# Fonterra Co-operative Group Limited
# Comments on:

## FSANZ Consultation - Food derived using new breeding techniques

### April 2018

## General Comments

Fonterra welcomes the opportunity to comment on this consultation regarding the extent to which foods derived using new breeding techniques require pre-assessment for safety, before they can be sold or used as ingredients in food in Australia and New Zealand.

Fonterra is committed to produce and supply safe, quality food.

We recognise that necessary outcomes of the overall review of New Breeding Techniques (NBTs) will be protecting and may include informing consumers. The review should seek to future-proof the Code without requiring further reviews, as this is a rapidly-evolving field.

Fonterra believes an outcome-based approach would be the best way to achieve this. An outcome-based approach where changes to the food characteristics and therefore food safety, to determine the need for pre-market assessment and approval.

1. *To protect consumers:*
   Food modified using New Breeding Techniques (i.e. a NBT was used and there is a difference in the food characteristics or no conventional counterpart) should be subject to a pre-market safety assessment.

   Pre-market assessment should consider whether there are any changes to the characteristics of the food, such as composition, structure or nutritional quality, rather than the nature of the genetic modification. Changes to these characteristics may alter the hazards present in the food e.g. an increased level of a substance that may be toxic, presence of a new allergen or contribution to the nutrients present in the diet, as well as the storage characteristics of the food/products.

2. *To inform consumers:*
   Food unmodified using New Breeding Techniques i.e. a NBT was used but there is no difference in the food characteristics from a conventional counterpart. In this case, the food is identical to an existing food, and no further pre-market safety assessment may be necessary.

   Future discussions may consider whether the method by which an intentional manipulation is made to the heritable traits of a plant, animal or microorganism is important in consumer information. However, it is not part of the scope of the current consultation.

FSANZ may consider a streamlined pre-market assessment and approval process. For example where a safety assessment has been made according to Codex Guidelines, reviewed and consistently approved by other jurisdictions, this could be the basis of a local approval based on equivalence.

Exclusions could continue to be made either for a breeding technique with a history of safe use and/or where labelling is not required. Examples based on safe history of use could include random mutagenesis (radiation-based or chemical-based), and examples of labelling exclusions remain as the existing text in Food Standard 1.5.2.

Consistency with Codex and the Cartagena Protocol e.g. definitions could be helpful.

Finally, although not the primary focus, Fonterra encourages 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.

## Responses to questions from FSANZ consultation

*3.1.1 Do you agree, as a general principle, that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval?*
*Should there be any exceptions to this general principle?*

Fonterra agrees that, as a general principle, food derived from organisms containing new pieces of DNA should undergo pre-market safety assessment and approval.

The introduction of a new piece of DNA may create or delete proteins and/or secondary metabolites that would normally be present in that food or change the amount.

A streamlined process could be considered, for example:

- where the food is unmodified using New Breeding Techniques
- where the food has already received pre-market approval (not mixed outcomes) following a safety assessment meeting Codex requirements.

FSANZ might consider whether there are any risk management principles being considered for the review of nutrient substances and novel foods (P1024) could be applied.

*3.1.2 Should food from null segregant organisms be excluded from pre-assessment and approval?*
*If yes, should that exclusion be conditional on specific criteria and what should those criteria be?*
*If no, what are your specific safety concerns for food derived from null segregants?*

Food from null-segregant organisms should not automatically be excluded from pre-market assessment and approval. 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.

It is not directly relevant that the OGTR has stated that, under the Australian Gene Technology Regulations, null segregants are not GMOs. FSANZ must consider that foods derived using new breeding techniques may be sourced globally.

*3.1.3 Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis?*
*If no, how are they different?*
*If yes, would this apply to all derived food products or are there likely to be some foods that carry a greater risk and therefore warrant pre-market safety assessment and approval?*

Genome editing is a broad range of techniques that may be used to produce organisms with novel traits. The resultant food may or may not have altered characteristics. The genomes of many organisms have not yet been functionally characterised. This means that even small genome changes may have unintended downstream effects on biological pathways.

The extent of the genome change is not a predictor of any impact on the food. A point mutation introduced into a gene promoter could result in increased levels of a protein, changing the amount normally consumed by the general population or a specific sub-population.

The details of the breeding technique used may help to identify any hazards as part of the pre-market safety assessment but should not, in itself, be used as a predictor of the need for a pre-market safety assessment and approval.

The genetic change to the organism may itself be of ethical concern and provision of consumer information through traceability and labelling may need to be considered. For example, the development of hornless cattle in the USA addressed animal welfare concerns regarding dehorning, and the characteristics of the meat are identical; however, consumers may still want to make an informed purchase.

*3.2 Are you aware of other techniques not currently addressed by this paper which have the potential to be used in the future for the development of food products? Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?*

Fonterra is aware of other techniques not currently addressed.

- Epigenetic modifications, such as DNA methylation, can alter gene expression without modifying genomic DNA sequences. These changes can be heritable.
- RNA interference (RNAi) techniques; whether or not they involve inserting sequences into the genome or invoke temporary changes. RNAi is most commonly used to silence

genes by inactivating the mRNA so that the encoded protein is not produced. For example, RNAi gene silencing has been used in cows to knockdown β-lactoglobulin; a major milk allergen. However, some RNA sequences that are complementary to parts of a gene promoter can increase gene transcription, a phenomenon dubbed RNA activation.

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.

The rapidly evolving technology in this area will create continued challenges to regulators and industry in determining whether foods derived using new breeding technologies require pre-market safety assessment and approval.

*3.3 Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs?*
*If no, what other approaches could be used?*
*If yes, how could a process-based approach be applied to NBTs?*
*Are there any aspects of the current definitions that should be retained or remain applicable?*

Fonterra considers that a process-based definition is not appropriate as a trigger for pre-market approval. The details of the breeding technique used may help to identify any hazards as part of the pre-market safety assessment but should not, in itself, be used as a predictor of the need for a pre-market safety assessment and approval.

Fonterra suggests that FSANZ could consider an outcome-based approach:

1. Food modified using New Breeding Techniques i.e. a NBT was used and there is a difference in the food – *to protect consumers*.

2. Food unmodified using New Breeding Techniques i.e. a NBT was used but there is no difference in the food – *to inform consumers*.

The product and therefore the potential changed hazard characteristics determine the nature of the pre-market assessment and approval is required. A risk-based approach should be taken and a streamlined review and approval process considered in certain circumstances.

Consideration should be giving to aligning the definition for gene technology to that used by Codex.

*3.4 Are there other issues not mentioned in this paper, that FSANZ should also consider, either as part of this Review or any subsequent Proposal to amend the Code?*

FSANZ may need to consider:

1. A step-wise approach to pre-market assessment and approval (as novel foods)
2. Impact on consumer information - traceability and labelling
3. Impact on trade, both on the ability of Australia and New Zealand to export products globally, and recognising that foods derived using NBT may be sourced globally
4. NBTs will continue to evolve at a rapid rate. Today's new techniques will, in due course, have a history of safe use
5. Continuing to acknowledge the history of safe use of random mutagenesis
6. Updates the approvals handbook/guidance notes
7. Consistency with Cartagena Protocol and Codex definitions

Yours faithfully