



19 April 2018

Via email; NBTConsultSubmissions@foodstandards.gov.au

Re: FSANZ Consultation Paper - Food derived using new breeding techniques

I am pleased to provide the following submission on behalf of the Australian Seed Federation which provides views on the reforms proposed in the Consultation Paper - Food derived using new breeding techniques

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:

Mr Bill Fuller
Chief Executive Officer
Australian Seed Federation
PO Box 3572
MANUKA ACT 2603
Telephone: 02 6282 6822
Facsimile: 02 6282 6922
Email: bfuller@asf.asn.au

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

ABN 66 003 160 638

**Australian Seed Federation
Submission
FSANZ Consultation Paper: Food derived
using new breeding techniques.**

April 2018



INTRODUCTION

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, all of whom were consulted in the preparation of this submission.

ASF members welcome the opportunity to provide comments to the Food Standards Australia New Zealand's (FSANZ) *Consultation Paper on Food Derived Using New Breeding Techniques*, and the consideration of the definitions in the *Australia New Zealand Food Standards Code* for 'food produced using gene technology' and 'gene technology'.

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 innovations, and to future-proof ASF members' ability to deliver the best seed and technology to farmers.

To this end, the ASF supports the overarching objective of this consultation to provide clarity regarding whether pre-market assessment and approval is appropriate for food derived using a diverse range of plant breeding innovations, referred to by FSANZ collectively as 'New Breeding Techniques'. We also believe that harmonisation of these techniques within Australia and New Zealand, and internationally, should also be a key objective of this review.

The ASF has long supported the position of the International Seed Federation that the underlying principle for regulating these new breeding techniques should be that *plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods*.

The genetic variation in a final plant product should not be covered under the scope of existing biotech/GMO regulations for plants if:

1. 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**;
2. The final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, **or**;
3. The genetic variation is the result of spontaneous or induced mutagenesis.

QUESTIONS

3.1.1 Do you agree, as a general principle, that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval?

Should there be any exceptions to this general principle?

The ASF believes that the regulation of food safety risks should be focussed on the final characteristics of the food derived from the new plant variety and not on the breeding process used to produce that variety. Food derived from conventional breeding methods, such as those that harness spontaneous or induced mutagenesis, can already generate large amounts of genomic variation within an organism and is not subject to pre-market safety assessment. As such, we believe food derived from similar genetic variation generated using newer plant breeding innovations should not be subject to pre-market regulation simply because the process was different.

We would suggest that FSANZ review their proposed definition for ‘new DNA’ to ensure that genetic variation in the final food is not covered under the scope of existing biotech/GMO regulations for plants if:

1. 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;
2. The final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;
3. The genetic variation is the result of spontaneous or induced mutagenesis.

3.1.2 Should food from null segregant organisms be excluded from pre-assessment and approval?

If yes, should that exclusion be conditional on specific criteria and what should those criteria be?

The ASF is of the view that food derived from null segregant organisms should be excluded from pre-assessment and approval. As per our regulatory principle mentioned above, such organisms would be indistinguishable from organisms produced through earlier breeding methods. These organisms do not contain any transgenic events due to normal segregation following conventional breeding with an organism that did not contain the transgenic event and, as such, food derived from these organisms does not contain any elements from a transgenic event. It should therefore not be subject to pre-market safety assessment and approval as a GM food.

In addition, we would highlight that the Office of the Gene Technology Regulator has specifically proposed to exclude null segregants from regulation under the *Gene Technology Act 2000*, as one of the conclusions of its technical review of the Gene Technology Regulations 2001. We would therefore propose that FSANZ adopt the same criteria and definitions as the OGTR for excluding food from null segregant organisms from regulation. Harmonisation and certainty is extremely important to plant breeders.



3.1.3 Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis?

If yes, would this apply to all derived food products or are there likely to be some foods that carry a greater risk and therefore warrant pre-market safety assessment and approval?

New plant varieties developed using genome editing applications are essentially a more precise way of cross-breeding or inducing mutagenesis than foods derived using chemical or radiation mutagenesis, and therefore should not be treated differently from a regulatory perspective than those new plant varieties developed through conventional breeding methods. There is no reason to believe that a genetic change (i.e. insertions, deletions or substitutions) that relies on the existing inherent diversity within a plant's gene pool would be more likely to present a new or novel food safety risk. Indeed, chemical and radiation mutagenesis generate large amounts of genetic variation. Such variation, when generated using new techniques, should not be regulated differently. This is inconsistent with the principles of proportionate and science-based regulation and would put ASF members choosing to use these newer, more precise techniques at a disadvantage.

We would also make the point that plant breeders use common and well-established practices to evaluate the quality and safety of new varieties introduced into the market. All varieties are checked over several generations for safety prior to launch. All foods introduced on to the Australian and New Zealand market are also subject to food safety recall and misleading and deceptive labelling requirements.

3.2 Are you aware of other techniques not currently addressed by this paper which have the potential to be used in the future for development of food products?

The ASF maintains that the principle that *"food derived from plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods"* should still apply to all techniques used to produce food for the Australian and New Zealand market.

The ASF also notes that the proposed exclusion of SDN-1 techniques from regulation under proposed amendments by the OGTR specifically refer to an organism 'modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was not added to guide homology-directed repair'. In addition to site-directed nucleases, plant breeders are looking to use recombinases or indeed other DNA modifying enzymes such as DNA methylases or deaminases (used for base editing) to produce the same effect. We would therefore like to recommend that in order to future-proof and cover other techniques, when covering specific techniques, focus should be on the intended result of a modification (for example, non-guided repair resulting from a break in genomic DNA) rather than the specific tool.



3.3 Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs?

If no, what other approaches could be used?

Are there any aspects of the current definitions that should be retained or remain applicable?

The ASF believes that the current process-based definitions are no longer fit for purpose. The final characteristics of food derived from a new plant variety are the best indicator as to whether a food derived from a new plant variety will present a food safety risk. Again, we would draw your attention to the regulatory principle we provided in our introduction: *“Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods.”* The same principle should apply to the regulation of food derived from those plant varieties to ensure harmonisation, fairness, certainty and enforceability, and to provide opportunity for innovation.

3.4 Are there other issues not mentioned in this paper that FSANZ should also consider, either as part of this Review or any subsequent proposal to amend the Code?

We have mentioned this previously, but it is important that the products resulting from any new technologies are regulated as consistently as possible between Australian Government regulatory agencies and between Australia and New Zealand (main trading and R&D partner countries). This is a matter of good regulatory practice and serves to avoid a situation whereby, for example, a product is regulated as a GMO regarding its release into the environment, but not as a GM food, and vice versa. Such an approach reduces red tape and provides certainty to the regulated and scientific community. This is vital when making investment decisions relating to research pipelines. Unnecessarily high regulation will limit utilization of these new techniques to the largest companies with negative impact on smaller companies and public researchers and will also limit utilization to the highest value crops (e.g., corn, soybeans) and negatively impact on specialty crops and crops with smaller markets. This is likely to result in limited numbers of new varieties available to farmers

We would also like to see the Australian and New Zealand governments to push for harmonisation of the regulation of these techniques internationally, to reduce regulatory hurdles and to provide the best environment for Australian and New Zealand innovation in plant breeding. Inconsistent policies make research collaborations difficult, have a negative impact on the commercial seed trade as well as trade in agricultural products, will limit the range of new varieties for farmers and new products for consumers, and will hamper global innovation and agricultural development.



CONCLUSION

The ASF supports the overarching objective of this consultation to provide clarity regarding whether pre-market assessment and approval is appropriate for food derived using a diverse range of plant breeding innovations, referred to by FSANZ collectively as 'New Breeding Techniques'. We also believe that harmonisation of these techniques within Australia and New Zealand, and internationally, should also be a key objective of this review.

The ASF has long supported the position of the International Seed Federation that the underlying principle for regulating these new breeding techniques should be that *plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods.*

Thank you again for the opportunity to provide input. The ASF would be happy to discuss any of our comments in more detail.

Ends