



SUBMISSION ON PROPOSAL P1055 – DEFINITIONS FOR GENE TECHNOLOGY AND NEW BREEDING TECHNIQUES

TO: Food Standards Australia and New Zealand



DATE: 3 December 2021

ABOUT THE LIFE SCIENCES NETWORK

The Life Sciences Network (LSN) is an organization which has, since May 2000, represented the interests of science and industry (including agriculture) in the public debates on science issues, in particular the regulation of genetic modification. The LSN was considered by the Royal Commission on Genetic Modification to have an interest greater than the general public and was thus awarded interested person status.

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1. INTRODUCTION

- 1.1 The Life Sciences Network welcomes the opportunity to submit to FSANZ on Proposal P1055 regarding the definitions for Gene Technology and New Breeding Techniques.

General comments on Food Regulation

- 1.2 The system of conventional food regulation (while it continues to evolve) has proved to be robust and proportionate to the risk. The LSN considers that the assessment of food safety should be product based rather than process based and this would mean moving GM food into the conventional regime. However, the LSN accepts that at present this is not politically acceptable so recognises that Proposal P1055 is partly science based and partly based on other considerations. The cost of this approach is that food which may otherwise be more nutritious and safer will be subject to the regulatory processes and costs that it would otherwise not need to have been. The

result is that the deployment of potentially safer and more cost effective foods will be delayed or at worst prevented.

- 1.3 Food has been produced using genetic modification for more than 25 years. The history of GM Food over that time has shown that it is as safe as (and potentially safer than) conventional food.

Consideration of evidence and assertions

- 1.4 Submitters have been asked to provide reports, papers and/or data or any other evidence to support the importance and the potential magnitude of any costs or benefits they identify in their submission. The LSN asks FSANZ to consider such evidence critically to ensure it is scientifically credible and to avoid the construction of a false equivalence. Divergent views by some submitters do not necessarily mean a balance of credible evidence. The LSN relies on the evidence already provided in the supporting material in making its comments.

2. Cost and Benefits when assessing Options 2 and 3

- 2.1 Regulation of GM Food is already significantly more onerous than conventional food. The LSN notes that FSANZ recommends retaining a “processed based” definition of gene technology take account of the “need to continue to exclude conventional food” and that a processed based definition is more politically rather than scientifically motivated.
- 2.2 The cost of unnecessarily onerous regulation is that its chilling effect on innovation means society may forego the opportunity to have improved and safer products.
- 2.3 Option 2 results in legal ambiguity which will be exploited by those opposed to genetic technology.
- 2.4 LSN supports Option 3 (but with amendments discussed below) for the reasons set out in the call for submissions and supporting documents).

3. General Submissions

Definition of Gene Technology

- 3.1 LSN seeks a change to the proposed definition of “gene technology” to include the word “directly” to avoid conventional breeding being inadvertently included in the definition. For example embryos produced through IVF which uses recombinant products such as FSH or protoplast culture using recombinant plant hormones. Not including the word “directly” could lead to the perverse outcome that use of a mutagen or plant hormone purified from a natural source does not trigger the definition whereas a chemically identical mutagen or plant hormone produced using recombinant technology does trigger the definition.

“...techniques that directly use recombinant, synthesised or amplified nucleic acid to modify or create a genome”
- 3.2 Access to safe food is a basic human right. Regulators are tasked with ensuring food is safe, however it is unrealistic to demand 100% safety or the elimination of uncertainty as this would result in no food approvals and starvation of the population.

Thus regulators must assess the relative risk and risk vs cost in any approval of food as “safe”. It is the LSN view that the degree of regulatory oversight should be proportional to the risk and that that is best done using a product bases rather than a process based definition.

- 3.3 That said the LSN is of the view that the proposed definition (process based) and exemptions (product based) provides a clear and practical approach, triggering in the first instance an assessment by the developer/importer.
- 3.4 The definition and exemptions should be constructed so they in effect result in a product based assessment - that is they need to avoid two identical products falling into different categories based simply on their production process.

Regulation should be flexible to respond to scientific progress and new knowledge

- 3.5 The consultation document states [page 22]

“There will also be capacity to add or remove exclusion criteria in the future through a Code amendment should that be appropriate” [page 22]

- 3.6 However we note that the current proposed changes to the code have been almost a decade in the making.
- 3.7 The Code should be amended so that FSANZ is enabled to respond quickly to changes in scientific knowledge. To this end LSN seeks that the Code be amended to allow the list of exemptions to be updated by FSANZ in response to new scientific information without the need for the Code to be formally amended.

Regulation to remain harmonised and scientifically based

- 3.8 The LSN is strongly opposed to specific ‘carve outs’ for New Zealand. It is critical that a collective FSANZ approach is continued which is evidence-based and relies on scientific objectivity.
 - The LSN opposes option two – Status quo combined with non-regulatory approaches will not provide the legal clarity required. History has shown that a lack of clarity has led to legal action by activists and in some cases to perverse outcomes. For example in *The Sustainability Council of New Zealand Trust vs The Environmental Protection Authority* in the High Court in 2013¹ resulting in many conventional crops becoming GM before the regulations were amended.

3.9 The LSN supports Option 3 with the (with the additional amendment sought):

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https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjsy62w4cb0AhV3SGwGHZEwAEgQFnoECCEQAQ&url=https%3A%2F%2Fforms.justice.govt.nz%2Fsearch%2FDocuments%2Fpdf%2Fjdo%2F76%2Falfresco%2Fservice%2Fapi%2Fnode%2Fcontent%2Fworkspace%2FspacesStore%2F1594ff52-8c2c-4bf5-8f15-29dbcecc6fa9%2F1594ff52-8c2c-4bf5-8f15-29dbcecc6fa9.pdf&usg=AOvVaw2ONQEcSlfptIze_W6lptj0

4. Specific Submissions

- 4.1 The LSN agrees that should an advisory committee be set up that consultation with it would be voluntary. [ref Page 23] Compulsory consultation would be onerous and risks capturing many conventional foods, adding to the bureaucratic burden.

Foreign DNA- Exemption criteria (i) [page 26]

- 4.2 There is no documented evidence that eating a gene or part of a gene per se has caused any harm to anybody.
- 4.3 LSN supports the use of the term “foreign DNA” and opposes the use of “recombinant DNA” [page 26]. This is because “foreign DNA” is consistent with the product based criteria in the list of exemptions as proposed by the consultation paper. The term “recombinant DNA” is process based and is not justified and therefore inappropriate. Using “foreign DNA” mean that food which is equivalent to “conventional” food is excluded, noting though that each of the other criteria must be met. It is acceptable for there to be a divergence between what is included in labelling and what is included in safety assessment since the application of food labelling is values-based whereas food safety assessment should be risk-based.
- 4.4 The LSN does not agree with the following statement [page 26]:
- “if either ‘foreign DNA’ or ‘recombinant DNA’ is used, food from cisgenic organisms, would not be captured for safety assessment by FSANZ, providing the food also meets all the other exclusion criteria listed. The exclusion of such food is supported by the safety assessment, which found the genetic changes introduced using cisgenesis would be equivalent to those introduced using cross-breeding (see Supporting Document 1).”
- 4.5 The use of the term “recombinant DNA” would risk capturing cisgenic organisms. The term “recombinant DNA” can be a widely interpreted and would risk FSANZ being open to legal challenge by those wishing to extensively broaden that food which is subject to safety assessment. Moreover, use of that term risks including food products which are indistinguishable from conventional food products and are not regulated as GMOs in supplying countries.
- 4.6 The first exemption point, (that is “no foreign DNA introduced using gene technology is present in the tissue or cells from which the food is derived”) is problematic because as all plant material is derived from cells of some type. For example refined sugars containing no DNA or foreign protein would be captured in the safety assessments. LSN seeks that the first exemption point be amended to read:
- “the food does not contain foreign DNA introduced using gene technology”
- 4.7 The consultation paper suggests [page 26] that using the term “foreign DNA” might affect the labelling requirements of food produced using gene technology. The LSN disagrees. The word “foreign” is not used in the ANZ Food Standards Code (ANZFSC) in reference to labelling and that the trigger for labelling (with the exceptions and inclusions listed) is the definition of “gene technology” [ANZFSC 1.1.2-2 and 1.5.2-2].
- 4.8 ICriteria (v)t appears counterintuitive to require a food which has had the level of allergens reduced from its conventional counterpart to undergo a safety assessment for three reasons:

- i. Natural mutation leading to gene silencing could have the same effect
- ii. In the absence of any other changes (which would be captured by the other criteria in the exclusion list), reducing an endogenous allergen in food would render the food safer
- iii. Creating a regulatory barrier to making a food safer makes it less likely such a food would be developed.

4.9 Thus the LSN submits that criteria v should read:

“v) the content of any endogenous allergen ~~content~~ of the food has not been ~~modified~~ increased as a result of gene technology

5. **Summary**

5.1 The LSN supports the general thrust of the consultation document and favours option 3 to avoid ambiguity and ensure safety assessment triggers align more closely with actual risk.

5.2 The LSN submits that the definition of gene technology and exemptions read as follows:

Gene Technology means techniques that directly use recombinant, synthesised or amplified nucleic acid to modify or create a genome

- (i) the food does not contain foreign DNA introduced using gene technology; and
- (ii) the trait introduced using gene technology does not modify the levels of key nutrients, endogenous toxicants or anti-nutrients so they are outside the documented range for an equivalent conventional food; and
- (iii) the trait introduced using gene technology does not result in the synthesis of a substance that is not present in existing conventional food; and
- (iv) the food does not contain endogenous proteins modified using gene technology that are now significantly similar to known toxins or allergens; and
- (v) the content of any endogenous allergen of the food has not been increased as a result of gene technology.

End