Australian Seed Federation
SOWING SEEDS

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28 November 2019

Gene Technology Implementation Secretariat
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Dear Gene Technology Implementation Secretariat

IMPLEMENTING RECOMMENDATIONS OF THE THIRD REVIEW OF THE NATIONAL GENE TECHNOLOGY SCHEME: PHASE 1

The Australian Seed Federation (ASF) is the peak national body representing the interests of Australia's sowing seed industry. The membership of ASF comprises stakeholders from all sectors of the seed supply chain including; plant breeders, seed growers, seed processors and seed marketers.

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.

Please do not hesitate to contact me directly should you have any questions or require further information regarding any aspect of this submission.

Yours sincerely,

Osman Mewett
General Manager

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

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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 Phase 1 Discussion Paper on *Implementing Recommendations of the Third Review of the National Gene Technology Scheme*. The ASF has previously provided comments 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; and the 2018 FSANZ Review of Food Derived from New Breeding Techniques.

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.

To this end, the ASF would like to express its frustration at the excessive and seemingly endless rounds of consultation to deliver much needed reform to the means by which gene technology is regulated in Australia. All agricultural peak industry bodies have expressed consistent views to the multiple consultation rounds regarding the need to update definitions, develop risk-proportionate regulation and streamline regulatory requirements. It not immediately clear why this substantial body of information was not considered sufficient to develop and consult on options for implementing the recommendations of the review.

PART ONE: DEFINITIONS

The ASF agrees that definitions in the *Gene Technology Act 2000* and Gene Technology Regulations 2001 have not kept pace with advances in gene technology. However, this will remain an inherent limitation of technology-based definitions. That a product is created using a static definition of 'gene technology' is an interesting fact, but it does not tell you anything about the risks (if any) of the product to human health and safety or the environment. Therefore, even if a product is captured by the definition of gene technology, there needs to be an 'early exit' from the regulatory scheme if the product meets pre-determined criteria that places it in a negligible or low-risk category. This concept is explored further in Part Two.

Products developed using very different technologies can carry the same type of change at the molecular level, thus presenting comparable risks. Therefore, it becomes illogical to regulate a product based purely on the fact that it is captured by a broad definition of gene technology.

The ASF notes that CropLife'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. These proposals are an example of how definitional change could make for a more agile, proportionate and future-proof Scheme and they are 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 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, and it would also have the effect of excluding certain organisms developed using other types of genome editing techniques (i.e. base editing, prime editing, SDN-2 and ODM), but it would not exclude those organisms currently captured (i.e. GMOs) by the Scheme. However, to ensure risk-proportionate regulation and to avoid undue regulatory burden for some products developed using gene technology (i.e. cisgenesis), additional mechanisms are needed.

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.

PART TWO: RISK-PROPORTIONATE REGULATION

The introduction of additional risk tiering is imperative to future proof the Scheme. In its 2016 submission to the Technical Review of the Gene Technology Regulations, CropLife proposed a 'Decision Tree' that added additional layers of risk tiering to the Scheme. The ASF supports such additional tiers where they would assist in ensuring the regulation of gene technology is proportionate to the risk (if any).

However, in line with the recommendations of the review to maintain a process-based trigger as the entry point to the scheme, the additional risk tiers suggested by CropLife in 2016 perhaps do not go far enough. Regardless of the suggested amendments to the definition of gene technology as described above being implemented, there needs to be immediate exit points from the Scheme for products that have been developed using gene technology, but are either: a) not a genetically modified organism (excluded through Regulation); or b) of such negligible or low risk that regulatory oversight is not required.

For products that fall into these categories, it should then be up to product developers to decide, either individually or collectively, what level of information is shared with regulators, traders and the public regarding the breeding process. Examples of products that could fall into this category are products where gene technology has been used, but there is no stable insertion in the genome of one or more genes that are part of a defined genetic construct. In this sense, the outcome is similar to that achievable through allelic variation, which is a normal part of conventional plant breeding.

It is likely to be technically feasible to detect DNA sequence changes made using different genome editing approaches; however, without prior knowledge, it is challenging if not impossible for certain applications (e.g. SDN1 and SDN2) to determine whether a specific change has occurred as a result of conventional mutagenesis, spontaneous mutations, or

genome editing. Molecular outcomes of these mutagenesis methods can be similar if not identical, thus, a DNA sequence change may not uniquely identify a specific technology, product, or developer.

To facilitate risk-proportionate regulation, the exclusions in the Gene Technology Regulations need 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, this should be excluded from regulation regardless of whether the technology used was SDN-1, -2, ODM, prime editing, base editing, or whatever the next technology may be. Whilst any form of mutagenesis can introduce risk, the use of gene technology for targeted mutagenesis does not automatically result in a risk any greater than that which arises through spontaneous or induced mutagenesis (i.e. conventional breeding). Therefore, from a risk-perspective, it makes no sense to regulate targeted mutagenic products purely on the breeding process used.

PART 3: STREAMLINING REGULATORY REQUIREMENTS

There is considerable regulatory overlap between the OGTR, FSANZ and the APVMA regarding gene technology. FSANZ and the APVMA currently recover their costs for processing applications, whereas the OGTR has (quite rightly) remained appropriation funded. If OGTR were to introduce cost recovery, there is the possibility that applicants could be paying twice or up to three times for a risk assessment of the same or highly similar data package.

There is certainly capacity to reduce regulatory red tape and remove overlap between these three regulators. Duplication of regulation imposes heavy regulatory burden, time delays, and costs on applicant, with no associated benefits. One immediate change that could be implemented with relative ease is for the APVMA to accept the regulatory risk assessments of OGTR and FSANZ. A longer-term option would be for APVMA regulatory responsibility for GM products with plant incorporated pesticides to be removed altogether. This is especially pertinent as the APVMA oversight of GM products is an artefact that predates the establishment of the Scheme.

The ASF would support reform of the Scheme that resulted in OGTR taking the overall regulatory responsibilities for all GMOs and GM products – in effect becoming a 'one stop shop' for users of the Scheme. This would result in significant regulatory efficiencies and reduce existing areas of duplication where similar risk assessments are being undertaken by different Commonwealth agencies.

CONCLUSION

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."

This commitment is essentially the crux of where the Implementation of the Recommendations of the Third Review of 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.