December 2016

Via email: ogtr@health.gov.au

Re: ASF submission to discussion paper on options for regulating new technologies

I am pleased to provide the following submission on behalf of the Australian Seed Federation which provides views on the discussion paper on options for regulating new technologies.

The Australian Seed Federation is also pleased to confirm that it is interested in receiving any updates about this consultation.

All correspondence regarding this submission and the consultation process can be addressed to:

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If you have any questions do not hesitate to contact me.

Yours sincerely

Bill Fuller
Chief Executive Officer
Australian Seed Federation

Australian Seed Federation
SOWING SEEDS

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Australian Seed Federation submission to discussion paper on options for regulating new technologies

December 2016

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Introduction

The Australian Seed Federation (ASF) welcomes the opportunity to submit comments on the Office of the Gene Technology Regulator's *Discussion paper on options for regulating new technologies*.

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 crucial to 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 New Breeding Technologies (NBTs), and in so doing providing 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.

History of Plant Breeding

Plant breeding is a product-oriented, science-based discipline for improving plants. Plant breeding is rooted in population development, selection theory, quantitative genetics, statistical analysis and an increasing number of support technologies. It involves generating genetic variation, selecting desirable plants, stabilizing inheritance of desirable characteristics, testing in multi-locations over many years, and multiplying the best performing plants.

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 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.

Some successful examples include:

- High-yielding and short barley for brewing industry.
- Heat tolerance and early maturity in cotton.
- Seedless watermelon.
- Multiple disease resistances in tomato.
- Ruby Red grapefruit.
- Gold Nijisseiki Japanese pear which is disease resistant.
- Peanuts with tougher hulls.
- Semi-dwarf rice with higher yields.
- Virus resistant cocoa plants.
- Canola with healthy fatty acid composition.

Breeders have historically integrated the latest technologies in plant biology and genetics into their methodologies to efficiently use existing variation, and to induce new genetic variation. Plant breeders continue to develop precise yet flexible methods to safely increase specificity and efficiency of breeding, decrease development time and cost, and increase genetic diversity for breeding programs. A major advantage of the latest breeding tools is the ability to precisely target a change to (a) specific gene(s) in a plant's genome to create the desired plant trait. They can also be used to identify a gene or allelic variant in a plant's gene pool (e.g. in wild relatives) and to precisely and efficiently introduce the desired gene/variant directly into an existing, high-performing commercial variety. By applying these methods, plant breeders can make the desired changes with greater precision and in a much shorter time than was possible with earlier breeding methods. Because these new methods are efficient and economical, they are accessible to public and commercial plant breeders (including from small and medium size enterprises) in developed and developing countries, and can be used across all agriculturally important crops, including field, vegetables and specialty crops – thereby speeding up innovation and sustainability. This is vitally important in the context of food security for an increasing global population in the face of climate change.

There is inherent variation in many characteristics considered to be important by plant breeders, and the expression of a trait is influenced by growing conditions. The development of a new plant variety normally involves many performance trials in different environments before introduction as a new commercial variety. Prior to the release of a new plant variety to farmers, plant breeders use well established, intensive assessments across growing conditions across locations and over multiple years to eliminate plants with undesirable characteristics, to ensure stability of the desired trait and to confirm performance. This evaluation is intended to not only confirm the performance of the new variety, but also to evaluate the variety's characteristics and eliminate those characteristics that are undesirable. The scrutiny that breeders routinely apply to new variety development is well established and has been the foundation for a food supply that is safe, nutritious and diverse. Importantly, plant varieties developed through the latest breeding methods are subject to the same critical performance evaluations and processes that breeders have used for many decades to create new plant varieties that are safe to grow and eat (see more below).

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 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.

Consistent Criteria for the Scope of Regulation

The Australian Seed Federation, 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 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.

Preferred Regulatory Option

The ASF strongly supports **Option 4** in the OGTR's Discussion Paper. It is the only Option that aligns completely with the seed industry's proposed criteria for regulating new breeding technologies 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 Discussion Paper only focusses on gene editing techniques, and does not address other new breeding platforms such as the cisgenesis and the proprietary Seed Production Technology (SPT). Clarity is needed across all of these technologies and we would encourage the Regulator to consider specific exclusion of these techniques, in addition to those considered in Option 4.

Supporting Technical Arguments

The ASF supports many of the technical arguments for exclusion presented in submissions concentrating on more technical aspects validating option 4, but offers some further information for consideration.

The Plant Breeding Testing Process

Plant breeding is often said to be a process not of selection, but of elimination. Any off-types, unstable lines, or lines showing characteristics such as significant differences in nutrient content, detrimental responses to environmental stresses, diseases, or the presence of other undesirable traits are discarded as soon as they are identified. An off-type is a seedling or plant that differs in one or more characteristic, such as flower colour or height. This winnowing takes place over several years, so the remaining lines identified for prospective commercial release will perform as expected. The environment in which a crop is grown often plays a significant role in affecting plant characteristics, such as the levels of certain anti-nutrients, overall yield and flowering. The trialling process occurs over multiple geographies and multiple years in order to observe that potential variability, keeping only the varieties that will meet consumer and grower expectations.

Genetically stable, potentially commercial varieties (including hybrids) are normally evaluated for:

- Geographic and production system adaptation.
- Performance characteristics, relative to existing commercial varieties.
- Processing characteristics appropriate for that crop, such as milling for wheat, sugar yield for sugar beets, oil quality for canola and sunflower or storage characteristics for fruits and vegetables.
- End-user characteristics (as appropriate for that crop), such as protein content for soybeans, bread-making characteristics for wheat and flavour characteristics for fruits and vegetables.

The advent of genomics, the ability to precisely sequence the genome of crops, and ultimately utilize molecular knowledge about favourable traits, has led to improved efficiencies in plant breeding and plant improvement capabilities. As an example, it was discovered that corn inbred lines can vary by up to 15% in the genes that are present in specific inbreds. In other words, inbred lines of corn, historic or recently developed, differ on average by 15% in the genes they contain and many genes will be absent from ones and present in others. This presence-absence variation is a natural phenomenon in corn that was only discovered by using modern genomics tools.

The discovery of this residual genomic variation may lead to new approaches to improving uniformity in products or further maximizing genetic potential. Genomics in breeding has not in any way changed the safety of the products; plants developed through breeding continue to have a record of safety while providing increased value (e.g. improved taste or disease resistance) for consumers and farmers. The few reported cases of crop toxicity so far have been associated with the elevation of known toxins, such that testing for their presence has become a routine part of the breeding process to prevent inadvertent increases in toxin levels. This provides a very strong scientific basis to use breeding, with its genetically discernible, yet phenotypically indistinguishable variations, as a baseline for safety evaluations – rather than the process used to create the variation.

Point mutations

Spontaneous and induced mutagenesis can introduce different types of mutation, one of which is the point mutation. A point mutation results in a change of one (or few) base pairs in the nucleotide sequence. Point mutations include substitutions (transitions and transversions) and insertions and deletions (known as frameshift mutations). Modifications that can be obtained from the targeted mutagenesis techniques of ODM, SDN-1 and SDN-2 techniques are comparable in type and extent to point mutations that can be obtained via spontaneous or induced mutagenesis, and are indistinguishable from such point mutations – as previously concluded by reputable regulatory agencies such as Food Standards Australia and New Zealand and the European Food Safety Authority. This is because such modifications are in fact substitutions, insertions or deletions.

The ASF further notes that the changes introduced by targeted mutagenesis techniques can be a continuum. Defining a specific base pair size threshold for regulation of these techniques is not supported as this will continue to stifle innovation and provide uncertainty to plant breeders. The criteria for regulation should be whether the technique results in the introduction of transgenes into the plant genome.

Off-target effects

The general finding to date has been that less off-target edits are observed with the use of SDN-1, SDN-2 and ODM techniques compared to conventional breeding techniques with a long history of safe use, including induced mutagenesis. In addition, when off target effects have been observed, they are typically similar or less than the generation to generation variability or variation among individuals in the genome of a species.

Cisgenesis and other techniques

A good technical reference relating to new breeding techniques is http://www.nbtplatform.org/. The fact sheets are very useful in describing a broad range of new technologies and the reasons why they should not be considered to result in genetically modified organisms. Cisgenesis, for example, is very similar to conventional breeding, but allows for a specific trait, such as disease resistance, to be transferred from a same or closely related crossable plant species to another - without altering the plant's overall genetic makeup. This breeding method therefore allows the natural breeding process to occur up to four times faster as the desired trait is exclusively introduced and no further breeding needs to be undertaken to eliminate unwanted characteristics in the new plant variety. As with conventional breeding, the donor plant must be crossable with the recipient plant, and the genetic transfer could also occur naturally as a result of crossbreeding. This is why the European Food Safety Authority has previously expressed the opinion that cisgenesis presents the same level of hazards as conventional breeding.

Conclusion

Disproportionate regulatory oversight mean higher costs, which limits the access of small and medium sized enterprises (SME) and public plant breeding institutions to the latest plant breeding innovation tools. Furthermore, it will impede the availability of a diversity of crops and varieties for farmers, including specialty crops and crops with niche markets – all of which are important to Australia's prosperity as it looks to be the food exporter of choice for the Asian region.

Regulations, if needed, should be based on sound scientific principles and proportional to any new potential risks to human health and safety or the environment. We believe specifically excluding low risk plant gene editing tools such as SDN-1, SDN-2, ODM, as well as the other techniques referenced in this submission (i.e.: null segregants and cisgenesis), from Australia's gene technology framework is in line with such an approach.

For our direct responses to the 8 questions raised in the discussion paper, please refer to Attachment 1.

Ends

Attachment 1 – ASF response to Consultation questions

1. Which option/s do you support, and why?

The ASF supports option 4. We refer to the conclusions of our submission:

'Disproportionate regulatory hurdles mean higher costs, especially for registration and approval, which limit the access of small and medium sized enterprises (SME) and public plant breeding institutions to the latest plant breeding innovation tools. Furthermore, such government policies will impede the availability of a diversity of crops and varieties for farmers, including specialty crops and crops with niche markets – all of which are important to Australia's prosperity as it looks to be the food exporter of choice for the Asian region.

Regulations, if needed, should be based on sound scientific principles and proportional to any new potential risks to human health and safety or the environment. We believe specifically excluding low risk plant gene editing tools such as SDN-1, SDN-2, ODM, as well as the other techniques referenced in this submission (i.e.: null segregants and cisgenesis), from Australia's gene technology framework is in line with such an approach.'

This conclusion fits best under option 4.

2. Are there other risks and benefits of each option that are not identified in this document?

Yes, options 1 – 3 lead to disproportionate regulation and therefore to the risk that development of new plant varieties (and therefore not only early-stage innovation) will be hampered: In case of regulation the new techniques will only be available for a few companies while many small and medium-sized companies are active in the breeding industry. Such companies will not have access to most efficient breeding methods which will lead to less innovation instead of speeding up innovation and will probably block innovation in smaller crops completely. We also refer to the first paragraph of our answer to question 1.

3. Is there any scientific evidence that any of options 2-4 would result in a level of regulation not commensurate with risks posed by gene technology?

We are not aware of such scientific evidence.

4. How might options 2-4 change the regulatory burden on you from the gene technology regulatory scheme?

This will differ per company. However, it is clear that just a few of the companies that are active in plant breeding worldwide will be able to absorb the regulatory burden. For all other companies, no change will occur: these companies do not have a regulatory burden now and will not be able to bear the regulatory burden in the future, as they will not be able to afford the cost of using regulated technologies.

5. How do you use item 1 of Schedule 1, and would it impact you if this item was changed?

   This varies per company therefore ASF cannot answer this question.

6. Might contained laboratory research on GM gene drive organisms pose different risks to other contained research with GMOs, and how could these risks be managed? Supporting information and science-based arguments should be provided where possible.

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7. What RNA interference techniques are you using, and are there RNA interference techniques that you believe have unclear regulatory status? Please provide details of the techniques and science-based arguments for whether these techniques pose risks to human health or the environment.

   ASF cannot give information about the use of the different techniques by the companies that are member of ASF. However, ASF believes RNA-dependent DNA Methylation should not be regulated under the GT Regulations. In this respect we refer to the following fact sheet from the NBT platform:

   http://www.nbtplatform.org/background-documents/factsheets/factsheet-rna-directed-dna-methylation.pdf

8. Do you have proposals for amendments to any other technical or scientific aspects of the GT Regulations? All proposals should be supported by a rationale and a science-based argument.

   As described in our submission, the ASF notes that the discussion paper only focuses on gene editing techniques, and does not address other new breeding techniques. This is an opportunity lost, as clarity is needed across all of these technologies. We would encourage the Regulator to consider specific exclusion of these techniques, including cisgenesis, the use of null segregants, and techniques such as the proprietary Seed Production Technology (SPT), in addition to those considered in Option 4.