Queensland
Government

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Dear Sir / Madam

Submission – Consultation paper – Food derived using new breeding techniques

Thank you for the opportunity to provide a submission on the consultation paper – Food derived using new breeding techniques.

This submission provides technical advice and comments related to this issue. 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 Australia New Zealand Ministerial Forum on Food Regulation.

The Queensland Department of Health has reviewed the Consultation Paper and associated questions. Please find below our responses to the specific questions below.

Question 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?

Yes. This retains consistency with existing Code 1.1.2 – 2 definitions for '*food produced using gene technology*', as well as associated requirements for safety pre-assessment under Code 1.5.2 before they can be sold as food or used as ingredients in food.

Should there be any exceptions to this general principle?

Yes. The use of the term 'using' in Code 1.1.2 - 2 definition '*food produced using gene technology*" would appear overly broad in the context of GM rootstock and/or null segregant producing

techniques. However, at a minimum there should be a requirement for demonstration and periodic verification that GM protein and/or DNA from the GM-parent/rootstock is absent from the scion or progeny. In addition, as expression of new GM DNA in rootstock may alter the characteristics of the scion in ways which may present an increased food safety hazard (e.g. increased levels of/expression of potential allergens), assessment as per Codex (2009) *GM food safety assessment* - including comparison to respective near-isogenic line – is advisable

Question 3.1.2
Should food from null segregant organisms be excluded from pre-assessment and approval?

No, complete exclusion would presumably obviate the need for initial and ongoing verification of null segregant status. At a minimum, documented verification of null segregant status should occur.

If yes, should that exclusion be conditional on specific criteria and what should those criteria be?

See above regarding suggestions regarding pre-assessment and possibly ongoing verification of, null-segregant status through production.

If no, what are your specific safety concerns for food derived from null segregants?

Our food safety concerns do not relate to null-segregants themselves, but rather the risk of potential breeding and/or production errors allowing entry of parent GMO into food in the absence of clear phenotypic and/or genotypic indicators verifying null segregant status which allow unambiguous parent GMO identification.

Question 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?

No. It is understood that loci can vary in their susceptibility to traditional mutagenesis. However, genome edited organisms are typically derived using site-directed mutation; rather than random mutation (and subsequent selection) obtained via conventional chemical/radiation mutagenesis. Hence, there is a lower risk of mutation of/impact on off-target loci/genes and/or unintended effects from genome edited versus traditional chemical/radiation-mediated mutagenesis.

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?

Pre-market safety assessment and approval is suggested for foods of major allergen classes (e.g. cereals, eggs, seafood, nuts, soy) and those known to contain compounds known to exert human (or animal if proposed stock feedstuff) toxicity/allergenicity if up-regulated/expressed at higher levels in associated foods. We suggest a formalised food safety risk assessment (FSRA) matrix to classify *foods produced using gene technology* via initial screening and ranking regarding food safety risk of (a) unlabelled food produced using gene technology entering the market (e.g. failure to identify null segregant in production), and/or (b) case-by case considerations of unintended effects of genetic modification. Such FSRA for pre-market assessment/approval could be based initially on documentation provided as per *FSANZ Application Handbook* (2016) Part 3.5.1 (Foods produced using gene technology). If ranked-risk is assessed as above a predefined quantitative/semi-quantitative threshold, further assessment by FZANZ (e.g. as per *FSANZ Application Handbook* [2016] Part 2.3) would be warranted.

Question 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?

There may be potential for techniques such as CRISPR to genome edit via successive incorporation of targeted-single or short nucleotide indels with the specific purpose of creating genes/sequences known to occur in other organisms/species. This would not constitute cis-, or intra-genesis in the case where the intention is ultimately to insert (or via selective deletion) a sequence/gene of known sequence from a non-same, or non-cross-compatible species. While insertion of such genes *in toto* via CRISPR or other techniques would constitute transgenesis, their in effect *in vivo* "synthesis" does not appear to be addressed in terms of terminology of genome editing and NBT classification.

Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

Yes. Principally due to potential for down-regulation of expression of genes associated with essential nutrient synthesis or up-regulation of potential allergens or toxins.
Risk assessment as described above under 3.1.3-Q2 could be designed to consider techniques specifically impacting gene expression and/or post-translational modification as a particular process-based class of genetic modification for risk assessment purposes.

Question 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?

Yes.

If yes, how could a process-based approach be applied to NBTs?
Please refer to answer provided to 3.1.3-Q2 and 3.2-Q2. A process-based risk assessment approach - to determine whether subsequent pre-market safety assessment is required - is recommended.

Are there any aspects of the current definitions that should be retained or remain applicable?

Please refer to the answer provided to 3.2-Q1 regarding terminology of genome editing and NBT classification in light of potential in-effect "*in vivo* synthesis" of transgenes.

Consideration should be given to clarification of Code 1.5.2 – 4(5) (Food produced using gene technology) regarding the definition of *novel protein* as *other than protein that*: 1.5.2 – 4(5)(b) *has an amino acid sequence that is found in nature*. Changes *produced using gene technology* to an organisms genomic DNA intended to produce a protein not naturally existing in the respective organism - when that organism is used for food production – appear to classify the food as *genetically modified* via the associated definition wherein it contains *novel DNA*. However, it is unclear whether the exemption regarding definition of *novel protein* for those with "naturally occurring amino acid sequences" is simply to define *novel protein sensu stricto* as novel if it does not naturally occur (e.g. *ex vivo* amino acid sequence modification), or whether this could potentially impact the definition of food produced using gene technology. In other words, if a food contains a protein produced in an organism which contains *novel DNA*, but the protein contains an amino acid sequence which can be demonstrated to be *found in nature*, no exemption from the *genetically modified food* classification applies.

Question 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?

It is acknowledged that labelling is outside the scope of the current consultation paper. However, any resulting proposal to subsequently amend the Code may need to consider whether labelling requirements should also be amended to allow consumers to make informed choices. Dependent on the specific changes proposed to the Code in relation to requirements for GM food pre-market assessment for safety, any subsequent proposal to amend the Code may need to consider whether additional labelling requirements are warranted to balance consumer's expectations regarding the ability to make informed choices. And to provide information on what may constitute relatively minor changes to organism genomes, or applications of GMOs in production which do not impact resultant food DNA or protein. For example, could use of GM rootstock where scion and derived food characteristics are phenotypically - but not genotypically - changed from comparator(s) require labelling as to use of GM in *production* (rather than as a processing aid of ingredient) distinct from that currently defined in Code 1.5.2 – 4a(i)? Or would such a food be exempted from GM labelling requirements as per this same Code section wherein; *the genetically modified food has been highly refined* (in this case *produced*) *where the effect of the refining* (in this case *production*) *process is to remove* (in this case *preclude introduction of*) *novel DNA or protein*?
As this is potentially a policy discussion, FSANZ may need to consider engaging the Food Regulation Standing Committee at an early stage to avoid potential subsequent delays in the latter stages of a proposal.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Department of Health on (07) 3328 9310 or at foodsafety@health.qld.gov.au

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