# 1 INTRODUCTION

ESA European Seed Association is the voice of the European seed industry, representing the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species.

Today, ESA has more than 35 national member associations, from EU Members States and beyond, representing several thousand seed businesses, as well as more than 70 direct company members, including from seed related industries.

**Mission**

ESA's mission is to engage on behalf of its members with all relevant European decision makers in order to represent their interests and to contribute to a

- fair and proportionate regulation of the European seed sector
- freedom of choice for customers (farmers, growers, industry, consumers) in supplying seeds as a result of innovative, diverse technologies and production methods
- effective protection of intellectual property rights relating to plants and seeds.

ESA welcomes the opportunity to provide comments to the Food Standards Australia New Zealand (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'.

ESA supports the overarching objective of the Review to provide clarity regarding whether pre-market assessment and approval is appropriate for food derived using a diverse range of breeding innovations, referred to by FSANZ collectively as 'New Breeding Techniques'.

ESA's long held view is that *food derived from plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during the plant's development if they are similar to, or indistinguishable from foods that could have been produced using plants developed through earlier breeding methods.*[1]

[1] https://www.euroseeds.eu/system/files/publications/files/esa_17.0510.pdf

# 2 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?

ESA strongly recommends that the future focus of assessing food safety risks should be on the final characteristics of the food derived from the new plant variety and not only the breeding process used to produce that variety. This would also facilitate international harmonization of scope of regulatory of oversight e.g. with the Regulation (EU) 2015/2283 ("Novel Food Regulation")[2] which in addition to the production process takes into account as a trigger for regulatory oversight the *"significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances".*

Food derived from conventional breeding methods, such as those that harness spontaneous or induced mutagenesis to generate large amounts of genomic variation is not subject to pre-market safety assessment. Food derived from similar genetic variation, when generated using newer plant breeding innovations, should not be subject to pre-market regulation purely on the process through which it was created.

In considering the different outcomes of plant breeding innovations, genetic changes can range from small nucleotide changes, deletions or additions; to re-creating an allele from a wild relative in a commercial variety; to introducing a transgene in a site-specific manner. Other products of genome editing, such as introducing a gene from an unrelated species, are similar to 'foods produced using gene technology' that are currently captured by the Code.

Several of these products of genome editing applications could also be accomplished, albeit more slowly and with less precision, through conventional plant breeding methods, such as crossing a commercial variety with a wild relative, or random mutation breeding. This is an important point to bear in mind when considering the potential for any new food safety risks.

There is inherent variation in many characteristics of a new variety considered to be important by plant breeders, and the expression of these characteristics 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

[2] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p. 1–22.

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 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. 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.

### 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?

ESA **strongly recommends** that food derived from null segregant organisms should be excluded from pre-assessment and approval. As mentioned above, a purely process based approach in regulation of foods derived from new plant varieties resulting from certain new breeding processes without taking into account the final characteristics of the food derived from the new plant variety would be scientifically unjustifiable.

There is no scientific basis to regulate food obtained from organisms that are derived from GMOs (that would be regulated under the *Gene Technology Act 2000*) that lost the transgenic event (insert) due to normal segregation following conventional breeding with an organism that did not contain the transgenic event. Food derived from these organisms does not contain any elements of the transgenic event and therefore should not be subject to pre-market safety assessment and approval as a GM food.

As discussed in ESA's response to Question 3.4 below, the consistency of regulation between government agencies is desirable. FSANZ should be aware that through the proposed interim amendments to the Gene Technology Regulations 2001, the OGTR is proposing to clarify the regulatory status of "organisms that are not themselves categorized as GMOs but have been derived from GMOs."[3] The OGTR is clear that the definition of 'GMO' in the *Gene Technology Act 2000* does not include organisms derived from GMOs that lost the transgenic event, also known as null segregants.

[3] See http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/amendment%20proposals-1 accessed 21 March 2018.

### 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 that are essentially a more precise way of cross-breeding or inducing mutagenesis 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.

As discussed previously, spontaneous or induced mutations could result in these same types of changes at the genetic level. Substituting an allele from a wild relative, either through cross-breeding or genome editing, would not result in a differing food safety profile.

Food products derived from plants produced using genome editing represent a step forward in the precision of change that can be brought about as part of the continuum of breeding processes available. Due to these significant improvements in the precision of genome modification processes, concomitant improvements in the food safety profiles of derived foods can be achieved.[4]

A discriminatory application of regulation would result in a situation where certain methods of gene technology are excluded from the scope of regulation based on their history of safe use, while regulation would be applied to methods that result in even more precise and more predictable outcomes than ever achievable with earlier excluded methods.

In ESA's view, this is inconsistent with the principles of proportionate and science-based regulation. Furthermore, such discrimination between various induced mutagenesis tools, does not help in addressing the potential risks associated with the resulting organisms and food derived therefrom. In our understanding, identical outcomes could be achieved with the application of different methods, some of which are more recent and more efficient than earlier ones. It is not scientifically justified to regulate the "novelty" of a process while not considering the outcome of the method – the resulting product. As the outcomes of genome editing can be equivalent to those of conventional breeding methods, the presumption of history of safe development should logically extend to these products as well.

As mentioned above, plant breeders use common and well-established practices to evaluate the quality and safety of new varieties introduced into the market. There will undoubtedly be

[4] Podevin, N et al. (2013) *Trends in Biotechnology* 31:375 383.

instances when food derived from a genome edited plant warrants pre-market safety assessment and approval; for example, if the nutritional profile of the food is significantly changed.

## 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?

One specific technique is 'base editing', which could be considered as similar to genome editing, but does not rely on double-stranded breaks. However, while technology development is accelerating and the pace of change is growing, food regulators need to be agile and regulations as future proof as possible to avoid stifling much needed innovation in the food industry.

While technology tools continue to advance, the same principle that "*food derived from plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during the plant's development if they are similar to, or indistinguishable from foods that could have been produced using plants developed through earlier breeding methods"* should still apply.

To be 'future proof', the Code needs to refrain from differentially regulating the latest breeding methods, if they do not result in food that poses new risks relative to the food resulting from plants derived from conventional breeding methods and that is already excluded. Mechanisms for the regular review and revision of the Code are crucial: food derived from technologies to be excluded from pre-market assessment and approval can be identified based on scientific evidence, and the body of accumulated knowledge and experience with gene technology; where that is not available today it should be considered as it develops.

Such an approach promotes regulation that is proportionate to risk, and regulation that is focussed on the protection of human health and safety.

While this question invites technological advances that can be 'foreseen', it is not appropriate to attempt to regulate concepts that are today merely speculation. The focus of this review should therefore be on providing regulatory certainty in the short to medium term, but also to provide the mechanisms that will enable the Code to be reactive in the longer term. A practical approach could be implementing the necessary legislative mechanisms or policy approaches that permit FSANZ to continuously 'scan the horizon' for new processes and products that could present novel food risks, and to ensure their approach to risk assessment remains robust and effective.

## 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?

ESA **submits** that the current process-based definitions are no longer fit for purpose and no longer deliver appropriate risk-based outcomes in terms of what foods are captured for pre-market safety assessment.

As above, the final characteristics of the 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.

This review provides the opportunity to improve the definitions used by FSANZ, particularly that of 'gene technology'. The question of process versus product based interpretation of the GMO definition in the European Union is currently part of a judgement at the European Court of Justice (Case C-528/16) on which Advocate General Bobek delivered his Opinion on 18 January 2018. According to this Opinion, the Advocate General also interprets the EU GMO definition in a way that takes into account the process as well as the final genetic characteristics of the product as a regulatory trigger.[5]

As discussed in ESA's response to Question 3.4 below, the consistency of regulation between government agencies within Australia, but also achieving harmonized scope of regulatory oversight between countries is desirable. The alignment of the definition of gene technology in the Food Standards Code and the *Gene Technology Act 2000* would be a step in the right direction. A revised definition should be based on the following principle:

"*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 as mentioned above.

[5] https://www.euroseeds.eu/system/files/publications/files/position_paper_on_advocate_general_bobek_opinion_c-528-16_final.pdf

## 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?

*Consistency regulation of new technologies across government agencies*

There are currently three reviews underway into the way Australia regulates Gene Technology, namely:

- 2016 Technical Review of the Gene Technology Regulations
- 2017 Review of the National Gene Technology Regulatory Scheme
- 2018 FSANZ Review of Food Derived Using New Breeding Techniques

ESA believes it is important that products resulting from new technologies are regulated as consistently as possible between Australian Government regulatory agencies, but also between 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.

ESA recognises that the OGTR and FSANZ operate under separate pieces of legislation and that they regulate different products of plant breeding innovation for different risks, therefore there may be unavoidable areas of divergence (differentiation of regulation of cisgenic organisms may be one example). We strongly believe, however, that efforts should be made to harmonise the way in which products resulting from the latest plant breeding methods are regulated as far as possible, consistent with Australian Government's high-level policy priority of minimising regulatory 'red tape'. ESA believes this is achievable as an outcome of the current reviews.

**International perspective**

Consistent policies among governments for products of the latest plant breeding methods, such as gene editing, would facilitate the development and uptake of advanced, innovative breeding applications by both industry and public breeders in developed and developing countries. Plant breeders need legal certainty so they can reliably plan their breeding programs, their product development and market potentials. 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 speciality crops and crops with niche markets.

ESA is therefore supporting a consistent approach among governments to the scope of regulatory oversight for products of plant breeding innovation. The first step in this process is agreement among countries on the criteria that would be used to determine the scope of regulatory oversight.

# 3 CONCLUSION

Food derived from conventional breeding methods, such as those that harness spontaneous or induced mutagenesis to generate large amounts of genomic variation is not subject to pre-market safety assessment. Food derived from similar genetic variation, when generated using newer plant breeding innovations, should not be subject to pre-market regulation purely on the process through which it was created.

ESA's long held view is that food derived from plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during the plant's development if they are similar to, or indistinguishable from foods that could have been produced using plants developed through earlier breeding methods.

New plant varieties developed using genome editing applications that are essentially a more precise way of cross-breeding or inducing mutagenesis 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 in a plant's gene pool and that results from one of the latest breeding methods would be more likely to present a new or novel food safety risk.

The final characteristics of foods derived from a new plant variety are the best indicator as to whether those foods will present a food safety risk and this needs to be recognised as part of the Food Standards Code.