Realigning the focus

FSANZ should take the opportunity to realign regulation to actual risks, rather than further embed the focus around the development technique.

FSANZ's call for comments to changes to it's code with respect to new biotechnologies (NBT) focuses on technical details of the DNA changes produced by each approach.

I recommend that this attention be redirected to what identifies risk in the resulting plants; it is not with how the organisms are developed.

What risks align with

A core issue is that the risks, if any, of a new variety do not lie with the techniques used to produce the new variety, but with the traits the new variety has.

A simple test would to be ask if the risk to a consumer is unique to a particular development technique, or if that risk is common to several techniques.

If the risk is common to many development techniques, then those techniques do not define risk categories or serve as useful proxies for risk categories.

It is unsurprising that examining this shows that discriminating on development methods does not align with risk. As the NZ EPA noted,[1]

"Regulating traits is a good way to manage risk **as any risks an organism poses to health and the environment are directly and exclusively related to its traits and intended use** — a product with a specific trait will have the same environmental effects regardless of which technique was used to develop it.

(Emphasis added.)

The MfE go on to note that,[2]

> It should be noted that the presence or absence of foreign genetic material is not highly correlated with risk as there are harmful naturally occurring organisms and safe transgenic organisms.

> **However, regulating foreign genetic material is aligned with detectability, and surveys on public concerns.**

(Emphasis added.)

Detectability might seem useful, but is moot if what you are detecting does not align with risk.

More recently public concern has moved away from food safety.

Public concerns over GE are now not with food safety

Almost all public concerns now raised are now either environmental or commercial. *Neither are FSANZ's remit.*

FSANZ's code should be updated to reflect this shift in public concerns.

Environmental concerns are (for NZ) properly the remit of the EPA.

Commercial concerns lie outside of environmental and safety regulation, and should be (re)directed to political spheres.

Observers of the debate over GM/GE/GMOs widely note that concerns over food safety are rarely raised in recent times, this author included.[2]

> The most notable change since the labeling campaigns has been the way anti-biotech groups have more or less given up on the safety issue in mainstream venues. I really think those campaigns backfired insofar as they made journalists finally pay attention to the issue long enough to figure out that the safety issue was an empty vessel.

Similar observations can be found elsewhere.

While anecdotal, it's an important shift in public interest, one this author has observed too.

Some quantitative support comes from studies undertaken as part of a Masters thesis[3] that indicate that the large majority of the public now accept genetic engineering (GE),[4]

> From 2001 to 2014 there has been a big shift to acceptance of genetic modification, from 92% opposed to genetic engineering (GE) to 80% accepting it.

Remaining food-related concerns

The main (possibly only) *substantive* concern related to food safety that could arguably be related to GMOs and NBTs that the author can readily identify from *current* wide-ranging commentary online is the potential to introduce new allergens, or otherwise altering the allergen profile of the product.

However, this risk is not aligned with how the plant is developed. Older techniques also have the potential introduce allergens. Furthermore some efforts using NBTs are *removing* allergens. Examples include reduction of allergens in dairy milk or peanuts.

The latter examples might serve as an useful illustration of why focusing on specific DNA changes is unhelpful.

Some of these efforts might, potentially, introduce new DNA, even if only a few bases associated changes around the edges of recombination ‘joins’ or similar.

However in terms of traits, an undesired trait is being reduced or eliminated.

Focusing on DNA changes can potentially obstruct these products, despite that they *increase* food safety rather than pose new risks. The focus with DNA changes is at odds with the outcome.

Responses to questions

With the above discussion in mind, below are brief responses to each question in the FSANZ discussion document. The author would like to note that while framing discussions with questions may seem pragmatic, the effect can be to frame the topic in ways that are unhelpful. As a general response all of these questions are moot as per the above discussion; it is not the changes in DNA *per se* that matters, but what the traits the resulting product has. (Note this relates to what is sold to consumers, not the whole plant or animal.)

There may be some scope for regulation, but not on the basis of the particular technique used, or the presence of ‘new DNA’. It is worth noting that rare risks are typically identified after release. This is true of medical products or therapies, too; pre-release testing realistically can only cover and identify common issues - rare issues are identified from later feedback.

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?

Should there be any exceptions to this general principle?

On the basis of DNA changes, no. The relevant question over risk relates to the traits, not the development technique, nor to the presence of 'new pieces of DNA' in and of itself.

In the author's experience, concern over 'new DNA' in and of itself is related to cultural perceptions of risk rather than substantive 'real-world' concerns.

3.1.2

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?

On the basis of DNA changes, yes, but because the question is essentially moot. As per the discussion earlier in this submission; it is (the change in) *traits* that matters, not that some new DNA is present.

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?

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?

No, they are likely to have *lower* risk. However this point itself is moot as it is the traits of the final product that is relevant, not the particular mutagenesis technique used.

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

Yes, one example is modification of epigenetic status of genes (as the discussion document notes), another is RNA editing (potentially delivered as a spray, rather than having a modified plant).

The latter example is outside of the scope presented. The former has the same issues as raised earlier in this submission: it is the resulting traits that are relevant, not that epigenetic modification was applied. (One simple example might be that epigenetic modification might be used to 'shut down' genes producing allergens; in this case it would be a loss of an unwanted trait.)

Appendix material

The author (Dr Grant Jacobs) is by training a computational biologist (PhD Cambridge University, 1992), who also works as a science communicator. His focus is particularly on molecular biology and genetics. He has a detailed understanding of the molecular biology techniques used, and has followed 'the GMO story' in New Zealand for the past ten years. This work includes reading the government reports, the court transcripts, opinion pieces, and literature.

This report is necessarily very brief, owning belated awareness of the call for submissions, and the late hour it was prepared. The author would welcome the opportunity to present a more substantive submission given more notice.

References

1. Regulatory Impact Statement
Options for reviewing the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

Ministry for the Environment (MfE), New Zealand.

Paragraph 2, Section 3: 'Trait based'.

Source: http://www.mfe.govt.nz/sites/default/files/media/Hazards/ris-for-options-reviewing-hsno-regulations_0.pdf

2. ibid, see Footnote 8, page 21.

3. Could 2018 mark the end of the anti-GMO movement? Marc Brazeau, Genetic Literacy Project

Source: https://geneticliteracyproject.org/2018/02/05/2018-mark-end-anti-gmo-movement/

4. Masters Thesis, Katherine Hope, 2014, University of Otago.

Source: https://ourarchive.otago.ac.nz/handle/10523/4895

5. Genetic modification now accepted by most New Zealanders. Sciblogs.

Source: https://sciblogs.co.nz/code-for-life/2015/12/09/majority-of-new-zealanders-now-accept-genetic-modification/