



Australian Seed Federation
SOWING SEEDS

ABN 66 003 160 638

**Australian Seed Federation
submission to the Open Consultation for
the Third Review of the National Gene
Technology Scheme**

September 2017



Introduction

The Australian Seed Federation (ASF) welcomes the opportunity to submit comments on the Department of Health's *Open Consultation for the Third Review of the National Gene Technology Scheme*. The 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, all of whom were consulted in the preparation of this submission.

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 Plant Breeding Innovation (PBIs) and to highlight current unintended consequences with the current scheme that are impacting ASF members' ability to deliver seed and technology to farmers who want it. In so doing, we hope this review can provide the industry with the necessary certainty to continue creating new plant varieties to provide better quality products for consumers, farmers and the processing value chain. Plant breeding has always responded to society's need for increased crop yields, better tasting varieties and pest and disease resistant crops. Ultimately, plant breeding fosters sustainable farming practices to meet the needs of a growing global population.

The ASF supports the Review's aims to improve and strengthen the National Gene Technology Scheme's (the Scheme) effectiveness whilst ensuring that it is appropriately agile and supports innovation.

Term of Reference 1

The ASF fully support the Review's consideration of assessing and making recommendations in relation to current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continued technological development. The international seed industry has been very vocal in this area for a number of years. Plant breeders have always used the creation of new variations of plant characteristics to provide solutions for resistance to plant diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Plant breeding depends upon genetic variability within and across related species as a basis for developing new plant varieties with improved characteristics. To create a new plant variety, plant breeders have generally relied on two sources of genetic variation as a basis for new characteristics; the inherent diversity in a plant's gene pool and new, naturally occurring variants of existing genes.

Breeders often make crosses between plants of diverse genetic makeup to produce new combinations of genetic characteristics which result in diverse morphological or quality characteristics in the progeny plants. The natural diversity of different sources of germplasm within a species or its close relatives is a primary source of genetic variation.



Genetic variation can also be increased by mutations – changes in the DNA sequences of the plants. In plants, spontaneous mutation mechanisms and induced mutagenesis (e.g. chemical and irradiation) have long been exploited to introduce different types of mutations that can confer desirable traits to breeding programs. Such mutations may range from point mutations, which include substitutions, insertions and deletions of one or a few DNA base-pairs, to larger changes including gene duplications and chromosomal rearrangements. Since the 1950s, well over 3200 crop varieties have been directly developed by mutation breeding.

Australian plant breeders have investigated the applications of several new breeding technologies in their breeding programs but the current lack of regulatory certainty prevents the implementation of these techniques in their programs resulting in a substantial reduction in innovation. The ASF notes, for example, that the US Department of Agriculture (USDA) has determined that some applications involving the use of techniques such as TALEN, ODM and CRISPR/Cas are not considered regulated articles by USDA. Food Standards Australia New Zealand has similarly reviewed several these techniques and reached similar conclusions.

The ASF, as part of the international seed industry community, believes that an underlying principle for determining regulation should be that plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods. We therefore propose that the Review consider that the genetic variation in a final plant product should be excluded from regulation under the *Gene Technology Act 2000* where:

- 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 designed 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.

As such, the ASF would strongly recommend to the Review that it seek to put in place the necessary changes to the Act that would allow the Gene Technology Regulator to implement Option 4 of the Office of the Gene Technology Regulator's *Discussion paper on options for regulating new technologies*. This Option aligns completely with the seed industry's proposed criteria for regulating plant breeding innovations mentioned above. It is also the only Option that fully meets the needs of harmonisation with other national regulators (e.g.: Food Standards Australia New Zealand) – providing necessary legal certainty for the industry. We would also like to note that the OGTR's Discussion Paper focussed only on gene editing techniques, and did not address other new breeding platforms such as the cisgenesis and the proprietary Seed Production Technology (SPT). We would encourage the Regulator to also consider specific exclusion of these techniques for the same reasons, or a mechanism for communicating to the broader industry where new, enabling breeding technologies have been reviewed and a position taken that they do not require regulation.

Term of Reference 2

The ASF also supports the Review's consideration of existing and potential mechanisms to facilitate an agile and effective Scheme which ensures continued protection of health and safety of people and the environment. This Objective must be viewed in the context of the continued focus on commercialisation of products that are safe to human health and the environment once approved, and the reality that agricultural systems are not closed systems and do interact with the open environment. The ASF would like to highlight two areas where the Scheme could be improved to introduce more agility and effectiveness into the system.

Transport of approved GM products

The ASF's position on GM crops is that we support free choice by participants in the food supply chain and consumers in relation to crop biotechnology, provided that choice is based on sound science and respects the right of others to also choose. We are encouraged by how the industry is working together in Australia to ensure that the needs of different market segments continue to be met – be they organic, non-GM or GM.

However, it is the ASF's view that the current restrictions on the transport of GM seed and grain through South Australia (SA) by the SA Government are imposing a logistical constraint on the operations of its members who are involved in this market sector, including significant additional costs being imposed on members who are actively working to supply the seed for sowing market nationally. The South Australian Government maintains a total ban on the transport of GM seed and grain through the State. This ban applies even to those products – including GM herbicide tolerant canola – that has been approved for legitimate commercial release in Australia by the Gene Technology Regulator, and would seem inconsistent with the spirit of the Intergovernmental Agreement on Biotechnology.

This ban is affecting the canola industry's ability to source seed from production areas in Eastern Australia in a timely manner to meet the increasing needs of Western Australian farmers, who have quickly adopted this new technology to help them address significant herbicide resistance issues. These same issues are also affecting SA canola growers. This situation effectively means that GM canola approved for planting in Australia cannot be transported directly by truck across Australia, and must be either sent by road around to WA via the Northern Territory, shipped via sea around South Australia, or air freighted. All of this adds time and costs, and has led to requested seed not being available for planting. Quality testing of seed has also been affected, with seed companies now having to send GM seed to testing labs further afield for results leading to further delays and increased costs.

This total ban on the trade and commerce of GM seed and grain originally arose as an unintended outcome following the drafting of technical provisions in the *Genetically Modified Crops Management Act 2004* (South Australia) and subsequent definitional changes made to the Federal *Gene Technology Act 2000* (Cth) relating to the inclusion of transport as a 'dealing' under the Scheme. We would therefore ask that the Review consider whether the transport of GM crops approved for general release in Australia could be something that the Regulator could consider excluding as a dealing under the Scheme, and whether it can look to regulate the field in this respect in order to provide the certainty and flexibility needed by the seed industry in order to meet the legitimate demands of growers. The seed industry is already working on best practice guidelines for the transport of such products.



Low Level Presence

Currently under the Scheme, situations of low level presence (where a trait approved in another country is detected in Australia) must be dealt with through emergency licences, with a view to complete removal of the unapproved trait. It is the ASF's position that a better policy for addressing LLP in seed needs to be introduced into the Scheme. In agriculture, as with all biological systems, 100 per cent product purity is impossible and as agricultural biotechnology continues to be rapidly adopted around the world and trade in GM grains and seed increases, Australia's current legislation which imposes 'zero tolerance' to LLP will be unsustainable.

A national seed LLP policy that incorporates both thresholds based on industry practices and existing varietal purity standards, coupled with the recognition of safety assessments from other countries, will provide both industry and the Regulator with a comprehensive policy that maintains safety standards while at the same time being proactive, transparent and science-based. The use of familiarity – including a history of safe use, availability of data and safety assessments – could be incorporated into such a policy to allow for a proactive approach to specify situations where or if a safety assessment is required.

It would also help the seed industry if the definitions within the Act were amended to be consistent with internationally-recognised definitions in this space. This will ensure continuity when dealing with AP/ LLP incidents should they occur. This would also require the Australian government to continue participating in international regulatory forums in this area.

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