



3 December 2021

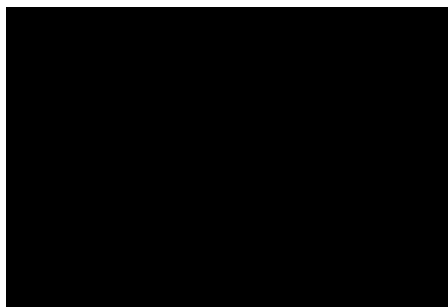
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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *1<sup>st</sup> Call for Submissions – Proposal P1055: Definitions for gene technology and new breeding techniques*.

Yours sincerely





# **1<sup>st</sup> Call for Submissions – Proposal P1055: Definitions for gene technology and new breeding techniques**

**Submission by the New Zealand Food & Grocery  
Council**

**3 December 2021**

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## NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (**NZFGC**) welcomes the opportunity to comment on the *1<sup>st</sup> Call for Submissions – Proposal P1055: Definitions for gene technology and new breeding techniques*.
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

## OVERARCHING COMMENTS

3. NZFGC supports the objectives of Proposal P1055 which are to update the Australia New Zealand Food Standards Code (**the Food Standards Code**) to accommodate and regulate new breeding techniques (**NBTs**) and to concurrently improve the clarity about the foods subject to pre-market assessment commensurate with the risks they pose.
4. NZFGC strongly believes that regulation that is science-based and proportionate to the risk posed, benefits all parties by protecting public health and safety while also facilitating innovation and consumer choice and promoting the efficient use of limited human and financial resources.
5. NZFGC agrees that in determining risk, the focus should be on the food itself and its characteristics, not the types of genetic change occurring in a food organism or whether the changes were intended or unintended.
6. NZFGC considers the regulatory approaches to NBTs in other countries to be revealing and to demonstrate the very clear global trend of comparing foods derived from NBTs to conventional foods to determine the need for pre-market assessment (Supporting Document 3). We note most of the adopted or proposed approaches to exclusions are based on either the absence of foreign/recombinant DNA in the organism or the similarity of products to those from conventional breeding methods, or a combination of both. These approaches are aligned with that proposed by FSANZ and supported by NZFGC.
7. In terms of the options presented (Option 1 – Status quo, Option 2 – Status quo combined with non-regulatory approaches, Option 3 – Amend the definitions in the Code) NZFGC strongly supports Option 3 for the reasons set out in the body of this submission.
8. NZFGC agrees with a revision of the definition for 'gene technology' in order to expand its scope so it captures the range of technologies now in use, as well as potential future technologies and food products that may be produced. NZFGC also agrees that the definition for 'food produced using gene technology' be revised to incorporate specific exclusion criteria for those products that are equivalent in risk to conventional food and therefore do not require pre-market safety assessment as GM food before being sold.
9. In terms of costs and benefits, costs primarily sit with FSANZ for the assessment, analysis of submissions, drafting and preparation of material for Ministers. There are some costs to stakeholders in relation to resourcing the preparation of submissions but the main costs for stakeholders would be at the implementation phase – amending operating manuals, training etc.

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10. The benefits at the implementation stage are extensive across government, consumers and industry. For governments, this is through more targeted application of resources for pre-market assessments and clear enforcement areas; for consumers, greater choice of products sooner than conventional breeding could ever deliver and greater contribution possible to food security through increased plant production (where permitted); for industry the benefits are for increased innovation prospects, clarity around what food is captured under the revised definitions (less grey areas), less resources applied to applications where foods are no different to conventional foods, continued protection of public health and safety through ensuring appropriate GM foods are captured, possible contribution to more sustainable production and the expansion of trade for the sale of NBT derived foods.

## DETAILED COMMENTS

11. When Standard 1.5.2 was adopted in 1998, a single technique (transgenesis) was being used to produce 'GM food'. As a consequence, the gene technology definition was based on this technique.
12. Genetic modification, unless defined, can refer to any breeding technique, including conventional breeding. FSANZ uses the term *conventional breeding* to refer to longstanding methods for genetic modification that do not include either gene technology or NBTs. 'Conventional breeding' also has specific legal meaning under the Code (see Section 2.2). Food derived using 'conventional breeding' methods is referred to by FSANZ as 'conventional food'.
13. We appreciate that NBTs, are a diverse collection of new techniques for genetic modification that have emerged over the last decade or so. As GM technology is still evolving, any category of NBTs needs to accommodate techniques that may emerge in the future.
14. NZFGC notes the distinction between NBTs and older GM techniques in that NBTs are inclusive of genetic changes made by older GM techniques as well as techniques making a wider variety of genetic changes. This includes being able to make the same genetic changes that conventional breeding delivers or that occurs naturally. We note the detailed technical information about NBTs and how they compare to conventional breeding in Supporting Document 1 which includes descriptions of:
- genome editing – a group of techniques that make precise changes (edits) at targeted locations in the genome of an organism. CRISPR<sup>1</sup> technology is a form of genome editing.
  - GM rootstock grafting – where a GM plant is used as the rootstock onto which a non-GM plant is grafted. Grafting is a very common breeding technique.
  - cisgenesis – DNA from the same/closely related species is inserted into the genome of an organism without changing the DNA inserted/arrangement.
  - intragenesis – similar to cisgenesis, except the DNA is changed/rearranged.
  - techniques producing null segregants.
15. NZFGC supports the objectives of Proposal P1055 which are to update the Australia New Zealand Food Standards Code (**the Food Standards Code**) to accommodate and regulate NBTs and to concurrently improve the clarity about the foods subject to pre-market assessment commensurate with the risks they pose.

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<sup>1</sup> CRISPR stands for *Clustered Regularly Interspaced Short Palindromic Repeats*.

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16. NZFGC strongly believes that regulation that is science-based and proportionate to the risk posed, benefits all parties by protecting public health and safety while also facilitating innovation and consumer choice and promoting the efficient use of limited human and financial resources.
  17. Under the current approach, GM food is prohibited from sale unless permitted in the Food Standards Code. NZFGC agrees that the definitions for 'food produced using gene technology' and 'gene technology' are central to this approach. This is because they perform a 'gate keeper' role, determining what food is subject to the prohibition, and therefore what requires pre-market assessment and approval. In revising the definitions, FSANZ is proposing a mix of process and product-based definitions that better reflect the foods, including NBT foods, that may be subject to prohibition.
  18. In considering options for revising the definitions, FSANZ had regard to technology development, the impact on foods produced (same characteristics as conventional food, or new or altered characteristics compared to conventional food) and refined foods currently exempt from GM food labelling.
  19. The safety assessment supported excluding NBT food from a revised definition if it had the same product characteristics as conventional food and therefore presented the same risks as conventional food.
  20. The safety assessment did not support excluding NBT food on the basis of the specific technique used. This is because a single technique may be used to produce a variety of different genome changes, which may or may not change food characteristics in comparison to conventional food.
  21. In relation to refined ingredients, the safety assessment noted that certain ingredients from GM food may also have equivalent characteristics to conventional food, when the ingredient is refined or purified in such a way that novel DNA or novel protein resulting from the foreign DNA insertion is removed. The safety assessment supported excluding certain refined ingredients from a revised definition. Such ingredients (that have equivalent characteristics) will also be identical in risk to the conventional food.
  22. We consider that Table 1 in the Consultation Paper provides a helpful framework to guide the development of a definition for 'food produced using gene technology'
  23. For implementation and enforcement, we are aware that the ability to identify food produced from NBTs (NBT food), in the food supply and distinguish them from conventional food has been a subject of ongoing discussion and research. Most of the focus has centred around food derived using genome editing because the types of changes introduced can be indistinguishable from those introduced using conventional mutagenesis methods, or that occur spontaneously in nature (Supporting Document 1).
  24. In applying specific exclusions, a key consideration by FSANZ was the ability to distinguish between captured and excluded NBT foods and refined ingredients. In adopting such an approach, exclusions needed to be based on unambiguous criteria that enable excluded products to be clearly and unequivocally distinguished from captured products.

#### **Process versus product-based definitions**

25. We agree that process and product-based definitions each have advantages and disadvantages. We also agree that a hybrid approach, using both process and product-based definitional criteria, is necessary to achieve appropriate regulatory outcomes that can be justified in terms of risk, as well as effectively enforced.

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26. The current definitions of 'food produced using gene technology' and 'gene technology' were drafted with the intent of capturing the types of GM foods that existed at the time the standard was developed (1996-98). The 'product-based' criteria FSANZ has now applied is a comparative approach to NBT food that explored issues around the appropriateness of using conventional food as a suitable benchmark against which to compare NBT food, and the similarity in product characteristics between an NBT food and a conventional food to indicate they are equivalent in terms of risk.
27. The safety assessment outcomes clearly showed that significant genetic changes to food have occurred as a result of conventional breeding or from natural processes. This has resulted in wide genetic variation, which has served as a basis for food improvement over centuries. Despite significant genetic changes to food organisms, conventional food has a long history of safe use.
28. The safety assessment found no evidence for novel or unique types of genetic changes from NBTs, either intended or unintended. The genetic changes introduced using NBTs are consistent with those from conventional breeding, older GM techniques or that occur naturally. The conclusion is that conventional food is therefore a suitable benchmark for assessing the risks from NBT foods.
29. When assessing the risks from NBT food, the most important consideration is whether the food has been changed in a way that may raise safety concerns. The method used to induce a genetic change; the size of the genetic change; or whether the change was intended or unintended, is irrelevant to food safety. Because NBTs can introduce similar genetic changes to conventional breeding, some NBT foods will be similar, or in some cases identical, in their product characteristics to conventional food. Some NBT foods will also have different product characteristics to conventional food. Similarly, some refined ingredients derived from GM food may also have the same or identical product characteristics as equivalent ingredients from conventional sources.
30. NZFGC agrees with FSANZ's overall conclusion that when the characteristics of an NBT food are equivalent to those in conventional food with a history of safe use, the NBT food is also equivalent in risk to conventional food. This is also true for refined ingredients from GM food that are identical to an equivalent ingredient from a conventional source. FSANZ's safety assessment also indicated it was not justified from a risk perspective to subject all food from organisms regulated as GMOs to pre-market assessment and approval as GM food.
31. NZFGC therefore also agrees that in determining risk, the focus should be on the food itself and its characteristics, not the types of genetic change occurring in a food organism or whether the changes were intended or unintended. This means a decision about risk equivalence of NBT food with conventional food can be made based on product characteristics alone, without the need to conduct a pre-market GM food safety assessment.
32. NZFGC considers the regulatory approaches to NBTs in other countries to be revealing and to demonstrate the very clear global trend of comparing foods derived from NBTs to conventional foods to determine the need for pre-market assessment (Supporting Document 3). The most interesting position appears to be that taken by Japan which permits such foods to be placed on the market with no intervention. Japan was the site of very early demonstrations against GM during Codex deliberations about GM hosted by Japan in the mid 1990s.

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33. The extent of current reviews is also revealing: (e.g. Canada, European Union, United Kingdom, United States). We note most of the adopted or proposed approaches to exclusions are based on either the absence of foreign/recombinant DNA in the organism or the similarity of products to those from conventional breeding methods, or a combination of both this last being the approach proposed by FSANZ.

### **The Options**

34. In terms of the options presented (Option 1 – Status quo, Option 2 – Status quo combined with non-regulatory approaches, Option 3 – Amend the definitions in the Code) NZFGC supports Option 3 for the following reasons (these align with FSANZ's reasons):

- public health and safety continues to be protected
- capturing all food that does not meet specific exclusion criteria limits the potential for gaps in regulatory coverage as technology develops
- it is more proportionate and risk-based because it excludes foods that pose no greater risk than conventional food
- it avoids the enforcement challenges because the foods to be excluded are ones that would be difficult to tell apart from conventional food
- it is compatible with the current product-based GM labelling requirements because exclusion of certain foods is based on food product characteristics.

35. NZFGC agrees with a revision of the definition for 'gene technology' in order to expand its scope so it captures the range of technologies now in use, as well as potential future technologies and provides the opportunity to identify whether new products require pre-market safety assessment or not. NZFGC also agrees that the definition for 'food produced using gene technology' be revised to incorporate specific exclusions for those products that are equivalent in risk to conventional food and therefore do not require pre-market safety assessment as GM food before being sold. Any revision of the definition of 'food produced using gene technology' must maintain the existing note under Standard 1.5.2—2 that reads:

*"This definition does not include food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or other organism is itself a product of gene technology."*

This continues the explicit exclusion of animal feed.

36. We support the recommendation for non-regulatory measures such as industry guidance, consumer education, and the establishment of an advisory committee. These would support industry in dealing with any ambiguity in delivering the best practice regulatory approach. We agree with the proposal to model an advisory committee on the existing Advisory Committee for Novel Foods.
37. We suggest that guidance documents should be developed in consultation with industry to ensure they are fit for purpose and address any issues that industry has had in the past.

### **Costs and Benefits**

38. The costs of undertaking the proposed amendments primarily sit with FSANZ for the assessment, analysis of submissions, drafting and preparation of material for Ministers. There are some costs to stakeholders in relation to resourcing the preparation of submissions, analysing but the main costs for stakeholders would be at the implementation phase – adopting regulatory changes into operational documentation, training etc.

39. The benefits also accrue at the implementation stage:

#### *Government*

- More targeted application of resources for pre-market assessment at those areas presenting substantial risk

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- Less pre-market assessments to undertake
  - More targeted application of resources on clear enforcement areas

#### *Consumers*

- Greater choice of products sooner than conventional breeding could ever deliver
- Greater contribution possible to food security through increased plant production (where permitted)

#### *Industry*

- Increased innovation prospects coupled with less resources applied to applications where foods are no different to conventional foods
- Clarity around what food is captured under the revised definitions (less grey areas)
- by ensuring appropriate GM foods are captured that public health and safety continues to be protected
- Continued protection of public health and safety through ensuring appropriate GM foods are captured
- Possible contribution to more sustainable food production
- Expansion domestically and internationally in the sale of NBT derived foods.

40. The key barrier for New Zealand in realising the full potential of NBTs is in permitting production of NBTs which is outside the scope of FSANZ area of responsibility.