Plant & Food Research: A New Zealand Crown Research Institute

Our organisation's relevant expertise

We are a NZ government owned research provider supplying science expertise and products for commercialisation to horticulture, viticulture, arable, vegetable, seafood and food industries. We have over 650 science staff spread across 15 sites mostly in New Zealand.

With respect to this submission our relevant expertise is in food science, food safety science, plant genetics, plant genomics and biotechnology. We develop cultivars for commercialisation by our partners in kiwifruit, pipfruit, potatoes, wheat, etc. We also develop novel food concepts, food ingredients and supplements for partners. Plant and Food Research currently produces transgenic and gene edited plants in containment for research purposes. We also have growing expertise in fish genetics and genomics.

Signoff

This submission has been signed off by the CEO of Plant & Food Research

Summary

Plant & Food Research submits that food products resulting from NBTs should not automatically require pre-assessment for safety. Instead, the threshold for pre-assessment should be on the genetic composition of the food itself.

We specifically submit that regulation regarding the need for pre-market safety assessment of foods sourced through NBTs should focus on foods that contain foreign or new DNA. Our Institute believes that where there is no foreign DNA present in the material to be consumed as food – i.e. the genome has been changed by gene editing but with no new DNA added, it is a null segregant or where it is produced from a scion grafted on a transgenic rootstock – that there is no compelling public safety benefit to be gained from additional pre-market assessment beyond that required generally of all foodstuffs (except for the situation below).

However we submit that where NBTs have been used on foods known to contain compound/proteins of potential concern to food safety, they should be tested for levels of these compounds in the NBT-derived foods and compared to those found in existing foods through reference to food composition databases, without the need for full pre-assessment.

Finally we suggest broadening the definition of gene technologies to better align it with the known suite of NBTs available now and predicted in the future, understanding that the trigger for pre-approval is better defined around the genetic state (no new DNA) and chemical composition of the product, rather than the process used to produce it.

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?*

Yes, we agree as a general principle that food containing new pieces of DNA should be captured for pre-market safety assessment and approval. This would include intragenics, cisgenics and although not NBTs under the current definitions, transgenics. This would include new pieces of DNA incorporated via Agrobacterium-mediated transgenesis and gene editing (CRISPR/Cas9) for the precise insertion of new pieces of DNA.

The major areas of potential risk are around the new DNA and the new DNA is policable as it is detectable using molecular assays such as PCR and whole genome sequencing.

Food produced from plant scions grafted on root-stocks that contain new pieces of DNA should not be captured for pre-market safety assessment as the new pieces of DNA are not transferred to the scion. However we do acknowledge that in some cases the RNA and proteins derived from the new pieces of DNA may be transferred to the scion via the plant vasculature. As such we content that evidence should be provided that neither the DNA, RNA or protein of the new pieces of DNA introduced to the rootstock should be detectable in the food produced by the scion.

- *Should there be any exceptions to this general principle?*

No. We believe that the principle of foods that contain new pieces of DNA should be captured for preapproval is robust and consistent with other food regulations. This position is consistent with a well-established and globally implemented situation where ingredients in formulated/processed foods that are derived from fermentations performed by GMO's (e.g. citric acid in beverages, most supplementary vitamins, most enzyme processing aids – including chymosin in cheese) are not treated differently from similar ingredients derived from direct extractions from natural sources.

3.1.2 Questions

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

Yes we believe they should. There is no evidence that inserted genes that are segregated out of the genome induce or influence genetic change in the null segregant. As such it is difficult to image how a null segregant could have any increased risk.

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

It would seem feasible using whole genome sequencing and bioinformatic analysis to require foods which are produced from null segregant organisms to provide sound evidence they are free from new pieces of DNA.

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?*

Yes, they are likely to be similar. Chemical and radiation mutagenesis produce the range of mutations possible by gene editing technology without insertion of foreign DNA. The mutations are largely random in their position within the genome, unlike the precision of gene editing. Even though there can be off target gene edits, these would be akin to the multiple mutations often

introduced through chemical or radiation mutagenesis tolerated for their perceived level of risk currently.

- *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?*

Some foods do carry a greater level of risk, for example those foods that contain levels of compounds known to be toxic at high levels (eg alkaloids in potatoes). When a known compound/protein detrimental to human health is naturally present, at acceptable levels, without genome editing, then the levels of these compounds should be assessed in the gene edited food and compared with the levels found in the unedited versions of the food. Comparisons could be made to levels of potential detrimental compounds outlined in food compound databases to enable a rapid pre-market assessment and approval, based on compound/protein composition alone.

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?*

There are a number of new technologies that we are aware of that have the potential to be used in the development of novel food products. Epigenetics, involved in the change in methylation state of the DNA, could potentially be used to modify the characteristics of foods. Transposable element mobilisation is a method to increase the potential resource of genetic variants by applying a stress to mobilise endogenous transposable elements.

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

We do not believe that DNA methylation or transposable element mobilisation technique warrant pre-market safety assessment and approval. Neither introduces any new DNA, but rather either methylate or mobilise existing DNA and are ongoing in nature. As such it is difficult to see how there would be additional risk.

3.3 Questions

- *Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs?*

  We do not think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs. The reasons for this are that the levels of risk do not directly translate from the process, that is, one process is not necessarily risker than another. Also a process based definition is not easily future proofed as decisions will need to be made for each new process as it is used in developing new foods.

- *If no, what other approaches could be used?*

A better system might involve addressing questions around where the greatest levels of risk is thought to be associated. If we agree that conventional breeding technologies are generally regarded as safe then we could ask whether the gene changes incurred by the new breeding technology could be achieved through convential breeding and if so do not require pre-market approval. If not they could be regulated in the same way as foods containing new pieces of DNA.

As argued earlier if additional risk analysis is thought to be warrented (for example because the food is known to contain levels of detrimental compounds) then a comparision of levels of these compounds could be made.

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

There probably still needs to be a definition of gene technologies to contrast resulting products against those made via conventional breeding. The definition of gene technology just needs to be broadened to include technologies that involve deletions and base changes. This would align gene technologies with NBTs and negate the need to redefine gene technology on a regular basis. However these process-based definitions should be not be the trigger for the need for pre-market approval, but rather the nature of the resulting product and it's DNA.

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?*

We contend that it would be desirable to align the regulations in regard to food safety (FSANZ) with those regarding the development of genetically modified organisms in both Australia (OGTR) and New Zealand (HSNO). In Australia the OGTR are undertaking a Technical Review of the Gene Technology Regulations providing the opportunity for alignment. However the HSNO Act in New Zealand is currently not up for review, so any amendments as to how FSANZ treats these foods could become out of step with how they are treated under HSNO, especially where they do not involve the addition of new pieces of DNA (eg gene editing, null segregants, etc).

Related issues involve the perception of the public of any regulation changes. Would the public of Australia and New Zealand perceive any relaxing of NBT associated regulations as a potential reduction in the safety of the food they are consuming and a bending to the wishes of multinational food produces. Would FSANZ loose trust with the public of Australia and New Zealand. Also international consumer who currently perceive New Zealand as a producer of safe GE-free foods might think it hypocritical that we allow certain foods derived from NBTs to be imported without the need for further testing.

Similar commercial issues also arise. Should we allow the importation of gene edited foods without food safety testing to compete with locally developed foods that if gene edited in NZ, for example, would have to make it over a set of very high hurdles under HNSO.