Queensland Government

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03 December 2021

Standards Management Officer
Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604

Dear Sir / Madam

Submission – Proposal P1055 - Definitions for gene technology and new breeding techniques: 1st Call for submissions (1st CFS)

Thank you for the opportunity to provide a submission on the 1st Call for Submissions (CFS) paper for Proposal P1055.

This submission provides comment on the proposed changes to the *Australia New Zealand Food Standards Code* (the Code). The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

Proposal P1055 proposes amending Code definitions for 'food produced using gene technology' and 'gene technology' which determine what foods are classed as genetically modified (GM.) Currently, all GM food available for sale in Australia and New Zealand must have been assessed for safety by FSANZ and expressly permitted and listed in relevant Code schedules.

Summary

Support is given to amending the Code definitions for 'food produced using gene technology' and 'gene technology' to reduce regulatory uncertainty regarding classification of New Breeding Techniques, particularly including the diverse genetic modification through "editing" methods developed since development of the current *gene technology* and associated *food produced using gene technology* Code definitions. We concur with the FSANZ assessment that the current definitions lack clarity and are no longer fit for purpose. We agree with the FSANZ Option 3 risk management approach to amend Code 'food produced using gene technology' and 'gene technology' definitions to clarify and better accommodate existing and emerging genetic technologies.

Please find below additional information and evidence below in relation to this summary. These include comments and suggestions regarding the proposed associated non-regulatory measures, e.g. industry guidance, consumer education, advisory committee to oversee implementation.

It would be appreciated if FSANZ could respond to the comments and recommendations raised in this submission. We look forward to review and comment on the proposed amended definitions and the 2nd P1055 CFS.

In response to the 1st CFS regarding Proposal P1055:

Support is given to the proposed FSANZ risk management approach in Option 3, in which an Expert Advisory Committee (EAC) is proposed that will assist in revising definitions, as well as review and/or production of industry guidance and consumer educational materials. The following are associated recommendations and comments regarding educational materials and in response to Proposal P1055:

Educational materials

Current FSANZ produced public educational materials related to Proposal P1055 would benefit from additional information regarding the following:

- Lay definitions of “recombination”, “foreign”, “gene editing”, trans- versus intra-genesis, knock-in, knock-out, genotype, phenotype, etc.

- The nature of potential risks presented by GM Foods (off-target, allergens, anti-nutrients, etc.) including why recombined “foreign DNA” in an organism specifically presents (increased) risk relative to New Breeding Techniques (NBT) - particularly “gene editing” techniques.

- General description of the aspects examined during in Pre-market safety assessment (PMSA).

- The status and applicability of currently available genomic analysis tools, e.g. whole genome sequencing to assess off-target or unintended genomic modifications.

- Example(s) illustrating how NBT and Conventional Breeding Techniques (CBT) might overlap and create inappropriate risk categorization requiring PMSA (impacts on innovation).

- Provision of genetic modification technique examples; “sentence cut-and-paste” (e.g. recombination) -v- “letter/word replacement” (gene editing, e.g. ZFN, CRISPR) to allow improved comprehension *and differentiation* between these techniques.

- A lay description of how a food produced using NBT might be assessed (and by whom) for determination of requirement for pre-market assessment.

- A single description (figure) illustrating how production of a food producing organism can lead to GM Food designation (including labelling), or not. Inclusive of GM organism-derived DNA/protein content criterion related to processing aids and ingredients.

- It is understood a goal is amending definitions to focus on potential health risk in food products rather than technological process used to derive food producing organisms. As existing definitions are specifically based on the latter, Code revisions in which the focus is potential health risk in the food – absent requirements for pre-market assessment specifically intended to assess health risk - may appear to suggest processes whereby foods produced using “artificial” (i.e. “technological”) genetic modification techniques may potentially enter the food supply absent health assessment requirements other than industry self-substantiation as “safe

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and suitable", etc. Assuming food producers will assess equivalency with a food produced using CBT, and health risk, a question arises as to whether the goal is specific *exclusion* of technological process used to derive food producing organisms from such assessment. Some clarification, along with a description of how a typical food may be assessed for safety (see above) by a manufacturer, is recommended.

Expert Advisory Committee (EAC)

- Include descriptions of the preferred discipline/sector membership of the proposed EAC, e.g. technical (genomics/bioinformatics [academic/NGO, industry], toxicology), molecular biological, regulatory, and operational (on-the-ground Code enforcement/surveillance.)
    - It is strongly recommended EAC membership is inclusive of members with *direct, applied* technical experience and knowledge of food production, regulation, genomics, gene editing/recombination and breeding techniques.
- An EAC task management approach is suggested where the group is initially provided general definition-revision guidance and scope by FSANZ to produce (a) draft revised 'food produced using gene technology' and 'gene technology' definitions, including careful consideration of existing, emerging, and future genetic technologies. Then, using these draft definitions, (b) generate criteria for industry to apply via a hierarchical decision tree, risk matrix (or similar) to classify NBT foods as equivalent to those produced using CBT or "transgenesis" in terms of risk, to reduce potentially *ad hoc* and/or inconsistent decision making as to GM Food classification and need for PMSA. Then (c) iteratively revise (a) and (b) using a variety of NBT, CBT and "recombinatorial" scenario-based assessments.
    - *Avoidance of ad hoc* and/or inconsistent decision is particularly germane as the currently proposed approach may permit foods containing DNA and/or protein from NBT-produced foods without PMSA or FSANZ permission via Application as a novel or GM Food.
    - The EAC may need guidance to avoid areas of *GM food* policy or regulation, i.e. clarify delineation of revised 'gene technology' → 'food produced using gene technology' → "GM Food" definitions from GM Food *policy* and *regulation*.
    - As a goal is to amend the Code definitions to focus on the potential health risk rather than technological process used to derive food producing organisms.

With respect to FSANZ' specific questions regarding the proposed regulatory and non-regulatory risk management approaches to address the problem:

1. What costs and benefits do you believe should be considered when assessing Options 2 (Status quo) and 3 (Amend the definitions in the Code)?
    - Agree that maintenance of status quo (Option 2) would lead to regulatory uncertainty, with Option 3 providing greater industry regulatory certainty considering rapidly developing application of New Breeding Techniques (NBT) for production of organisms used to produce food.
    - Option three may act to reduce costs to the food industry and regulatory agencies by providing a defined framework and criteria for determination of risk associated with food produced using NBT-derived organisms. For industry via reduced need for costly PMSA based solely on the technology used to derive the food producing organism, as opposed to the food itself. For regulators via clarity regarding how foods produced using CBT, NBT and

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"recombination/transgenesis" are treated in terms of Code definitions, food safety risk, industry guidelines and expectations regarding food-industry food-risk assessment.

2. Can you provide any reports, papers, data or any other evidence to support the importance and the potential magnitude of any costs or benefits you have identified?

   • None currently.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Department of Health on (07) 3328 9310 or at [redacted]

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