AusBiotech submission in response to the *Food Standards Australia and New Zealand Consultation Paper: Food Derived Using New Breeding Techniques*

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1. Introduction

AusBiotech is pleased to submit feedback on the *Consultation Paper: Food Derived Using New Breeding Techniques* as released for public comment in February 2018. This submission represents a collation of comments and submissions from AusBiotech members engaged in delivering economic benefits to Australia through the commercialisation of biotechnology.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology, food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies and employs in excess of 69,000 Australians.

Within AusBiotech the agriculture, food and industrial biotechnology sectors are represented by the AusAg & Foodtech Committee, a special interest industry group dedicated to support AusBiotech with its mission to:

> "…foster a growing, strong and profitable biotechnology and life science industry in Australia through representation, advocacy and the provision of services and benefits to its members to help the industry realise its nationally important economic potential."

AusBiotech supports the objectives of the Review of the Food Standards Code, in particular exploring options for regulation of food derived using new technologies. AusBiotech welcomes this opportunity to respond and comment on the *Consultation paper: 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'.

AusBiotech Response to Consultation 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?

AusBiotech **disagrees** that any food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval. AusBiotech maintains that all regulation must be commensurate with risk. AusBiotech argues that there is no foundation to the assumption that food derived from organisms that contain 'new' pieces of DNA are of greater risk than food developed using 'conventional' breeding. Pre-market safety assessment and approval should only be required if the final characteristics of the food warrant such an assessment and not based on the process or technique(s) that may be been applied to produce the product. The adoption of the proposed general principle would advocate a process regulatory trigger for new breeding techniques that is not commensurate with risk.

The introduction of 'new pieces of DNA' should not in itself imply that a food product poses additional risk to food safety. In fact, there are multiple technologies and approaches available that can lead to food products with the same trait. For example, certain crop traits can be achieved via plant cell or tissue culture and other traditional plant breeding techniques, chemical/radiation-mediated mutagenesis breeding, transformation of a plant with either native or mutant resistant genes (i.e. transgenesis, cisgenesis or intragenesis) and more recently genome editing. Currently, the use of some of these breeding techniques in the development of new and improved crop varieties are excluded from pre-market safety assessment and approval on the basis of a demonstrated history of safe use.

AusBiotech recognises that the current approach to assess and include in Standard 1.5.2 Food Produced Using Gene Technology has worked very well over the past 20 years. Many of the products that have been assessed and approved by FSANZ perhaps could now be considered as having a history

of safe use. However, AusBiotech does not support an over-arching principle as this would undermine the scientific credibility of the regulatory system when similar products are subject to vastly disparate regulatory requirements. With regulation of all products resulting from a new breeding technology it is inevitable that there will progressively be overlap in end-products that are derived from different processes and therefore a process-based regulatory system will become increasingly discredited[1].

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?

If no, what are your specific safety concerns for food derived from null segregants?

The generation and use of null-segregants **should not require pre-assessment and approval**. AusBiotech contends that there is no scientific basis for organisms that are derived from genetically modified organisms (GMOs) that no longer contain a functional DNA insert that was integrated into the genome to be regulated under the Food Standards Code. Null-segregants are no longer a transgenic event due to loss of the transgene by segregation following conventional breeding with a sexually compatible plant that did not contain the transgenic event. These organisms do not contain any elements of the transgenic event and therefore cannot be classified as being a GMO, or derived from one, using molecular detection tools. Null-segregants are therefore indistinguishable from that obtained through conventional breeding methods and should not be regulated.

AusBiotech advocates, where appropriate, harmonisation and consistency of regulation. It is important for FSANZ to note that the Office of the Gene Technology Regulator (OGTR) have suggested amendments to the *Gene Technology Regulations 2001*, proposing to clarify the regulatory status of '*organisms that are themselves categorised as GMOs, but have been derived from GMOs*'[2]. The OGTR have proposed that organisms derived from GMOs that have not inherited traits that occurred because of gene technology (null-segregants) not be considered a 'GMO' and therefore not be regulated under the *Gene Technology Act 2000*. AusBiotech recommends that in the interests of harmonisation and regulatory consistency that FSANZ align with this determination.

AusBiotech notes and supports the recent statement from the U.S. Secretary of Agriculture providing clarification on the U.S. Department of Agriculture's (USDA) oversight of plants produced through innovative new breeding techniques which include techniques called genome editing[3]. Under the US biotechnology regulations, USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests.

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 no, how are they different?

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?

[1] Morris and Spoillane (2008). GM directive deficiencies in the European Union. EmBO Rep 2008; 9:500-4; PMID:18516083; http://dx.doi.org/10.1038/embor.2008.94
[2] See http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/amendment%20proposals-1
[3] https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation

New mutagenesis techniques based on cellular DNA repair (SDN-1, SDN-2 and ODM techniques) outlined in the FSANZ Consultation Paper are increasingly being used in product development applications for the targeted mutagenesis of endogenous genes to induce the loss of gene function, modulate activity or alter function.

AusBiotech supports the same regulatory treatment of products developed with new technologies to those that can similarly be obtained with various 'conventional' tools – such as use of the allelic variation within an organism, spontaneous mutations, or traditional chemical or radiation induced mutagenesis. The application of DNA repair mechanisms, such as mutagenesis, have a long safe history of use in the development of useful agricultural traits particularly in plants including, for example, herbicide tolerance, changed nutritional composition, and resistance to biotic (e.g. disease) and abiotic stresses[4].

The scientific literature consistently reports that new breeding technologies such as SDN-1, SDN-2 and ODM, present no greater risk to human health safety and the environment than those posed by conventional mutagenesis techniques[5] [6] [7] [8] [9] [10]. Further, the weight of evidence supports a key benefit of new technologies, namely their precision and the enhanced predictability of off-target effects compared to conventional random mutagenesis techniques. As such, and with due consideration of the pros and cons presented within the Consultation Paper, AusBiotech does not support the 'general principle'.

Further, AusBiotech advocates that any application/addition of regulation should adhere with the principles outlined in The Australian Government Guide to Regulation[11].

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 the development of food products?

Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

AusBiotech argues that regulation must be commensurate with risk. As such, pre-market safety assessment and approval should only be required if the final characteristics of the food warrant such an assessment and not based on the process or technique(s) that may be been applied to produce the product. New techniques, such as DNA methylation or the addition of traits that are not necessarily associated with a gene product and would present several challenges for product developers in making submissions to FSANZ. Such non-genic techniques will undoubtedly continue to be identified. This review offers the opportunity for FSANZ to re-shape the regulatory system so that it can be responsive to new and emerging technologies, particularly one that is risk based.

[4] The FAO/IAEA Mutant Variety Database (https://mvd.iaea.org)
[5] Carroll D, Van Eenennaam AL, Taylor JF, Seger J, Voytas DF. Regulate genome-edited products, not genome editing itself. Nat Biotechnol. 2016 May 6;34(5):477-9. doi: 10.1038/nbt.3566
[6] Ishii, T and Araki, M. Consumer acceptance of food crops developed by genome editing. Plant Cell Rep (2016) 35:1507-1518.
[7] Ming, L., Gilbert, B. and Ayliffe, M. Applications of CRISPR/Cas9 technology for targeted mutagenesis, gene replacement and stacking of genes in higher plants. Plant Cell Rep (2016) 35:1439-1450.
[8] SNF. (2016). Results and recommendations of NRP 59. Retrieved from Swiss National Science Foundation (SNF) Press Conferences: http://www.nfp59.ch/e_portrait_details.cfm
[9] Sprink, T. Eriksson, D., Schiemann, J. and Hartung, F. Regulatory hurdles for genome editing: process- vs. product-based approaches in different regulatory context. Plant Cell Rep (2016) 35:1493-1506.
[10] Tizard M, Hallerman E, Fahrenkrug S, Newell-McGloughlin M, Gibson J, de Loos F, Wagner S, Laible G, Han JY, D'Occhio M, Kelly L, Lowenthal J, Gobius K, Silva P, Cooper C, Doran T. Strategies to enable the adoption of animal biotechnology to sustainably improve global food safety and security. Transgenic Res. 2016 Oct;25(5):575-95. doi: 10.1007/s11248-016-9965-1. Review
[11] The Australian Government Guide to Regulation

The application/addition of regulation should adhere with the principles outlined in The Australian Government Guide to Regulation.

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?

If yes, how could a process-based approach be applied to NBTs?

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

AusBiotech agrees that the current process-based definition has generally worked well in Australia and New Zealand, particularly for the rigorous assessment of transgenic GM foods. As discussed above in our response to 3.1.1, AusBiotech does not consider a process-based trigger to be a sustainable regulatory model. Regulation must be risk based backed by scientific rigour and not generalist in application. With the advent of many new techniques and processes that could deliver essentially the same outcome ('product') there will inevitably be an increase in regulatory inconsistencies. As such, this review offers an opportunity for FSANZ to reassess the current definitions. AusBiotech suggests that definitions be considered that examine the risk/characteristics of the 'end-product' rather than the process by which it was generated. To this end, AusBiotech supports CropLife's proposed definitions for the *Gene Technology Act 2000*.

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.

The inserted text (underlined) above would exclude upfront from regulatory scope foods derived from organisms developed using the techniques of ODM, SDN-1 and SDN-2. It also does not change the regulatory status of food derived from organisms that are currently, and have historically been, within regulatory scope of the Food Standards Code.

Further, AusBiotech recommends that the definitions should clarify what modifications would require pre-market safety assessment and approval (e.g. modifications that impact allergenicity or toxicity). Other changes that have a history of safe use should not require such assessment.

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?

Regulatory harmonisation and consistency

AusBiotech welcome the opportunity to contribute to the three reviews currently underway in Australia examining how gene technology is regulated:

1. Technical Review of the Gene Technology Regulations (lead by the OGTR).
2. Review of the National Gene Technology Regulatory Scheme (lead by the Department of Health).

3. Review of Food Derived Using New Breeding Techniques (lead by FSANZ).

AusBiotech contends that it is important for government agencies to ensure that regulation is harmonised and applied as consistently as possible. AusBiotech recommends that the regulation of gene technology should be considered in accordance with the Australian Government's Regulatory Reform Agenda that focuses on enhancing innovation, competitiveness, productivity and economic growth, as well as reducing regulatory burden.

Revised policy on gene stacking

AusBiotech notes that FSANZ does not require separate approval or safety assessment for foods derived from a stacked GM line that is the result of traditional breeding between several GM parent lines for which food has already been approved. Plants with stacked genes now form a significant part of GM crops grown throughout the world and will only increase as the costs of deregulation increase and to support the advanced breeding of complex traits such as yield and quality.

AusBiotech supports the recommendation from CropLife that FSANZ consider clarification regarding the 'unstacking' of genes through conventional breeding. For example, if a plant with three unlinked GM events (i.e. insect resistance, herbicide tolerance and drought tolerance) has been assessed and approved by FSANZ as a 'stack' then a new plant variety containing one or two or those events segregated by conventional breeding, should not be subject to separate regulatory oversight.