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Dear Standards Management

Thank you for the opportunity to review Proposal 1055. I understand that this is an important and potentially controversial subject. I believe that FSANZ has done an excellent job in preparing a comprehensive background for this subject which will be helpful to all interested parties. Indeed, I am not surprised regarding the general direction of the Proposal having managed the GM food safety risk assessment, risk management, and risk communication for FSANZ from 2000 - 2015, and noting that government food regulatory agencies around the world have faced a barrage of challenges, not the least of which is that we know that GM foods are safe but we regulate them to satisfy consumer expectations. This area is highly controversial and politically charged, although not nearly as much today as in the past as it seems that GM food safety is very low on the list of consumers food-related concerns, and I would hasten to add that the vast majority of consumers would not even be aware of foods derived using gene-editing techniques. I have always been concerned about regulation being driven by a few politically motivated regions of the world with vastly different ALOP, entities such as Greenpeace and FoE, and mostly uninformed but passionate individuals. I also recognize that social media platforms can significantly alter such a lack of awareness by consumers in a very small amount of time and so it is correct to be cautious and have set in place appropriate regulations.

I have copied and pasted parts of your Proposal below where I agree with the approach as a potential way forward in the context of a political climate where FSANZ must be seen to be protecting public health and safety. The idea that the introduction of foreign DNA into food should warrant a risk/safety assessment may have been relevant in the late 1990's and early 2000's and was based on a cautionary approach driven mostly by uncertainty at the time and a great deal of politics. But to my knowledge, after hundreds and hundreds of safety assessments completed around the world by just about every food regulatory agency across the globe, often {mostly} on the same GM food products and using the same datasets, we have a situation where there has ***never*** been any risk to human health and safety identified by all the safety assessments combined. Indeed, one could argue that the very existence of the regulatory regime in itself creates an environment that results in a huge cost to society in terms of the enormous cost to industry, governments, academia, and consumers all over the world via taxes to support the present system, conservatively estimated I believe to be in the order of hundreds of billions of dollars (trillions ?) since the inception of the technology. I realise also that GM food safety assessments are a source of revenue to government regulators who are able to charge a fee to complete them. I am also fully aware from my discussions with them that the Life Sciences companies would prefer to avoid adverse political focus on their products and are prepared to pay the regulatory fees to avoid problems even though they, and also the regulators, know that the food products are safe.

But I often wonder whether all of this money and effort would be better spent on real food safety problems? Alas, probably not in my lifetime.

In the context that FSANZ must be seen to be protecting public health and safety, even when it is highly likely that there will never be a food product that poses any risk to the public, all politics aside, I agree with the following items :

Preferred approach under Option 3

FSANZ's assessment is that the current definitions should be amended as follows:

- revise and expand the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding; and

- revise the definition for 'food produced using gene technology' to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM food. Foods not meeting all relevant exclusion criteria would require an application to FSANZ.

This approach is preferred for the following reasons:

- it continues to protect public health and safety by taking into account the potential unknowns in relation to future technology development and future products;
- by capturing all food that does not meet specific exclusion criteria it will limit 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. There will also be capacity to add or remove exclusion criteria in the future through a Code amendment should that be appropriate;
- because the foods to be excluded are ones that would be difficult to tell apart from conventional food, it avoids some of the enforcement challenges that would occur if such products were captured by revised definitions;

- because exclusion of certain foods is based on food product characteristics, it is compatible with the current product-based GM labelling requirements.

The rationale for the preferred approach is discussed below.

A revised and expanded process-based definition for 'gene technology'

FSANZ's assessment is that the process-based definition for 'gene technology' should be expanded for the following reasons:

- it will provide FSANZ with the capability to capture future products for pre-market safety assessment as GM foods, should that be warranted. Technologies and methods that fall outside the scope of a revised definition for gene technology will continue to be considered conventional, and therefore not subject to the GM food prohibition in the Code;

- continuing to rely on a process-based definition as the primary basis for capturing products for pre-market assessment and approval is the most effective way to maintain the exclusion for conventional food. While product-based definitions offer certain advantages (Table 2), it may be more difficult to clearly exclude conventional food using product-based criteria, while at the same time providing the capability to capture future products.

Product-based pre-market safety assessment exclusions for certain foods

FSANZ's assessment is that product-based exclusions for certain foods (as set out in Table 1 in section 4.1.2) should be applied for the following reasons:

- it will enable criteria to be consistently applied across a range of products, irrespective of the specific technology used to develop that product. This will also reduce the potential for revised definitions to become outdated as technology continues to develop;

- exclusion criteria will be focussed on food characteristics, resulting in more risk-based regulatory outcomes (in terms of what foods are captured versus excluded from pre-market assessment) than an approach based entirely on process.

FSANZ's assessment is that exclusions should apply to NBT foods that have the same product characteristics as conventional food with a history of safe use. The reasons for this are:

- the safety assessment indicates there is no risk justification for subjecting such foods to pre-market assessment as GM as the foods will be equivalent in risk to conventional food;

- capturing NBT food for pre-market safety assessment that has the same product characteristics as conventional food would pose significant enforcement challenges because of the difficulty telling such foods apart.

It is also FSANZ's assessment that exclusions should be applied to processed food ingredients from GM food and GM-derived food additives, processing aids and nutritive substances, where no novel DNA and novel protein is present in the food for sale. The reasons for this are:

- it ensures consistency with the exclusions proposed to apply to NBT foods. Many processed food ingredients and substances from GM sources that are added to or used in food will be chemically identical to the same ingredient or substance derived from a non-GM source. Novel DNA and novel protein resulting from the foreign DNA insertion is also unlikely to be present.

- there are no safety concerns with excluding processed food ingredients from pre-market assessment as a GM food as they will be no different in risk to equivalent processed ingredients from non-GM sources.

- there are no safety concerns with excluding GM-derived food additives, processing aids and nutritive substances from pre-market assessment as a GM food. Such substances will be chemically identical to equivalent non-GM derived substances already assessed and permitted in the Code, or if not, will require pre-market assessment and approval as a new food additive, processing aid or nutritive substance.

- their exclusion will simplify compliance and enforcement as it will be difficult to tell many GM-derived ingredients and substances apart from equivalent non-GM derived ingredients and substances.

Specific product-based criteria for excluding certain NBT foods and GM derived refined ingredients and substances are further discussed under Section 4.3 Definitional criteria.

Non-regulatory measures

It is FSANZ's assessment that an advisory committee should be established to facilitate implementation of revised definitions by jurisdictions, as well as assist product developers to interpret and comply with the new provisions. The committee would be modelled on the Advisory Committee for Novel Foods. The purpose of such a committee would be to serve as a point of

enquiry in situations where a developer remains uncertain about whether an application to FSANZ may be required. Consultation with the advisory committee would be voluntary.

It is also FSANZ's assessment that guidance material, especially in relation to excluded products, should be developed to provide further assistance to product developers. This material would outline the steps a developer should take to determine if their product either does or does not meet specific exclusion criteria, including what evidence should be retained in order to demonstrate complianceRevised definition for 'gene technology'

The purpose of revising the definition for 'gene technology' is to expand its scope so it captures the range of technologies now in use, as well as potential future products. In revising the definition, it will be important to ensure that conventional breeding methods are not inadvertently captured.

FSANZ has considered current definitions in the GT and HSNO Acts and their regulations, Codex guidelines for foods derived from modern biotechnology, the EU GMO Directive, as well as recently developed or revised definitions in other countries that may be applicable (e.g. United States) (Table 2, Supporting Document 3). A common strategy is to define methods of genetic modification (or gene technology or modern biotechnology) as well as methods that are not considered genetic modification or that give rise to a GMO. FSANZ notes many of these approaches result in definitions that are technically complex and contain multiple interacting elements.

FSANZ's preference would be to keep the definition for 'gene technology' as simple and clear as possible to avoid potential confusion about what products are captured for pre-market assessment and approval. In revising the gene technology definition, the main focus is on expanding it beyond the use of recombinant DNA techniques to ensure appropriate regulatory coverage of NBTs as well as potential future technologies, which could involve the development of synthetic organisms and/or novel types of nucleic acid.

FSANZ notes the United States Department of Agriculture recently adopted the following revised definition for 'genetic engineering':

> "techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome"

This language has appeal because it is simple yet has broad coverage in terms of how genomes may be modified and also recognises it is now possible to create genomes. The ability to create genomes was also highlighted recently in considering possible revisions to the definition for 'gene technology' in the GT Act. FSANZ therefore proposes adapting the language in the United States definition for incorporation into a revised Code definition for 'gene technology'.

If FSANZ decides, after considering submissions, to proceed with such a measure, consideration would have to be given to whether a definition for conventional breeding is required. Currently, the Code defines conventional breeding as any method used to produce plants that does not involve gene technology. In revising the definition for 'gene technology', FSANZ will consider whether to retain this approach.

In relation to other aspects of the current gene technology definition, in particular the reference to altering the 'heritable genetic material of living cells or organisms', FSANZ considers this language would be redundant if the definition is revised to refer to modifying or creating a genome.

Exclusion criteria for certain foods

It is proposed the definition for 'food produced using gene technology' be revised to incorporate specific exclusions for certain products that FSANZ has determined are equivalent in risk to conventional food and therefore do not require pre-market safety assessment as GM food before being sold. Some products proposed for exclusion from pre-market assessment as a GM food, e.g. certain substances added to food, may still require pre-market assessment and approval under other parts of the Code (e.g. as a food additive).

While FSANZ has concluded that equivalence to conventional food is a legitimate basis for excluding certain foods from pre-market assessment as a GM food, specific criteria will be required so that a developer can determine if their particular product qualifies for exclusion or requires an application to FSANZ as a GM food. As noted above, it is important such criteria provide a clear basis to distinguish between food that is subject to the GM food prohibition in the Code, and food that is not.

Considerations around exclusion criteria for each of the food categories identified in Table 1, Section 4.1.2 are discussed below.

Food from null segregants

FSANZ noted in the final report for the NBT review that the definition for 'food produced using gene technology' is ambiguous with respect to null segregants. This is because the current definition refers to food that is "derived or developed from an organism which has been modified by gene technology". This could be interpreted as capturing food from null segregants, even though the final organism used to produce the food has not itself inherited the genetic modification introduced using gene technology.

It is FSANZ's assessment that food from null segregants not be a GM food for Code purposes. The reasons for this assessment are:

- it had not been intended that food from null segregants be captured as GM food;
- it has been longstanding practice by FSANZ to accept null segregants as non-GM comparators for the purpose of GM food safety assessment;
- the safety assessment indicates there is no risk justification for subjecting such foods to pre-market assessment as GM food as the foods will be equivalent in risk to conventional food.

To clarify the intent of the original definition, and remove any doubt, it is proposed to explicitly exclude food from null segregants from the definition of 'food produced using gene technology'.

If FSANZ decides, after considering submissions, to proceed with such a measure, consideration will be given to whether the Code should define 'null segregant' for the purposes of excluding food from null segregants from the definition of GM food. FSANZ notes null segregants are defined under Schedule 1 (Organisms that are not genetically modified organisms), Part 7 of the *Gene Technology Regulations 2001* as "An organism that is descended from a genetically modified organism (the **initial organism**), but which has not inherited any traits that occurred in the initial organism because of gene technology." Similar language could be adopted for a null segregant definition in the Code.

NBT food that is the same as conventional food

FSANZ's assessment is that NBT food should not be GM food for Code purposes if the NBT food is equivalent in its characteristics and risk to conventional food. To that end, the Code should exclude a NBT food from pre-market assessment as a GM food if each of the following criteria are met:

(i) no foreign DNA introduced using gene technology is present in the tissue or cells from which the food is derived; 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 endogenous allergen content of the food has not been modified as a result of gene technology.

In relation to the above criteria, the following should be noted:

- food that does not meet one of more of the criteria may still be safe, however, a safety assessment by FSANZ would be required to confirm this.
- the intent of criterion (i) is to ensure that GM food continues to be captured, consistent with current policy. FSANZ notes however this will depend on how this criterion is worded and in particular how 'foreign DNA' is interpreted. Currently, there is no definition for 'foreign DNA' in the Code, but typically it is taken to mean DNA derived from a different species.
- the use of the term 'foreign DNA' as a means to capture GM food will need to be carefully considered, including whether the outcome in terms of what is captured as a GM food is consistent with current policy. All GM foods approved to date and listed in Schedule 26 of the Code are derived from either transgenic or intragenic organisms. If 'foreign DNA' is used, it would ensure that food from transgenic organisms is subject to a safety assessment by FSANZ before it is sold, but it may not capture food from intragenic organisms. If 'recombinant DNA' is used instead of 'foreign DNA' it would result in food from both transgenic and intragenic organisms being captured. FSANZ notes continuing to capture food from transgenic as well as intragenic organisms will also ensure such foods are subject to GM labelling, as is currently the case.
- 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).
- because criterion (i) refers to no foreign DNA being present in the tissue or cells from which the food was derived, this would result in food from GM rootstock grafting being excluded from pre-market assessment as GM food, but only if that food was also able to meet exclusion criteria (ii) through (v).
- food derived from an organism which <u>does not</u> contain foreign or recombinant DNA as a result of gene technology, would still be captured if it was unable to meet all of the other criteria. For example, if genome editing had been used to alter the endogenous allergen content of a food. While no novel DNA or novel protein would be present in the food for sale (because foreign or recombinant DNA would be absent from the organism from which the food is derived), such food would not meet criterion (v) and therefore would require an application to FSANZ.

- guidance material will be developed to assist product developers to determine if their product meets relevant exclusion criteria. The guidance material would explain each of the criteria, the types of analyses that would need to be done to determine if a food meets each criterion, and provide relevant examples for different types of organisms and food products. Such guidance material would be revised and updated as the technology develops.

Refined ingredients

For the purposes of developing exclusion criteria, the refined ingredients category of products has been divided into the following sub-categories: (i) processed food ingredients and nutritive substances; and (ii) food additives and processing aids. This distinction was made to align with labelling considerations around altered characteristics, which only apply to processed food ingredients and nutritive substances.

For processed food ingredients (such as oils or sugars) and nutritive substances, exclusion would need to be based not only on whether novel DNA or novel protein is present in the food for sale, but also whether the ingredient or substance has a new or altered characteristic as a result of gene technology compared to an equivalent ingredient or substance derived from a conventional source. Such products may warrant pre-market safety assessment by FSANZ as GM food.

For the exclusion of certain processed food ingredients to be of any practical consequence, all intended food products from the GM organism would need to meet the exclusion criteria. For example, this might apply in the case of sucrose from GM sugarcane or refined oil and linters from GM cotton. However, if a number of different food products are derived from the GM organism, some of which contain novel DNA or novel protein or a new or altered characteristic, then an application to FSANZ would still be required. This exclusion would therefore only be of use in a limited number of cases.

For nutritive substances, FSANZ is not currently aware of any examples with a new or altered characteristic as a result of gene technology. However, this approach would ensure any nutritive substances developed in the future, which have a new or altered characteristic, would be subject to pre-market assessment as GM food and also be subject to GM labelling.

For the exclusion of GM-derived food additives and processing aids, the only relevant consideration is whether novel DNA or novel protein is absent from the food for sale.

The outcome of FSANZ's assessment is that a refined ingredient should not be a GM food for Code purposes if it is:

(i) a processed food ingredient that is identical in composition to an equivalent ingredient derived from a conventional source and where no novel DNA or novel protein is present in the food for sale; or

(ii) a substance used as a nutritive substance that is identical in chemical structure to an equivalent substance from a conventional source and where no novel DNA or novel protein is present in the food for sale; or

(iii) a substance used as a food additive or a processing aid where no novel DNA or novel protein is present in the food for sale.

These proposed exclusion criteria for refined ingredients align with current product-based labelling requirements and exemptions (refer to Section 2.1).

https://www.foodstandards.gov.au/industry/novel/novelcommittee/pages/default.aspx

'gene technology' means recombinant DNA techniques used to alter the heritable genetic material of living cells or organisms.

http://www.fao.org/3/a1554e/a1554e00.pdf; the Codex definition for *modern biotechnology* is the same as that used in the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*

Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms

https://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf

https://consultations.health.gov.au/best-practice-regulation/gene-technology-scheme-cris/supporting_documents/20201214%20GeneTech_CRIS%20Explanatory%20Paper_Approved%20Version.pdf

Exclusion of foods using criteria based on specific food product characteristics is an approach recently proposed by Health Canada (see Table 1, Supporting Document 3).

A key nutrient is a nutrient with an Estimated Average Requirement (EAR) and/or an Upper Level of Intake (UL) as described in the *Nutrient Reference Values for Australia and New Zealand.* Available from https://www.nrv.gov.au/

Toxicologically significant compounds known to be inherently present whose toxic potency and level may be significant to human health.

Compounds that interfere with the absorption of nutrients.

>35% identity over a window of 80 or more amino acids.

If a nutritive substance is excluded from pre-market assessment as a GM food, it may still require assessment and approval as a new nutritive substance.

If a food additive or processing aid is excluded from pre-market assessment as a GM food, assessment and approval as a new food additive or processing aid may still be required.