to those we do not yet know about, and avoid undue regulatory burden when there is no evidential basis for risks to human health and safety and the environment.

The ASF looks forward to working with the reviewers as this consultation progresses.