My relevant expertise

Over 25 years' experience as a plant biologist and 15 years in lecturing plant biology and new technologies

Background to this submission

All my comments and points are based on my own scientific knowledge, in the area of plant yield, secondary metabolism, crop production and consumer response.

Summary

I know, and have measured, the effects of genetic change that can be achieved by long term conventional breeding, mutagenesis, gene editing, and gene transfer. The technique that induces the most numerous of changes is conventional breeding – thousands of new combinations and selection of random mutations linked to beneficial traits. There is no possibility that gene editing or selection of null segregants can increase risk above that seen in breeding. There is risk in all new selections, but no additional risk is caused by using a newer, more accurate techniques.

Recommendation

- New breeding technologies, such as editing without introducing new DNA, should have no pre-market safety assessment or approval. They have LOWER risk than methods used since plant breeding was first used (approx. 10,000 years).
- Food obtained from null segregants should be excluded from pre-assessment and approval. Null segregants are no different from organisms obtained using classical breeding and they do not contain any foreign DNA.
- The current FSANZ process that considers insertion of "*new pieces of DNA*" using gene technology continues on a case by case basis. These remain defined as organisms produced through gene technology.

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, including the use of CRISPR/Cas9 for the precise insertion of DNA is equivalent to a transgene.

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

There is an issue with defining "new pieces of DNA". Is the pluot (a plum/apricot hybrid), currently available in our supermarkets, a "*food derived from organisms containing new pieces of DNA".* Certainly – this plum has 37,000 new apricot pieces of DNA. Testing of this organism is achieve by eating it. "*new pieces of DNA"* really means *"new recombinant pieces of DNA"* in the public's perception.

3.1.2 Questions

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

Yes. There is no evidence that inserted genes that are segregated out of the genome induce or influence ANY genetic change in that null segregant. Perplexingly – how does someone test for a null segregant?

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

If the new plant has been examined using whole genome sequencing and there is an absence of any transgene, then that plant, or food product should go straight into the market. Otherwise NZ and Australian products are being assessed at a level that cannot be applied to the same products from other countries.

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?*

No. They are lower in risk. The number of events caused by editing is an order of magnitude lower than chemical or radiation induced mutagenesis and 2 or 3 orders of magnitude lower than breeding. So, risk must be lower.

- *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 new foods should always "*warrant pre-market safety assessment and approval?"* A new plant species can be introduced into our food chain (Chia seeds? Are they safe? Kale – is this ok?), but evidence of INCREASED risk should be the only guide. New breeding techniques lessen the risk. So, why single this out?

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?*

Yes, new techniques are being developed every month. All are improvements on existing processes. E.g. there are new editing systems that are not "in vitro" manipulation of nucleic acid, and therefore outside the HSNO Act.

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

No. DNA methylation status is constantly changing during development in any organism, in plants in response to a stress such as drought. DNA methylation also changes after harvest and during food processing. It would be impossible to judge safety of something so fluid in its methylation status.

3.3 Questions

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

No, a risk-based approach is the only defendable system. Does the product have a measurable increase in risk? Is the product better? (for the consumer, for the grower).

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

There should be a product based process. Applying simple stage-gate system:

1. Can the genetic changes be achieved using conventional breeding technology, without a limit on time to achieve and select for those events.
    a. Yes, proceed to gate 2.
    b. No, regulated in the same way as "*new pieces of DNA*".
2. Is the derived food composition comparable with a standard compound/nutrition food database, in terms of off target effects on compound/nutrition composition.
    a. Yes, doesn't need regulation.
    b. No, assess under schedule 26 for compound/nutrition composition only.

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

The definition in the code for ***gene technology*** needs to be modernised to fit with NBT's.

e.g. **Gene technology** means the insertion of recombinant DNA into a genome, that alter the heritable genetic material of living cells or organisms. Recombinant needs to be defined as "in vitro manipulated DNA".

The definition of New DNA in appendix 1 is misleading if taken in isolation, "*new pieces of DNA*" should also be changed to "*new pieces of recombinant DNA*". Somatic hybridisation introduces new DNA (not recombinant) but has been an accepted non GMO technology for over 50 years.

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?*

Yes, there is potential conflict with the current HSNO act.

The FSANZ developed standards are for Australia and New Zealand. The Australian OGTR is reviewing the gene technology area but in NZ the HSNO act is not being reviewed. How will this be aligned?

FSANZ standards are about food safety –these new breeding technologies have the potential to IMPROVE food safety – eg. removal of allergens (non-allergic peanuts, glutan free wheat). Why should more regulations and approvals be applied to something that has less risk, and in some instances improved safety?