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Australian Seed Federation
SOWING SEEDS

3 DECEMBER 2021

[redacted]

BY EMAIL: submissions@foodstandards.gov.au

Dear Dr Kelly

RE: FSANZ PROPOSAL P1055 – Definitions for Gene Technology and New Breeding Techniques

The Australian Seed Federation (ASF) is the peak national association representing the interests of Australia's sowing seed industry, worth over $1 billion annually to the Australian economy and providing hundreds of jobs in rural and regional Australia. The membership of ASF comprises stakeholders from all sectors of the seed supply chain including plant breeders, seed growers, seed processors and seed marketers.

The ASF welcomes the opportunity to provide a response to *FSANZ Proposal P1055 – Definitions for gene technology and new breeding techniques*. The ASF supports FSANZ's preferred Option 3 and the proposed adoption of a regulatory approach that is commensurate with risk for "NBT foods". While we support the overarching objective of the proposal, amendments and/or more information and clarity are required regarding the role of the proposed Advisory Committee; guidance materials, definitions and the Exclusion Criteria.

Our thoughts around these aspects of the consultation paper form the basis of this submission. Please do not hesitate to contact me directly should you have any questions or require additional information about any aspect of this submission.

Yours sincerely

[redacted]

Australian Seed Federation
SOWING SEEDS

FSANZ PROPOSAL P1055

DEFINITIONS FOR GENE TECHNOLOGY AND NEW BREEDING TECHNIQUES

3 DECEMBER 2021

INTRODUCTION

The Australian Seed Federation (ASF) is the peak national body representing the interests of Australia's sowing seed industry, worth over $1 billion annually to the Australian economy and providing hundreds of jobs in rural and regional Australia. The membership of ASF comprises stakeholders from all sectors of the seed supply chain including plant breeders, seed growers, seed processors and seed marketers.

The ASF welcomes the opportunity to provide comment on behalf of our members on *P1055 – Definitions for gene technology and new breeding techniques*. The ASF supports FSANZ's preferred approach, Option 3 – Amend the definitions in the Australia New Zealand Food Standards Code (the Code),[1] which is presented in the Consultation Paper, and proposals to adopt a risk-based regulatory approach.[2] This is crucial reform for future-proofing the regulatory approach and to provide clarity and certainty on the regulatory status and assessment requirements for food produced using new breeding techniques (NBT foods).

In Australia, the seed industry is a vital link in the development of crops that are critical to the nation's agricultural productivity, sustainability, and food security. The ASF is providing this submission in the interest of developing a nationally and internationally consistent approach towards the regulation of food derived from gene technology, and to future-proof ASF members' ability to deliver the best seed and technology to farmers.

Since the commercial introduction of genetically modified (GM) plants in Australia a quarter of a century ago, technology developers and regulatory authorities have gained significant experience in evaluating their safety based on identifying and assessing risks to human health and safety, and the environment. Over 3,500 independent regulatory agency reviews have reached positive conclusions on the safety of GM plants used for food and feed. The approvals have unanimously found in each case that the GM plant in question was as safe as its conventional counterpart, and there remains no credible evidence to the contrary.

The ASF supports the finding of the Review that NBT foods should be regulated in a manner that is commensurate with risk and welcomes the recognition that some NBT foods have the same characteristics as conventional foods, and as such, should not require pre-market assessments in the same manner as GM foods. This is consistent with current scientific knowledge and understanding, as elaborated in the detailed safety assessment of NBTs. Furthermore, this approach is in line with progressive approaches being implemented in other international jurisdictions.[3]

[1] Food Standards Australia New Zealand, 'Food Standards Code' <https://www.foodstandards.gov.au/code/Pages/default.aspx>.
[2] Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques' <https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx>.
[3] Page 19 to 20 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

However, the ASF believes greater consideration needs to be given to some aspects of the Proposal, in particular:

- the role of the proposed 'Advisory Committee';
- the new definitions; and
- the Exclusion Criteria.

Our thoughts around these aspects of the consultation paper form the basis of this submission.

KEY POINTS

- The ASF supports the preposition that if it can be demonstrated that NBT food is equivalent to conventional food, then a pre-market safety assessment is unnecessary.
- The ASF would like more information regarding the structure and function of the proposed Advisory Committee before we can indicate our support.
- The ASF proposes that a revised definition for 'gene technology', coupled with a new definition for 'foreign DNA', and removing the definition for 'conventional breeding' will better meet the objectives of the proposal.
- The ASF proposes clarifications for the Exclusion Criteria.

DISCUSSION

Plant Breeding is Built on a Long History of Safety

Plant breeders are working to address the need for affordable food and develop solutions for a changing climate by applying gene editing as an additional, and critical, plant breeding tool. Gene editing is included in the list of "new breeding techniques" considered by FSANZ, and it includes a suite of tools that are becoming standard in plant breeding as they provide improved efficiency compared to more traditional (or "conventional") breeding methods. These innovative tools will allow plant breeders to develop and deliver new varieties adapted to changes in climate, biotic and abiotic stresses, and to contribute to a healthy, safe, and secure food supply more rapidly and efficiently.

In the same way researchers develop other complex products like vehicles or medicine, plant breeders spend time understanding how a gene edited crop will be used, taking into account any safety and risk considerations.

Before any new plant variety is made commercially available, it undergoes a series of tests. This includes meeting the basic requirement that all food is safe and suitable. If at any point during these tests, a new plant variety fails to meet expectations, those plants are discarded until the plant breeding process produces a suitable variety. This same process is applied when gene editing is one of the breeding methods used, and these products are subject to the same checks and balances any other products on the market.

The ASF therefore supports the preposition that if an NBT food is equivalent in its characteristics to conventional food, then a pre-market safety assessment is unnecessary.

The ASF supports the regulatory approach proposed by FSANZ that places greater emphasis on the risk posed by the product, but we share CropLife Australia's concerns with the proposal for an all-encompassing definition of *gene technology* that extends the regulatory ambit of FSANZ, and do not believe this to be risk-proportionate, scientifically justified, or consistent with FSANZ' s policy mandate to regulate GM foods.

We propose some revised definitions in this submission that we believe better meet the objectives of the proposal.

An Advisory Committee may add Cost for Little Reward

Before expressing our support (or otherwise), the ASF would like to better understand the structure and function of an Advisory Committee to provide clear and consistent advice to applicants on whether their NBT food meets the threshold set for pre-market safety assessment. Our concern with an Advisory Committee is threefold:

1) It is not clear whether the advice will be binding on both FSANZ *and* the applicant.
2) It is not clear whether regulatory information submitted to the Advisory Committee will be confidential.
3) It is not clear whether the decisions of the Advisory Committee will be published

Too often, we have seen the establishment of Government Boards and Advisory Committees add costs for regulated entities in exchange for little, or no, reward. Therefore, we are extremely cautious regarding the proposal to establish a new Advisory Committee in this instance.

As an alternative to an Advisory Committee, the ASF would prefer to see FSANZ have the power to directly provide clear and consistent advice, in writing, to applicants concerning whether a product meets the criteria for a pre-market safety assessment as a GM food. For transparency reasons, it is important this advice be published on the FSANZ website following notification to the applicant.

The ASF is concerned that an Advisory Committee will simply add cost and an additional pseudo-voluntary, quasi-regulatory process, that will have no benefit to the applicant that could not be derived from clear and consistent advice provided directly by FSANZ. Even though seeking advice from an Advisory Committee would be framed as 'voluntary', in practice it would be mandatory as no product developer would bring a product to market without first seeking advice from such a Committee.

If an Advisory Committee is to be established, the ASF would like to engage in additional consultation regarding transparency and data security before expressing our support. We would also like to explore with FSANZ the potential to accommodate independent industry-nominated experts on an Advisory Committee.

Guidance Materials

The ASF agrees with CropLife that the development of a comprehensive set of guidance materials may remove the need for an advisory committee. Particular attention should be given to guidance materials regarding the exclusion criteria. Guidance materials should take the form of a clear and concise 'Decision Tree', with well-defined yes/no examples provided to assist applicants in their self-determination. Most-importantly, applicants should be able to seek assistance from FSANZ in working through the guidance materials to ensure that decisions are made in accordance with the requirements of the Code.

Definitions

Revisiting the definitions for 'gene technology', providing a new definition for 'foreign DNA', and removing the definition of 'conventional breeding' may assist FSANZ in better delivering the outcomes of the safety assessment undertaken as part of P1055.

FSANZ's proposal to expand the definition of 'gene technology' to capture all methods of genetic modification, effectively captures *everything* that is not a 'conventional' breeding method as gene technology, and therefore the ASF believes it is important to revisit the definition of 'conventional breeding' in the Code as part of this Proposal.

FSANZ's overarching policy driver is to regulate 'food derived from gene technology', so there is no need to create a definition for 'gene technology' that is all-encompassing when FSANZ are not looking to regulate conventionally bred (or similar) foods.

We have seen through the Technical Review of the Gene Technology Regulations, and the Review of the National Gene Technology Scheme, that a clear dichotomy between 'gene technology' and 'conventional breeding no longer exists and attempting to maintain such a split in the Code is a fool's errand. Plant breeding tools exist as a continuum, as recognised by FSANZ, and as FSANZ says, "the most important consideration is whether the food has been changed in a way that may raise safety concerns". In other words, the 'how' is less important that the 'what'.

As technology evolves, it is important that the Code evolves alongside it. In simple terms, if a developer is using a "new breeding technique" to develop a new product that is similar if not identical to one that could arise through either naturally occurring mechanisms or conventional breeding, then this does not belong within the scope of a pre-market safety assessment. The ASF does not have any concerns with transgenic techniques that result in GM foods continuing to be subject to pre-market assessment, though we continue to encourage FSANZ to engage in safety-assessment sharing initiatives (such as that with Health Canada) as these initiatives result in both time and cost savings to product developers (and Regulators).

Gene technology, Foreign DNA and Conventional Breeding

The ASF agrees with FSANZ that the definition of 'gene technology' should be as simple and as clear as possible. However, it should not be so simple so as to not be useful. We are concerned that the definition proposed in the consultation documents introduces several new, technical terms, not currently in the Code that would need to be defined – 'recombinant', 'synthesised', 'amplified', 'modified' and 'create'. The inclusion of the term 'create' is particularly problematic as this is not a scientific term and carries biblical inferences to 'creationism'. As a science-based regulatory agency, the ASF strongly encourages FSANZ to avoid the use of such emotionally loaded, non-scientific terms.

The ASF does not propose any changes to the definition of 'food produced using gene technology'

The ASF agrees with the definition for 'gene technology' as proposed by CropLife Australia:

> ***Gene technology*** *means techniques that modify a genome by introducing* ***foreign DNA*** *that remains in the final organism used for food.*

The inclusion of the term 'foreign DNA' into the definition of 'gene technology' refines the regulatory scope of the Code and reduces the burden on applicants seeking to use the proposed Exclusion Criteria. This proposed definition will exclude oligo-directed mutagenesis (ODM) and any site-directed nuclease (SDN) that uses a template for guided repair provided the template is not introducing DNA that is 'foreign'.

It is anticipated that allele-replacement type applications of SDN-2 and cisgenic SDN-3 products would also be excluded under this definition.

It follows that by including the term 'foreign DNA' we also need to define it, and the ASF agrees with CropLife's proposed definition:

> *Foreign DNA means the stable integration into the genome of one or more genes that originate from outside the organism's cross-compatible gene pool and are inaccessible through conventional methods.*

It is important to the ASF that the definition of 'foreign DNA' does not include products developed with conventional plant breeding. It is also important to avoid confusion between 'foreign DNA' and oligos/repair templates; this will hopefully be obvious from the proposed definitions.

When read together, the proposed definitions for 'gene technology' and 'foreign DNA' meet FSANZ's policy goals by capturing 'actual' transgenic applications for pre-market safety assessment as GM foods, but excluding those NBT foods that are comparable to those which could be produced using conventional breeding upfront without the additional unjustifiable burden of satisfying the set of NBT food exclusion criteria.

The ASF agrees with CropLife's proposal to remove the definition of 'conventional breeding' from the Code, as it would no longer be necessary should the proposed changes to 'gene technology' and 'foreign DNA' be adopted. The proposed changes do not rely on the outdated process-based conventional versus biotech dichotomy. Rather, it is consistent with FSANZ's safety assessment, which concludes that there are GM foods, which are the foods within its regulatory scope; and there are conventional/conventional-equivalent foods that are not within its regulatory scope.

These definitional changes provide a simple stepwise approach that is both clear and proportionate for the regulation of food derived from gene technology. GM foods created using transgenesis would still be captured under these definitions, but foods created using "new breeding techniques" that are similar if not identical to foods produced using conventional breeding will be excluded from regulatory scope.

Exclusion Criteria

The ASF applauds FSANZ for the comprehensive and science-based safety assessment undertaken to inform P1055. We fully support the conclusion of the safety assessment regarding the exclusion of NBT foods and refined ingredients considered equivalent in risk to conventional food, from the requirement for pre-market safety assessment in the same manner as a GM food.

However, we believe further consideration needs to be given to the five proposed 'exclusion criteria' as currently they may require product developers to generate internal company regulatory data that exceeds that required for pre-market safety assessment as a GM food. This outcome would be perverse to the stated intention of P1055 to ensure NBT foods are regulated in a manner commensurate with the risk they may pose. In fact, these exclusion criteria should not even be necessary if FSANZ adopts the proposed amended definitions of 'gene technology' and 'foreign DNA'

It is clear to the ASF that FSANZ has modelled the proposed exclusion criteria on guidance prepared by Health Canada when consulting on Canada's novel food regulations earlier in 2021. However, as the 'trigger' for the Canadian regulation is quite different to that in the Food Standards Code, the proposed Exclusion Criteria do not quite work in the Australian regulatory context.

Despite the intention for product developers to 'self-assess' whether their NBT food meets all the exclusion criteria (or not), developers will still need to generate and retain substantial regulatory data in the event of legal challenge from well-funded multinational anti-technology activist organisations.

Criteria 1: "no foreign DNA introduced using gene technology is present in the tissue or cells from which the food is derived"

By integrating the requirement for "no foreign DNA" into the definition of "gene technology" this criterion would no longer be required. The ASF agrees with the argument raised by CropLife that the presence or absence of foreign DNA is based on the process used, and does not relate to any risk of the final product.

Criteria 2: "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"

The current proposal is unclear regarding what exactly FSANZ is referring to by 'key nutrients', and whether FSANZ propose to provide a list of 'key nutrients' in each plant species for product developers to use as a comparison. The ASF does not believe that it is the intention of FSANZ that a developer provide data for all possible nutrients, only those that may reasonably be expected to be affected by the targeted trait change. It is also unclear what is considered a 'documented range', as this can vary by isotype within a plant species. Will this need to be a published 'documented range'? Or if a developer has bred a proprietary variety of an equivalent conventional food and privately documented 'key nutrients' within a given range, will it be clarified what will be an acceptable comparison for FSANZ?

The ASF argues that when a 'key nutrient' is outside the 'documented range' of variability, there also needs to be a reasonable hypothesis that the change could result in a higher level of risk regarding food safety. To facilitate more clarity in interpretation in this area, it would also be beneficial to state situations that would not require pre-market assessment, for example, where the change lowers the level of a key nutrient below a documented limit and there is no concern of deficiency from this nutrient; or, conversely, increasing the level of a key nutrient above a documented range where there is no harm associated with overconsumption of this nutrient.

This criterion could benefit from the inclusion of the word 'known', and an acknowledgment of previous safety approvals of food produced using gene technology. It could be re-written as: '*the trait introduced using gene technology does not modify the **known** levels of key nutrients, endogenous toxicants or anti-nutrients so they are outside the documented range for an equivalent conventional **or previously approved food produced using gene technology***'.

Criteria 3: "the trait introduced using gene technology does not result in the synthesis of a substance that is not present in existing conventional food"

Clarity is needed with the application of this criterion for scenarios such as the substance being present in other conventional or previously approved foods produced using gene technology, but not in the food that has been modified. The ASF believes this criterion could benefit from the addition of the qualifying phrase 'known to be' and be re-written as: '*the trait introduced using gene technology does not result in the synthesis of a substance that is not **known to be** present in existing conventional or **previously approved food produced using gene technology***'. This would make the language of this criterion consistent with that of Criteria 4.

Criteria 4: "the food does not contain endogenous proteins modified using gene technology that are now significantly similar to known toxins or allergens"

The ASF is unclear if there is an existing definition for 'significantly similar' in the Code. It is unclear how FSANZ will categorise alterations in endogenous proteins with significant homology with a known allergen or toxin before the changes were introduced and retains this homology after the modifications.

The ASF recommends that FSANZ need to clarify that alterations to endogenous proteins that have previously established homology to toxins/allergens would not trigger this criterion provided the level of homology is not impacted by the change, and the allergenicity or toxicity of the plant is not altered. This could be accomplished with the following minor adjustments:

"The change introduced using gene technology does not alter an endogenous protein in a way that introduces or increases homology with a known allergen or toxin relevant to human health."

This proposed language by the ASF focuses on the outcome of the modification using gene technology, and whether there are risks to human health and safety from the changes that have been introduced.

Criteria 5: *"the endogenous allergen content of the food has not been modified as a result of gene technology"*

As per the comment for criterion 3, the aspect of being 'known' is an important qualifying description omitted in the criterion 5 description. The ASF believes this criterion could be re-written as: '*the known endogenous allergen content of the food has not increased beyond the documented range as a result of gene technology*'.

Where a NBT product is captured due to a broad process-based definition but it cannot be distinguished from a conventional product, having to address a list of exclusion criteria is clearly not a proportionate or justifiable burden and could also prove prohibitive for smaller developers.

The ASF suggests that FSANZ could consider having 'inclusion criteria' as opposed to 'exclusion criteria', in combination with the revised definitions of 'gene technology' (and 'foreign DNA'). This would in effect exclude all products that are not already excluded by the revised definition of 'gene technology' but may not be differentiated in the end product from a food derived from conventional breeding, unless one (or more) of the 'inclusion criteria' were met. 'Inclusion criteria' could be based on relevant exclusion criteria in the consultation document, such as (example only):

- *the trait introduced using gene technology results in the synthesis of a substance that is not known to be present in existing conventional or previously approved food produced using gene technology*
- *the change introduced using gene technology alters an endogenous protein in a way that introduces or increases homology with a known allergen or toxin relevant to human health*
- *the known endogenous allergen content of the food has increased beyond the documented range as a result of gene technology.*

From a developer perspective, this approach can be more closely linked to a risk-proportionate approach to the regulation of NBT foods.

CONCLUSION

It is now widely accepted that unintended genetic changes that may result from gene technology are no different from those that can occur through conventional plant breeding or because of plant-environment interactions. This supports the argument that the ability of a plant breeder to determine if a product has any new characteristics should be the same regardless of the breeding method being used. Therefore, FSANZ can place the same level of trust in plant breeders to self-determine whether an NBT food is subject to pre-market safety assessment as they currently place in plant breeders when using conventional breeding processes.

Information requirements should focus on developer self-assessment and rationales wherever possible. Specifically, full compositional comparative assessment should not form the base expectation needed to demonstrate an NBT food is equivalent to its conventional counterpart. The ASF supports the development of Guidance documents with multiple pre-developed yes/no statements to assist developers navigate the regulatory scheme.

Results from hundreds of compositional equivalency studies conducted on genetically engineered plants over the past 25 years have not detected any meaningful differences. The comparative approach was developed over 20 years ago, at a time where the experience with recombinant DNA technology was new, and there was uncertainty around possible unintended effects that could arise from the insertion of rDNA into a plant. This original hypothesis of unknown risk or the potential for unintended food safety impacts to occur has not eventuated.

Generally, the ASF advocates that FSANZ should only require pre-market risk assessment where there is a plausible hypothesis that demonstrates a food safety risk. For too long, regulation has been based on a fishing expedition for hypothetical risks posed by gene technology, mainly to appease the concerns of multi-national anti-GMO activist groups, all of which have proven unfounded. P1055 is the opportunity for FSANZ to put the past behind them and focus on those risk indicators of foods derived from gene technology that have a genuine impact on food safety. Within the regulatory landscape, there is a lot of information that is 'nice to know'; but it is time Australia's regulators focussed their risk assessments on what they 'need to know'.