

3<sup>rd</sup> December 2021

Food Standards Australia and New Zealand  
Definitions for gene technology and new breeding techniques  
PO Box 5423  
KINGSTON ACT 2604

**Re: Submission: Proposal P1055- Definitions for Gene Technology and New Breeding Techniques**

Dear Standards Management,

The La Trobe Institutional Biosafety Committee (LTIBC) appreciates the opportunity to provide this submission in response to the Proposal P1055 – Definitions for Gene Technology and 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 around the definitions for gene technology particularly considering the rapid adoption of New Breeding Technologies (NBTs) across the agricultural and food sectors.

The LTIBC supports FSANZ's preferred **Option 3** and supports the proposed adoption of a regulatory approach that is commensurate with risk. However, there remains uncertainty around several aspects put forward in the proposal that are highlighted and discussed in our submission.

Should you have any questions or require additional information about any aspect of this submission, please don't hesitate in contacting me.

Yours Sincerely,

[Redacted signature block]

[Redacted text block]

[Redacted text block]

## 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: Proposal P1055- Definitions for Gene Technology and New Breeding Techniques***, and the consideration of the definitions in the *Australia New Zealand Food Standards Code*.

## LTIBC Response to Proposal P1055

### The LTIBC Agrees with Option 3—Amend the definitions in the Food Standards Code

The increase in new techniques for enhancing plants, animals and foods presents both a regulatory challenge and opportunity for FSANZ. The LTIBC maintains that regulation must be commensurate with risk and therefore 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. 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 breeding techniques based on cellular DNA repair outlined in Proposal P1055 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 areas.

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 conventional and having a history of safe use. However, La Trobe University does not support an over-arching regulatory principle that undermines 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<sup>1</sup>.

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 example, herbicide tolerance, changed nutritional composition, and resistance to biotic (e.g., disease) and abiotic stresses<sup>2</sup>. Therefore, to ensure such alignment it may be of significant benefit that a new definition for ‘*Conventional*’ breeding also be considered.

#### *Regulatory harmonisation and consistency*

The LTIBC does note that a hybrid process/product-based definition may be required. However, any changes to the definitions of ‘*gene technology*’ and ‘*food produced using gene technology*’ should be consistent with international definitions (i.e., not unintentionally lead to asynchronous regulatory systems). Further, definitions should be aligned with or adopted by other Australian and New Zealand regulators to ensure further consistency.

The LTIBC notes that there have been several reviews in Australia examining how gene technology is defined and regulated:

---

<sup>1</sup> 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>

<sup>2</sup> The FAO/IAEA Mutant Variety Database (<https://mvd.iaea.org>)

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).

Additionally, many of Australia's export markets are also developing processes for the assessment of products from new breeding techniques. Across Southern and Central America and throughout Asia, many economies are using definitions centred around the absence of foreign/recombinant DNA as a key characteristic to guide decision making<sup>3</sup>.

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. Further, any application/addition of regulation should adhere with the principles outlined in The Australian Government Guide to Regulation<sup>4</sup>.

With these considerations in mind, the LTIBC proposes that the definition of *gene technology* be consistent with terminology used internationally. That is, for example, *gene technology* means techniques that modify or construct a genome by introducing foreign or recombinant DNA that remains in the final product used for food.

#### **Further information is required on 'Exclusion Criteria'**

The LTIBC advocates for the provision of comprehensive guidance materials to support developers in understanding if a product requires a pre-market safety assessment. It will be important for FSANZ to clearly define both inclusion and exclusion criteria and provide examples and decision trees that assist developers in self-assessment.

The LTIBC notes that Proposal P1055 does not provide sufficient information on these criteria. FSANZ need to be very clear on what the characteristics are that would either qualify or disqualify a product as being a food derived from gene technology. More information is required to understand what are the characteristics that will be compared. For example, in Japan, the absence of foreign/recombinant DNA is a key characteristic whilst in Canada, similarity to conventional breeding within documented ranges are key considerations. In the former, it is clear that products with foreign DNA require a pre-market assessment. This could align well with the current proposal and internationally with key trading partners. However, if an approach like the latter is adopted there are several outstanding questions. What is considered conventional breeding? What if there is little or no information documented for some characteristics of a product? The LTIBC notes that the Canadian regulatory trigger and definitions differ to that of the Food Standards Code. As such, FSANZ will need to clearly articulate both the inclusion and the exclusion criteria under such an approach.

Proposal P1055 states "*Foods not meeting all relevant exclusion criteria would require an application to FSANZ.*" This suggests that FSANZ could include some criteria that just can't be met

---

<sup>3</sup> Entine, J., Felipe, M.S.S., Groenewald, JH. et al. Regulatory approaches for genome edited agricultural plants in select countries and jurisdictions around the world. *Transgenic Res* (2021). <https://doi.org/10.1007/s11248-021-00257-8>

<sup>4</sup> [The Australian Government Guide to Regulation](#)

or that are not science or risk based. That is, they could be overly restrictive. Further, would exclusion criteria be reviewed and amended from time to time? If so, by who?

**What value will an Advisory Committee add?**

Proposal P1055 suggests the establishment of an advisory committee based on a model used for Novel Foods. The terms of reference for such a committee seem unclear with several questions raised, for example:

1. What will be the scope of this committee's responsibilities?
2. What expertise would be included on the committee?
3. What would be required by applicants?
4. How would confidentiality of information be managed?
5. What would it cost?
6. Would outcomes be legally binding? Made public?

The LTIBC would like to see further information and consultation on the proposed Advisory Committee.

**Conclusions**

The LTIBC supports the Proposal P1055 to revisit the definitions for gene technology and new breeding techniques and supports Option 3 to amend the definitions. The LTIBC maintains that regulation must be commensurate with risk and that a pre-market safety assessment should only be required where there is a scientifically sound justification.

The LTIBC looks forward to further consultation with FSANZ on this important opportunity to enhance innovation, competitiveness, productivity and economic growth, as well as reducing regulatory burden.