Ministry for Primary Industries
Manatū Ahu Matua

12 April 2018

Food Standards Australia New Zealand
PO Box 10559
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WELLINGTON 6036

Dear Sir/Madam

Consultation Paper – Food Derived using New Breeding Techniques

Thank you for the opportunity to comment on this Consultation Paper.

The Ministry for Primary Industries (MPI) has the following comments to make. MPI has consulted the Ministry for the Environment regarding this Consultation, however the views expressed represent those of MPI.

MPI welcomes the approach taken by FSANZ, to address the issues raised regarding foods derived using New Breeding Techniques (NBTs). We agree that the regulatory status of these foods needs to be clear, with respect to the definitions in the Food Standards Code (the Code) regarding genetically modified foods (GM foods). We are aware that defining the regulatory framework for NBTs is a developing area internationally, and it is timely that this work is undertaken by FSANZ. As any clarification or changes to the definitions in the Code are likely to require further consultation under a Proposal, we have provided general comments, and our position could change if a Proposal is developed.

The comments provided in this submission relate to the regulation of foods, and do not apply to definitions of genetically modified organisms (GMOs) under the Hazardous Substances and New Organisms Act (HSNO). We do not think the definitions necessarily need to align, as the use of these techniques are regulated under legislation with different purposes (food safety versus preventing or managing the adverse effects on the environment and people of new organisms including GMOs). Current definitions already do not align. We note however that a further widening of the definitional gap may have implications. For example, if in the future some food products using NBTs do not require assessment as GM foods, they may still require a GMO approval under the HSNO Act to be used in New Zealand. Likewise, in the future some food products developed through NBTs could have FSANZ approval for consumption in New Zealand, while the same product (organism) does not get HSNO approval to be imported or grown in New Zealand.

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We are however of the view that any decisions made in the Australia-New Zealand food standards setting system are, as far as possible, consistent with definitions that will in due course be developed internationally for foods.

MPI considers that in assessing the risk from any NBT that the benchmark should be the outcomes of conventional breeding techniques. Where a NBT results in an outcome for the genotype and phenotype that would not significantly differ from the capabilities of conventional breeding techniques then there is not a risk basis to support additional regulation of food from the resulting organism.
A precautionary approach for pre-market assessment of food produced from an NBT could be warranted where there is uncertainty in the genotypic and phenotypic outcomes of the technique and as such an inability to benchmark as equivalent to conventional breeding techniques. The risk assessment requirements may be less (using a graduated risk based approach), for some techniques. In time, as definitions are agreed internationally, some NBTs that might be captured may eventually be able to be excluded.

We note that some of the foods produced using NBTs cannot be distinguished from conventional foods using currently available analytical techniques. We comment that enforcement using testing should not be the basis of decisions to exclude or include these foods from the definition, as it may be possible to develop other measures, where warranted, to determine if a technique was used to produce the food (such as food production records or traceability methodology). However, this may only be an interim solution, as we acknowledge that determination of techniques used will become progressively more difficult as more crops and animals developed using NBTs become commercially available internationally.

3.1.1 Questions
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?

Yes. MPI agrees that food derived from organisms containing new pieces of DNA should be regarded as GM foods and therefore captured for pre-market assessment and approval. The presence of new DNA from intragenesis and cisgenesis is likely to present an identical risk profile to transgenic food, which is already captured for pre-market approval.

GM rootstock presents a difficulty noting that no DNA is likely to enter the scion and thus the food is unlikely to fit the same criteria as food produced on transgenic plants. Any monitoring approach for newly introduced genes in a fruit from the scion would not be able to distinguish against control lines.

An approach may be to consider a streamlined approval format whereby the insert identification and characterisation of the rootstock can be simplified. The pre-market appraisal would predominantly focus on the safety assessment aspects for any new proteins that are produced in the rootstock and that may be translocated into the scion, this would allow the rootstock approval to be used generally with any scion cultivar.

Exceptions –no exemptions come to mind at the present time.

3.1.2 Questions
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?

Yes. Our initial view is that because none of the introduced DNA remains in the final organism line and it does not functionally differ from a food organism developed through conventional breeding techniques, these do not need to be assessed as GM foods.

3.1.3 Questions
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?

Our initial view is that that food from genome edited organisms, where the genome editing is for deletion, knock-out and single or small nucleotide changes, should be excluded from a GM food pre-assessment and approval. The produced foods would not functionally differ from a food developed through conventional breeding technologies, or spontaneous mutation in nature, and may in fact show a reduced risk profile given the increased ability to identify and control off-target changes. However, if there is evidence that these foods still require a premarket assessment to assure safety, it is our view that all assessmenst for foods derived from gene technology should be assessed under the same process (which could include a simplified process if the final food is indistinguishable).

3.2 Questions
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?

MPI is only aware of the potential use of RNA directed DNA methylation (RdDM). MPI is not aware if there is the ability to monitor for heritable epigenetic changes to an organism, if not the technique whilst allowing for heritable changes to the characteristics of an organism may also suffer from an inability to enforce any regulation upon.

3.3 Questions
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?

This issue needs further exploration. While the pre-market assessment decision is risk based (i.e. which techniques are captured and which are not), the definitions in regulation needed to achieve this outcome needs further consideration. While this might end up being process based, there could be other options that achieve the same outcome.

3.4 Question
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 would be prudent to consider the implications for regulatory regimes if a single organism/product ends up being considered GM under one system and not under the other. Part of this may also include how clarity on regulatory requirements can be maintained for food producers and consumers.

Yours sincerely

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