Submission to
Food Standards Australia New Zealand

1st Call for submissions – Proposal P1055

Definitions for gene technology and new breeding techniques

3rd December 2021

Introduction

This submission on behalf of Danisco Australia and Danisco New Zealand, is made in response to 1st Call for submissions – Proposal P1055, Definitions for Gene Technology and New Breeding Techniques.

Danisco/IFF

Danisco Australia and Danisco New Zealand operate as subsidiaries of International Flavors & Fragrances Inc. (IFF), manufacturer/marketer of, amongst others, specialty food ingredients, food additives, flavourings and food processing aids. IFF is a world leader in the field of the biosciences, with an annual research and development spend over $500 million and more than 180 manufacturing facilities globally.

Upon consideration of the areas covered in the P1055 1st Call for Submissions and supporting documentation, we welcome the opportunity to provide our comments to Food Standards Australia New Zealand (FSANZ) on the proposal to update the definitions in the Australia New Zealand Food Standards Code for 'food produced using gene technology' and 'gene technology'.

General Comments

Food produced using gene technology, whether it be those technologies covered under the current Food Standard Code definition, or a broader definition to encompass new breeding technologies, are essential to maintaining a sustainable, nutritious, and affordable food supply. Advancements in gene technology are also integral to food security. IFF champions the use of these technologies across the food industry for the betterment of our food supply.

At IFF we consider it important that the development of food regulations is commensurate with risk based on scientific evidence. We commend FSANZ for taking this approach to inform appropriate amendments to the definitions for 'gene technology' and 'food produced using gene technology' in P1055. In principle, IFF support FSANZ's preferred approach, Option 3, 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.

There is sound rationale to uncoupling of the scientific process-based definition for 'gene technology' from the product-based regulatory definition for oversight of 'foods produced using gene technology'. The intent of this approach is to ultimately lead to a regulatory burden proportionate to the risk associated with these technologies when applied in food innovation. This is particularly the case where foods derived from gene technology are substantially equivalent to their conventional counterparts, for example food from null segregants, food of unchanged composition compared with conventional food, and food with no increase in food safety risk compared with conventional food. Note that, as previously raised by one of IFF's experts in the recent FSANZ webinar- Revising GM food definitions, novel DNA or protein are not valid indicators of risk, unless that novel DNA or protein constitutes a safety hazard (for more discussion, see below). Instead, the absence of viable organisms containing novel DNA or protein may be more appropriate, especially for modified microorganisms.

However, if the intent is for a "foods produced using gene technology' definition to be product-focused with exclusion criteria for certain outcomes of modification that are outside the scope of the definition, then this definition should not be referred to as 'foods produced USING gene technology' as the "USING" verbiage in that definition still points at a process approach, which may be confusing and raise false expectations with stakeholders. Instead, reference to food products "resulting from gene technology" or food products "modified by gene technology" might be easier linked to an outcome that is exclusively resulting from gene technology, i.e., an outcome different from conventional food / not possible to produce using conventional breeding. Alternatively, one could envision an entirely different term for 'food produced using gene technology', for example 'bioengineered food', analogous to the same term used in the US for food modified via *in vitro* techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Further comment to some specific areas of interest document is provided in the paragraphs that follow.

3.1 Background Assessment approach

On the regulation of GM Foods, IFF agrees with the proposal to take a risk-based approach which focuses on safety of the product, as opposed to a focus on the process used to produce it. P1055 CFS document calls out that >80 GM foods have been assessed and approved in the years following the development and implementation of Standard 1.5.2. Collectively, these approvals are implicit to the safety of GM foods in general. It follows, that with the benefit of time, experience, and knowledge through safety assessment, there is no longer a need to hold fast to the current extreme approach to the precautionary principle with respect to the regulation of GM foods.

3.2 Safety Assessment outcomes and conclusions

The FSANZ NBT report [1] provides the case for some NBT foods to be excluded from pre-market safety assessment. IFF see no risk-based justification for continuing the requirement for pre-market assessment of GM Foods in all cases.

We caution, however, that exclusion criteria be developed with consideration to the facts of the preceding years of GM food assessment by FSANZ, and indeed other comparable agencies worldwide. Dissociating the magnitude (size of the genetic element), method (whether using recombinant techniques, NBT or conventional breeding) and certain aspects of nature (e.g., intraspecies vs interspecies) of the intended change from actual determinants of food safety is key.

4.3.1 Revised definition for 'gene technology'

The current definition for 'gene technology' is no longer fit-for-purpose if one were to consider the range of *in vitro* gene technologies that have developed in the years since Standard 1.5.2 was developed and implemented. The FSANZ preferred approach to expand the process-based definition for 'gene technology' beyond recombinant DNA techniques, to capture all *in vitro* methods for genetic modification other than conventional breeding is tenable. It is important that the regulation is unambiguous and able to capture additional emerging *in vitro* gene technologies.

However, IFF is of the opinion that the mere use of techniques classified as 'gene technology' should not elevate the regulatory burden (mandatory GM approvals) or other obligations (e.g. mandatory GM labelling). Any impactful regulatory approval burden should be risk-proportionate, and any meaningful GM disclosure to consumers should reflect whether a retail

[1] https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Final%20report.pdf

food is changed beyond changes that are achievable by conventional breeding. In other words, we would not be supportive of the use of a process-based expanded definition of 'gene technology' to dictate the regulatory burden or consumer disclosure obligations.

4.3.1 Exclusion criteria for certain foods

FSANZ 1st Call for submissions – Proposal P1055 outlines criteria for possible pre-market assessment exclusions, according to safety assessment conclusions, including: -

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 (>35%) to known toxins or allergens; and
v. the endogenous allergen content of the food has not been modified as a result of gene technology.

We applaud FSANZ on defining clear exclusion criteria for pre-market approval requirements. However, as stated above it would be our assertion that the introduction of foreign DNA should not be a determining factor for safety assessment/review, let alone the presence of foreign DNA. FSANZ acknowledged this in their safety review, and yet there remains a focus on foreign DNA being inherently higher risk than endogenous DNA. As discussed in the CFS document, the term 'foreign DNA' would need to be considered carefully. In our opinion, this is not straightforward and could lead to ambiguity and confusion.

In fact, in a risk-based approach that considers multiple worthy criteria such as criteria ii. to v. above, the novelty of the expressed DNA seems redundant and would easily lead to unnecessary restrictions. It may be much more effective to focus on 'novel traits' (as partially captured under criterion iii) instead of 'foreign DNA'. The mere transfer of DNA from one species or genus to another (= foreign DNA) does not automatically result in a novel trait. For example, expressing a bacterial gene encoding an enzyme commonly found throughout animal, plant, and various microbial kingdoms (such as alpha amylase) as foreign DNA in a fungal species does not lead to a novel trait and does not carry additional risk. Conversely, the expression or even mere suppression of endogenous genes involved in complex metabolic pathways may lead to elevated levels of endogenous metabolites of concern, which is effectively captured under criterion ii. above.

Beyond the complexity and lack of relevance to safety of the term 'foreign DNA' or 'novel DNA', the presence or absence of rDNA is generally irrelevant to safety, hence should not be referred to in exclusion criterion. Instead, the trait this introduced DNA encodes for is more relevant, as is the presence of transformable rDNA sequences for traits of concern. In addition, reliance on an analytical measure of absence of generic rDNA is a logistical nightmare given 1) the ever-increasing sensitivity of assay methodologies, hence what today is considered 'absent' will be considered 'present' tomorrow and 2) complexity of setting up and validating analytical methods especially for the plurality of fermentation products and product matrices (liquid vs dry, concentrates vs different formulations and premixes, etc.).

If it is desired to still have an exclusion criterion i. based on the nature (not presence) of the introduced DNA, then IFF would favour a more focused approach, for example around

‘sequences of concern’ e.g. antibiotic resistance markers or coding sequences for toxins and allergens. Another category would be ‘sensitive traits’ based on sequences encoding enzymes or inhibitors that would be relied upon to detoxify mycotoxins or inhibit other metabolites present in commodities. If consideration were taken for objective criteria around sequences of concern or ‘sensitive traits’ as opposed to less targeted ‘foreign DNA or protein’ this would be commensurate with a more risk-based approach. Note that any alteration to an endogenous protein sequence by precise techniques (such as introduction of ‘foreign’ DNA encoding an analogue or by NGT resulting in a mutation) can be efficiently verified as being of concern or of no concern based the proposed criteria, including assessment of functionality (does the protein still have the same basic function or is it actually a novel substance) and absence of similarity to known food allergens or toxins using objective criteria. Ironically, as FSANZ is well aware, it is much harder to assess these aspects for foods modified by random mutagenesis, which is considered to be part of the conventional breeding toolbox that is out of scope of regulatory oversight.

Regarding exclusion criteria ii. and v. as currently defined, we’d like to point out that this includes reduction of endogenous toxicants, allergens, or anti-nutrients, which should be in the best interest of all, and should not prevent exemption simply because it’s “outside the documented range for an equivalent conventional food”. In addition, the loss of a trait does happen in nature, and in many cases can be achieved by conventional breeding. Hence, it would be better to rephrase criteria ii. and v. to specifically point at increasing endogenous toxicants, allergens or anti-nutrients outside the documented range for an equivalent conventional food.

In conclusion, IFF is pleased to see the direction FSANZ is taking, with the caveats that:

1) a rephrased definition for ‘food developed using gene technology’ is warranted to specifically focus on outcome rather than process and hence, avoid confusion, and
2) a product-based oversight process and associated exclusion criteria need to be well defined and focused on risk. Here we request FSANZ to consider abandoning the simplistic yet vague ‘no foreign DNA’ concept as a regulatory exclusion criterion, and replace it with a more meaningful, risk-based approach as discussed above.