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18th April 2018

Food Standards Australia and New Zealand
Food derived using new breeding techniques - review
15 Lancaster Place
Majura Park ACT 2609

Re: Submission: Consultation Paper- Food Derived Using New Breeding Techniques

Dear Mr Booth,

The La Trobe Institutional Biosafety Committee (LTIBC) appreciates the opportunity to provide this submission in response to the Consultation Paper – Food Derived Using New Breeding Techniques.

The LTIBC values input into Australia's food regulatory system and is committed to providing appropriate governance and oversight to biosafety across the University's teaching, research and development portfolio. The LTIBC believes that clarification and certainty is required in the assessment and management of New Breeding Technologies (NBTs) across the diversity of current and future applications.

Yours Sincerely,

Dr Carl Ramage

Chair, La Trobe Institutional Biosafety Committee
Ethics and Integrity, Research Office
La Trobe University

La Trobe Institutional Biosafety Committee Submission

Introduction

La Trobe University has a fine history as an excellent university with an enduring social conscience. We continue to support access, diversity and inclusivity while undertaking world- class research that aims to address the global forces shaping our world and make a difference to some of the world's most pressing problems, including climate change, securing food, water and the environment, building healthy communities, and creating a more just and sustainable future

This approach is based on our values of:

- Inclusiveness, diversity, equity and social justice
- Pursuing excellence and sustainability in everything we do
- Championing our local communities in Melbourne's north and regional Victoria
- Being willing to innovate and disrupt the traditional way of doing things.

Our Mission

Advancing knowledge and learning to shape the future of our students and communities.

Our Vision

To promote positive change and address the major issues of our time through being connected, inclusive and excellent.

In line with our strategic plan, the LTIBC 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'.

LTIBC 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?

The increase in new techniques for enhancing plants, animals and foods presents both a regulatory challenge and opportunity for FSANZ. The LTIBC **does not agree** that any food derived from organisms containing new pieces of DNA, *per se*, should be captured for pre-market safety assessment and approval. The LTIBC maintains 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 applied to produce the product. The adoption of the general principle would advocate a process regulatory trigger 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, crop herbicide tolerance 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 gene editing. Currently, the use of some of these breeding techniques in the development of new and improved herbicide tolerance varieties are excluded from pre-market safety assessment and approval on the basis of a demonstrated history of safe use.

La Trobe University 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, La Trobe University 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 discredited¹.

The LTIBC reiterates that regulation must be commensurate with risk. The current system that has assessed plants developed using transgenesis has worked well, and this needs to be recognised. However, where traits have been assessed previously for food safety or have a demonstrated history of safe use, such products should not be required to undergo a pre-market safety assessment or approval.

La Trobe University 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 editing².

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 <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>

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.

3.1.2 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**. 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 '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 identified 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.

The LTIBC supports, 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*'³. 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*.

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?

New mutagenesis techniques based on cellular DNA repair (SDN-1, SDN-2 and ODM techniques) outlined in the Consultation paper have been used in several research and product development applications for the targeted mutagenesis of endogenous genes to induce the loss of gene function, modulate activity or alter function. At La Trobe University, the techniques are a valuable tool for the study of important areas with direct community impact across all Research Focus Areas.

The LTIBC advocates 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

³ See <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/amendment%20proposals-1>

example, herbicide tolerance, changed nutritional composition, and resistance to biotic (e.g. disease) and abiotic stresses⁴.

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 (Supplement 1). 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 Pro's and Con's presented within the Consultation Paper, the LTIBC does not support the 'general principle'.

Further, any application/addition of regulation should adhere with the principles outlined in The Australian Government Guide to Regulation⁵.

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?

The LTIBC maintains 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 applied to produce the product. New techniques, such as DNA methylation or the addition of traits that are not associated with a gene product (e.g. gene edited POLLED trait in cattle) will undoubtedly continue to be identified. This review offers the opportunity to shape the regulatory system so that it can be agile and adapt to new and emerging technologies.

The application/addition of regulation should adhere with the principles outlined in The Australian Government Guide to Regulation⁵.

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?

The current process-based definition has generally worked well in Australia and New Zealand. FSANZ have established a rigorous and transparent process for assessing the safety of GM foods. Their approach is internationally recognised with the safety assessment undertaken in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development (OECD), Food and Agriculture Organization (FAO) of the United Nations, World Health Organization (WHO) and the Codex Alimentarius Commission. However, to date, FSANZ have only examined products from GM plants and no products derived from NBTs have yet been put forward for assessment.

⁴ The FAO/IAEA Mutant Variety Database (<https://mvd.iaea.org>)

⁵ [The Australian Government Guide to Regulation](#)

As discussed above in our response to 3.1.1, the LTIBC does not consider a process-based trigger to be sustainable. Regulation must be risk based backed by scientific rigour and not generalist in application. With the advent of many techniques and processes that could deliver essentially the same 'product' there will inevitably be an increase in regulatory discrepancies. As such, this review offers an opportunity to reassess the current definitions. The LTIBC suggests that definitions be considered that examine the risk/characteristics of the 'end-product' rather than the process by which it was generated. Further, 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

The LTIBC notes that there are currently three reviews 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).

It is important for government agencies to ensure that regulation is harmonised and applied as consistently as possible. The LTIBC 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.

Construct/trait based approvals

Currently, food regulation applied through 'Standard 1.5.2 – Food produced using gene technology' requires a technology provider to submit an application to FSANZ to amend the Food Code for each individual GM event. This means that FSANZ may assess the same genetic construct/trait several times and the technology provider would be required to provide data for each and every event. In these cases, a construct-based approval or a reduced data pack might be more commensurate to the potential food risk? This would serve to reduce the regulatory burden for technology providers and reduce the administrative assessment impost on FSANZ.

Supplement 1 – New Breeding Technology Literature Reviewed

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