



Dairy for life

3 December 2021

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Dear Standards Management,

**Proposal P1055 - 1st Call for submissions - Definitions for gene technology and new breeding techniques**

Fonterra welcomes the opportunity to provide comments and information to FSANZ on **Proposal P1055 - 1st Call for submissions - Definitions for gene technology and new breeding techniques** with objectives to improve clarity about what foods are captured for pre-market approval, better accommodate new and emerging genetic technologies, and regulate New Breeding Technique (NBT) foods in a manner that is commensurate with the risks they pose.

Fonterra acknowledges the well-considered, and balanced approach in the preparation of the supporting material for this consultation.

We refer to Fonterra's 2018 submission, regarding the extent to which foods derived using NBTs require pre-assessment for safety before they can be sold or used as ingredients in food in Australia and New Zealand.

We thank FSANZ for the consideration of the comments outlined in this submission. If there are any queries relating to this submission, please contact [Redacted]

Yours sincerely,

[Redacted]

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## General comments

Fonterra is a global dairy nutrition company owned by 10,000 farmers and their families. With a can-do attitude and collaborative spirit, we are a world leading dairy exporter. We draw on generations of dairy expertise and are one of the world's largest investors in dairy research and innovation, to produce more than two million tonnes annually of value-added advanced dairy ingredients, food service and consumer products for over 140 markets.

Fonterra is committed to produce and supply safe, quality food. Fonterra supports a regulatory framework that is risk based, agile, ensures food safety, supports science and innovation, and is consistently enforced in different jurisdictions.

We listen carefully to our consumers and customers and recognise the value in New Zealand's global reputation for its GM status, as supported by the current New Zealand regulatory framework.

We see genuine value in the possibilities offered by new and emerging life science technologies such as gene editing that could offer significant benefits for sustainable nutrition, animal welfare, human health, biosecurity, and the environment.

With the likelihood of rapidly evolving technologies such as New Breeding Techniques (NBTs) increasingly being used within the future global food supply, we recognise the need for and support the proposed revision of these definitions in the Food Standards Code. Fonterra relies on robust traceability processes to meet specific customer or market preferences and requirements, while providing verification to customers and consumers regarding the genetic status of our products (including voluntary market claims such as the non-GMO Project and Organics).

Fonterra strongly values the global recognition of the FSANZ approach to food safety assessment to support New Zealand and Australia's trade opportunities. Fonterra continues to encourage FSANZ to consider any implications to Australia and New Zealand exports of food and dairy products in addition to its primary mandate of the protection of Australian and New Zealand consumers.

We recognise the challenges in ensuring the proposed definitions meet the principles outlined by FSANZ in the *1<sup>st</sup> call for submissions – P1055* and welcome the opportunity to review the proposed definitions through a second consultation process.

In summary, Fonterra:

- Supports FSANZ's continued science and risk-based approach and consideration of consistency with international guidelines and principles, recognising that foods derived using NBT may be sourced and sold globally.
- Supports the principle of the hybrid (process and product based) approach to achieve the objectives outlined.
- Supports *Option 3: Amend the definitions in the Code*.
- Considers these definitions will be key to achieving the proposal objectives outlined in P1055, to protect and inform consumers, while enabling sound food business decisions, and futureproofing of the Code.
- Considers supplier traceability of food made using "gene technology" will continue to be relevant to the food industry, regardless of whether the food is subject to a FSANZ pre-market assessment.

## Specific comments

### 3. Safety Assessment outcomes and conclusions

**FSANZ concluded** *When the characteristics of a 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.*

#### Fonterra Response:

- Fonterra supports continuation of the current risk-based assessment processes used by FSANZ for robust assessment of food safety, consistent with internationally agreed guidelines and principles for conducting such assessments<sup>1</sup>
- We support the overall outcome-focused principles and acknowledge the rigorous evaluation that has been carried out by FSANZ in their risk-based assessment of NBT foods.
- We generally support consistency in food safety evaluation principles across the Food Standards Code.

### 4.1.2 Excluding foods from pre-market assessment and approval

**FSANZ proposed** *Table 1: Possible exclusions according to safety assessment conclusions*

#### Fonterra Response

- In principle, we support the product-based exclusions from pre-market assessment and approval as outlined in Table 1. Please refer to section 4.3.2 below for further comment on the detail within Table 1.
- We consider that Table 1 provides a helpful framework to guide the development of a definition for “food produced using gene technology”.

### 4.1.3 Process versus product-based definitions

**FSANZ concluded** *it will be necessary to rely on a combination of both process and product-based definitional criteria.*

#### Fonterra Response

- We support the hybrid, outcome-based approach to the definitions:
  - **a process-based** definition of *gene technology* to ensure all modern (and future) gene technologies are captured in the scope.
  - **a product-based** definition of *food produced using gene technology* to allow for exclusion of certain foods (considered to be very low risk) from pre-market assessment
- We support the ability to capture all technologies within the definition for gene technology, to enable any specific change to be captured and recognise the relevance of the overlay of a product-based assessment to align with safety assessment principles applied in other parts of the Code.
- This approach provides adequate safeguards while supporting an efficient route to market with a clear risk-based assessment pathway for products which may be subjected to pre-market assessment.
- A streamlined process could be considered, for example, where the food has already received pre-market approval in another market recognised by FSANZ.

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<sup>1</sup> FSANZ has established a rigorous and transparent process for assessing the safety of GM foods. The safety assessment is undertaken in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development (OECD), Food and Agriculture Organization (FAO) of the United Nations, World Health Organization (WHO) and the Codex Alimentarius Commission

<https://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx>

#### 4.1.4 Alignment between food and gene technology regulations

**FSANZ concluded** *the definitions for a GMO in Australia and New Zealand are not aligned. It would not be possible for FSANZ to align the Code definitions to both sets of GMO definitions*

##### Fonterra Response

- We agree with FSANZ that it would be difficult to align definitions across jurisdictions, particularly given the difference in approach between Australia and New Zealand regarding environmental GM regulations which are not in scope for FSANZ. Therefore, it is appropriate for FSANZ to consider the most appropriate definition for managing risk arising from food.

#### 4.2.1 Possible regulatory and non-regulatory options

**FSANZ proposed Option 3: Amend the definitions in the Code** *as the preferred option because it is the only available option that directly addresses the problem.*

##### Fonterra Response:

Fonterra supports Option 3: *Amend the definitions in the Code*

- We agree options 1 and 2 are not viable for the reasons outlined by FSANZ.
- We consider option 3 allows for a risk proportionate approach.
- We agree the approach will limit the potential for gaps in regulatory coverage as technology develops and help future-proof the regulation for emerging technologies.
- 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 navigating ambiguity to realise the best practice regulatory approach. We agree with the proposal to model this on the existing Advisory Committee for Novel Foods.
- Further, guidance documents should be developed in consultation with industry to ensure they are fit for purpose.

#### 4.3.1 Revised definition for 'gene technology'

**FSANZ proposes** adapting the language in the United States definition for incorporation into a revised Code definition for 'gene technology'. *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"*

##### Fonterra Response:

- We support the consideration of terms used in the definition adopted by USDA. We also suggest consideration of the *modern biotechnology* definition used by Codex (and Cartagena Protocol) in that it provides relevant international synergies.

#### 4.3.2 Exclusion criteria for certain foods

**FSANZ 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.*

##### Fonterra Response:

- In principle we support the product-based exclusions in Table 1. Please consider the below comments for consideration in future definition development.

- Any revised definition of “food produced using gene technology” needs to maintain the existing note under FSANZ 1.5.2-2:  
*“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 clause aligns with the principles outlined in Table 1 and we request that it is maintained, for clarity that feed is excluded.
- Clear guidance and objective criteria are needed on which to base and define an appropriate term to express “same”, “similar” or “equivalent”. This is to ensure risk assessment for NBTs is effective and captures NBT food that may pose a greater risk compared to conventional food, particularly where changes may be heritable.<sup>2</sup>
- We support the principles of the criteria referenced on page 26. We note the wide range and evolving<sup>3</sup> natural variation in conventional foods which ultimately impacts on the assessment of food products using gene technology.
- We note the reference in Table 1 to “new or altered characteristics”. By implication this suggests food not meeting the defined criteria for “food that has the same characteristics as conventional food” may be considered as having “new or altered characteristics”. We note the text in 4.3.2 references the term “altered characteristics” currently used by FSANZ<sup>4</sup> to refer to labelling requirements for specific refined GM foods in FSANZ Schedule 26. We wish to clarify whether the criteria for “altered characteristics” that currently applies to labelling is intended to align with the proposed criteria for “new or altered characteristics” in relation to pre-market assessment.

**FSANZ assessed** that food from null segregants not be a GM food for Code purposes.

#### Fonterra Response

- Food from techniques producing null-segregants could be excluded from pre-market assessment and approval if the definition of null segregants is met (i.e. evidence exists they have not inherited a genetic modification).<sup>5</sup>

**FSANZ noted** 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 and 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).

#### Fonterra Response

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<sup>2</sup> For example, epigenetic modifications, such as DNA methylation, can alter gene expression without modifying genomic DNA sequences *Fonterra submission – Food derived using new breeding techniques, April 2018*

<sup>3</sup> The Food Labelling Standards will be partially amended because soybean with high oleic acid content can now be produced with conventional breeding techniques and are not subject to definition of “specific GM products” anymore. *WTO notification, Japan, G/TBT/N/JPN/714 – 1/11/2021.*

<sup>4</sup> Labelling is also required for GM foods that have an altered characteristic (e.g. altered nutritional profile) when compared to a counterpart non-GM food  
<https://www.foodstandards.gov.au/consumer/gmfood/labelling/pages/default.aspx>

<sup>5</sup> Although progeny are selected that have not inherited any new DNA and do not display the GM trait, it is unclear whether there could be other unintended outcomes. For example, if the GM parent was produced using NBTs, it may be difficult to distinguish GM progeny from non-GM progeny unless specific markers are used. Also, it may also be possible for GM progeny to be mistakenly released as null segregants. A streamlined process could be considered where, for example, a particular GM plant cultivar that had previously gone through rigorous safety assessment could be used again but the cross be made with the original non-GM parent cultivar, e.g. non-browning apples. *Fonterra submission – Food derived using new breeding techniques, April 2018*

- We support the rationale for this hybrid approach<sup>6</sup>
- This will require processes for knowing what foods have been produced using “gene technology” – meaning supplier traceability/transparency of what food is “gene technology” is still required and a key aspect of ensuring process-based visibility.

### 6.1.1 b) The provision of adequate information relating to food to enable consumers to make informed choices

**FSANZ** *did not change the current approach to labelling as part of this proposal.*

#### **Fonterra Response**

- We believe that the implications of definition changes and their potential impact to in Clause 1.5.2-4 need to be considered.
- We recognise that FSANZ does not intend to change the GM labelling approach under this proposal. We note that a change in the definition of “gene technology” and “food produced using gene technology” may impact the definitions of “genetically modified food” and “novel DNA” and “novel protein” which could in turn impact labelling requirements and therefore overall product traceability throughout the supply chain.
- Also note our above comments in section 4.3.2 relating to the existing use of the term “altered characteristics”. Should FSANZ proceed with this term in relation to pre-market assessment criteria, its current meaning in terms of labelling should be reviewed.

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<sup>6</sup> Techniques that are used to turn “off” a gene of interest and thus not produce a particular protein, even if temporary, could alter the food produced. Turning “off” or down-regulating a major protein can alter the levels of other proteins; such compositional changes could increase the presence of an allergen. As previously stated, it is not the technique used, but rather what it produces. *Fonterra submission – Food derived using new breeding techniques, April 2018*