CSIRO Submission 18/622

Review of food derived using new breeding techniques

Food Standards Australia New Zealand

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Introduction

Thank you for the opportunity to comment on the FSANZ review into Food Derived Using New Breeding Techniques. CSIRO recognises that there are several organisations that have a different part to play in regulating the undertaking of research and commercialisation of products of specific genetic technologies. It is highly desirable that all regulators in Australia (and globally) use similar or the same definitions, triggers and approaches related to the regulation of genetic technologies. CSIRO supports regulation being commensurate with the level of risk posed by each technology.

In summary, our responses suggest a re-look at definitions and triggers; an investigation of ways of future proofing the Code against an inevitable backdrop of the continuing technology development that will challenge rigid Codes; regulating commensurately to the level of risk; and as much as possible harmonising approaches with other regulators.

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?

No.

"New pieces of DNA" has a specific meaning in this discussion of the code. Application of these definitions would capture nearly all of the products of conventional plant breeding which we believe was not the original intention of the regulatory system.

1. "The DNA sequence was not previously present in the host organism" – this would capture many of the previous successful breeding technologies involving wide crosses where parts of chromosomes, whole chromosomes (e.g. sugarcane) or even whole genomes (e.g. triticale wheat x rye hybrid) have been added to the "host organism". This definition would also describe natural genetic re-arrangements and the result of meiotic recombination.
2. "The DNA sequence is present in the host organism but has been reintroduced at a different location in the genome". This definition would capture natural re-arrangements or chromosomal translocations.
3. "The DNA sequence is present in the host organism but has been rearranged or introduced into the host organism in a different orientation". This definition would capture natural re-arrangements or chromosomal translocations.

The definition should be refined to indicate the extent to which the DNA is 'new' or specific exemptions should be put in place to exclude changes made to genomes through traditional breeding methods as has been done in the Gene Technology regulations.

Regulation in this context would not be commensurate with risk unless it was established that technological methods of DNA rearrangements pose an increased risk of inadvertent harm above natural/undirected processes of DNA rearrangement.

Should there be any exceptions to this general principle?

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.
To be consistent with recent proposed changes to the Gene Technology Act that would exempt null segregants from being considered GMOs, FSANZ should have the same requirement. There may be a need for some verification to be provided that all the GM components in the parent organism have been removed during segregation but this is easily achieved these days using Next Generation Sequencing or other molecular diagnostic technologies.

3.1.3 Questions

Are foods from genome edited organisms likely to be the same in terms of risk to foods derived from chemical or radiation mutagenesis? If no, how are they different?

Yes.

CSIRO believes that food from simple gene edited organisms carry the same risks as foods derived from organisms generated by more traditional breeding processes, subject to some caveats. Genome editing was sub-divided in the OGTR discussion paper[1] as SDN-1, -2 and -3. For SDN-1 and SDN-2 the risks in foods are likely to be similar or even less than those derived from chemical or radiation mutagenesis and therefore should not require any pre-market safety assessment and approval. This is because the same mechanisms of the plant are being used to repair DNA after the initial breakage of the genomic DNA, but in the case of genome editing techniques the number of places affected in the genome are much reduced and more predictable. For SDN-3, where the changes to the genome are directed by a recombinant DNA molecule, the risks are likely to be similar to more conventional gene technology methods of introducing the same piece of DNA and should therefore receive pre-market safety assessment and approval until sufficient evidence for safety has been generated over time.

The same regulations should apply equally to all types of foods captured by the regulatory trigger to provide certainty to the developers or importers of new foods.

If yes would this apply to all food 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?

As with conventionally bred or mutated organisms used for foods there is always the rare potential for inadvertent alterations to genomes to increase the production or toxicity of existing toxins/toxic chemicals produced by those organisms and their near relatives. The regulations should be sufficiently robust that should any unintended deleterious outcomes occur through NBT that it would trigger withdrawal of products and a reassessment of their safety when first identified.

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?

It is important to be aware of the most recently developed techniques when determining any revisions to the code. However, new techniques will continue to be developed so can the code be designed in a manner that can accommodate decisions about whether products of new techniques are regulated or not? Finding 13[2] of the preliminary review of the national gene technology scheme addresses this point and is worthy of consideration here.

[1] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf
[2] https://consultations.health.gov.au/best-practice-regulation/review-of-national-gene-technology-scheme-phase3/supporting_documents/Third%20Review%20of%20National%20Gene%20Technology%20Scheme_Preliminary%20Report.pdf

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

Food Safety assessment has always been through a combination of process and product based approach and CSIRO believe that this should continue for conventional GM and SDN-3. The bulk of NBT applications to food organisms will likely fall into the SDN-1/2 category which are tending to be globally regulated as not GMOs. Organisms generated using more complex NBTs may be as safe as these first generation products, but will require case by case assessment until their safety is supported by evidence. It is critical that Australian regulations is compatible with other jurisdictions to avoid international trade implications.

The issue of a process vs an outcome based trigger is not straight forward. Below is an extract from CSIRO's submission to the phase 2 consultation of the National Gene Technology Scheme review addressing this issue:

> "Whilst the Scheme uses a process trigger there will continue to be regulatory challenges around the ability of aging definitions to accommodate new techniques and processes. These challenges can be minimised in a variety of ways. For example by:
>
> i. exploring ways to introduce more flexible legal mechanisms for more rapidly introducing changes to definitions within any revised Scheme
> ii. giving the Regulator more discretion to determine whether to regulate or exempt new technological developments, and to exempt technologies on the basis of experience and new information
> iii. codifying policy principles that express the intent of the Act, and the technological changes it intends to cover
> iv. moving to a product-based trigger rather than process-based trigger, or some hybrid model combining elements of both process and product
>
> Technologies are emerging that challenge the current process trigger, others are likely to follow, highlighting the need for increased flexibility. Specific examples we believe are being described by other submissions in detail include:
>
> i. the potential to alter the epigenetic marks on DNA using catalytically dead Cas9 enzymes fused to chromatin modification or DNA methylation or de-methylation enzymes
> ii. Cas9 variations fused with deaminases to allow base changes at specific sites, without cutting DNA
> iii. ribonucleoproteins gene editing via a transient system without use of a DNA template or genetic integration"

3.4 Questions

Are there other 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?

None