Sustainability Council Submission on

Food Derived Using New Breeding Techniques

April 2018

1. Flawed analysis at the foundation of this proposal

FSANZ's proposal for far-reaching changes to the regulation of foods produced using gene technology is based upon a narrow and flawed interpretation of key terms in the Code: namely, that to qualify as "a food produced using gene technology", DNA must be introduced or changed.

A first instance of this interpretation, which is then repeated throughout the document, is: "The definitions refer to gene technology techniques that result in *inserting new pieces of DNA into a genome*." (Consultation document, page 4. Emphasis added)

In effect, FSANZ is shrinking the scope of the Code on the fly as its interpretation narrows the scope of the Code without an adequate justification for doing so. The definitions of gene technology and food produced using gene technology are broad:

> **food produced using gene technology** means a food which has been derived or developed from an organism which has been modified by gene technology.
>
> > Note This definition does not include food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or other organism is itself a product of gene technology.
>
> **gene technology** means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms. (Standard 1.5.2)

Further definitions in the Code - concerning GM foods – also underscore that the introduction of DNA or changes to DNA is not the sole qualifying feature of a GM food or foods produced using gene technology. Novel proteins – whether introduced or modified in vivo – are also relevant.

The term on which FSANZ's proposal rests - "recombinant DNA techniques" - is not defined in the Code. Noting that "[t]here is no single definition for recombinant DNA techniques", FSANZ selects a 'general meaning' (the recombining or joining of DNA from two or more sources and inserting it into an organism). (Consultation doc, footnote 8)

It is wholly surprising that, in the absence of a definition of a key term in the code, FSANZ did not at least look to the international authority that a state food safety agency would be expected to consult: the Codex Alimentarius.

The term "recombinant DNA" is a key term in the three guidance documents on the safety of GM foods that Codex has developed, specifically:

- *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003)
- *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-Organisms* (CAC/GL 46-2003)
- *Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Animals* (CAC/GL 68-2008)

In those three guidance documents, "recombinant-DNA" plants, animals and microorganisms are organisms:

> "in which the genetic material has been changed *through in vitro nucleic acid techniques, <u>including</u> recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles"* (emphasis added)

Codex is therefore clear: 'recombinant DNA' is a term which:

- Is not restricted to the use of DNA; and
- Covers a wide range of approaches, *including* but not limited to rDNA and direct injection of nucleic acid into cells or organelles

For FSANZ to take a different interpretation to the international norm, it would need to offer good reason. Yet the consultation document offers none.

In light of this, it is difficult to avoid the conclusion that FSANZ's narrow interpretation is driven by its predisposition to a particular outcome: a path to deregulation of new genetic engineering techniques.

Whatever the explanation, the proposal lacks a credible basis as the underlying analysis is flawed. The proposal is a house of cards.

Box 1

Codex Alimentarius: Definition of Recombinant DNA

Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)

SECTION 2 – DEFINITIONS

Recombinant-DNA plant means a plant in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles

Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-Organisms (CAC/GL 46-2003)

SECTION 2 – DEFINITIONS

Recombinant-DNA micro-organism means bacteria, yeasts or filamentous fungi in which the genetic material has been changed through in vitro nucleic acid

techniques including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Animals (CAC/GL 68-2008)

SECTION 2 – DEFINITIONS

Recombinant-DNA animal means an animal in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

2. Proposal Jettisons a Key Principle of Food Safety

The proposal upends a principle underpinning the Food Code: history of safe use.

This principle, as the consultation document states, determines which technologies require pre-market safety assessment. It is the reason that foods produced using conventional breeding do not require such examination, while foods produced using gene technology do:

> "Foods derived using conventional breeding, referred to as 'conventional foods', are generally considered to have a long history of safe use and are not typically subject to pre-market safety assessment before entering the food supply." (Consultation doc, p. 5)

In the case of new genetic engineering techniques – for which FSANZ is proposing to waive pre-market regulatory risk-assessment - there is no history of safe use of the gene editing techniques to produce foods: in fact, **there is no history at all, safe or otherwise.**

It is alarming that a regulator charged with ensuring the safety of foods that millions of people eat on a daily basis is standing on the threshold of a new technology era and proposing to waive independent risk assessment for technologies for which there is no track record when like products are subject to its scrutiny.

One would expect a responsible food safety regulator to require risk assessment for new era genetic engineering techniques, at least until an independent knowledge-base has been developed that would allow for subsequent review of regulatory settings, based on assessment of actual foods.

3. The Food Safety Case for Risk Assessment

A key question is whether there is a food safety case for continuing to regulate foods produced using new genetic engineering technologies.

The consultation paper itself provides no substantive analysis to support the 'safe by design' claim or the case for deregulation, yet asks submitters to provide such detail.

Comprehensive reviews by authorities such as the Austrian Environment Agency and the Austrian Ministry for Public Health consider whether pre-market risk assessment is necessary for products of new genetic engineering techniques.[1]

Their conclusion is that broadly, **new techniques warrant the same regulatory risk assessment as GMOs under current law.**

They also specify that **case-by-case assessment** is required due to the diversity of "approach, methodology and unique characteristics" across the different techniques. (See Box 2 for further conclusions from the reviews)[2]

Box 2

Key conclusions of Austrian agency reviews

Insufficient biosafety data on new GM techniques

- "uncertainties associated with potential risk issues are far from being resolved […] due to the quite limited availability of relevant scientific data" (AEA 2014: 73)
- "For the majority of the new techniques, no concrete data is available on the biosafety of the new phenotypes." (Vogel 2012: 88)
- "insufficient knowledge is available as regards their potential for adverse effects." (AEA 2014: 76)

New GMOs require same risk assessment as GM 1.0

- The necessary response to "the current situation of insufficient knowledge" is to "apply[] requirements to identify and assess such uncertainties similar as for GM plants" (AGES 2012: 6)
- "biosafety considerations conducted for NPBT [New Plant Breeding Techniques] crops have indicated that the general approach developed for the risk assessment of GM crops in principle would also be appropriate to address the currently identified risk issues for NPBT-crops.' (AEA 2014: 76)
- "the basic principles implemented in relevant biosafety regulation frameworks – European legislation, Cartagena Protocol, Canadian 'Plants with Novel Traits' regulation – are considered to be appropriate for NPBT-crops" (AEA 2014: 76)
- "for all new plant breeding techniques core elements of the current risk assessment requirements for GM plants are mandatory". (AGES 2013: 5)

[1] Austrian Agency for Health and Food Safety (AGES). 2012. *Cisgenesis. A report on the practical consequences of the application of novel techniques in plant breeding.* Report for the Austrian Federal Ministry of Health. Austrian Agency for Health and Food Safety (AGES). 2013. *New plant breeding techniques. RNA-dependent methylation, Reverse breeding, Grafting.* Report for the Austrian Federal Ministry of Health. Eckerstorfer M, Miklau M and H Gaugitsch. 2014. *New Plant Breeding Techniques and Risks Associated with their Application.* Report by the Austrian Environment Agency (AEA) for the Swiss Federal Ethics Committee on Non-Human Biotechnology.

[2] AEA (2014), p. 75

Unintended effects

- "Scientific publications indicate that neither the efficiency nor the specificity of the technologies aiming at targeted alterations of plant genomes can be controlled sufficiently. Unintended effects cannot be excluded." (AGES 2012: 135)
- "Indirect and delayed effects may also result from unintended effects of modifications by NPBTs or result from stability issues of the modifications and traits in NPBT crops" (AEA 2014: 74)
- "the molecular characterization has to be as substantial as for transgenic plants" (AGES 2012: 135)

We note that FSANZ's presumptions about the scope and nature of risk from genetic engineering techniques also draw from its narrow interpretation of the regulatory definition of a food produced using gene technology.

The implication from the consultation document is that food safety risk only arises with changes to the DNA or from the introduction of DNA.

Simply put, there is no scientific basis to the claim that changes effected by RNA, for example, are always or even routinely benign. On the contrary, there is a wealth of literature, of which FSANZ will be aware, of potentially harmful effects from modifications to RNA and proteins.

4. Fundamental Change of Assessment Approach

Also within the proposal is a move to fundamentally change the approach to regulating GM foods. It would involve a shift from assessing the process by which a food came into creation, to one that regulates based on the resulting product. The first is open-ended as to the nature and scope of risks that can be present in the process of modifying a genome, and so allows for changes currently unrecognised. The latter instead relies on an ability to assess and compare final products, and a procedure of deeming equivalence.

Irrespective of what might be regarded as the best approach in technical terms for securing food safety, an astounding feature of the proposed move from process-based to product-based regulation is that it represents a departure from the international norm (as defined by Codex) and the practice of the great majority of food safety regulators, without serious analysis being offered.

Such analysis is needed not just to underpin food safety, but also to examine the wider impacts of such a change. A key sector affected is food exporters. Under the proposal, they would need to take responsibility for excluding food ingredients that can be sold locally as non-GMO but which may well trigger GMO contamination alerts in destination markets where they are classed as GM.

The problem is not just one of avoiding deliberate use of an ingredient that is potentially classed as a GMO in an export jurisdiction. As even trace levels of contamination have been enough to trigger product rejection of entire shipments, food exporters are forced to scrutinise their supply chains for risk of trace levels entering their production through a myriad of pathways – from farm machinery owned by external contractors, to segregation standards in transport and storage facilities, etc.

This is a very significant consequence for Australian and New Zealand food exporters - a serious negative impact that has not been examined or accounted for.

5. Detection

The notion that the products of certain new GM techniques cannot be reliably detected is simply false. There is no technical barrier to developing reliable detection tests.

A clear demonstration of this ability arose with the first food produced using a new technique. There the developer submitted a test that uniquely detects and identifies the product (a herbicide resistant 'ODM' canola) to the Canadian food safety regulator.[3]

The idea that the products of certain new genetic engineering techniques cannot be readily identified has been the basis for claims that regulation of them and would be an empty gesture that would undermine confidence in the law. Yet the above example shows that governments have the ability to ensure there is no credibility gap: regulators just have to require that the developer furnish it with a detection test – as the EU also requires.

The above also helps extinguish the argument that it will be too costly for government to develop and apply such tests – as patent holders will need to meet development costs. Note that their needs for IP protection will also be driving such development in any case.

With respect to the cost of applying the tests, those costs seem set to occur regardless of FSANZ's proposed change, so long as other significant jurisdictions continue to take a process-based approach to regulation and so generally regard the new techniques as producing GMOs. For retail gatekeepers will then track at least that regulatory standard (which often flows into a labelling standard) and will insist on disclosure of how a product was made (what techniques was used) and that will effectively track any products incorporating the new GM techniques.

6. Public Costs and Private Benefits

New Zealanders remain by and large concerned about GM in foods and want GM foods to be tested and labelled to ensure choice (a consistent message from polling and social science research over two decades.)

[3] http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd-2013-100/eng/1427383332253/1427383674669

Loss of confidence in the food safety regime is a further potential, negative outcome if FSANZ does not ensure the safety (by way of pre-market assessment) and transparency over the use of emerging genetic engineering technologies in food. Trust in the system is vital, not just for FSANZ's credibility but for food producers and food companies. That trust, once lost, can be difficult to rebuild.

FSANZ's proposal shifts risk from GMO developers to food producers and the public, with no net public benefit.

Premature deregulation of food safety and labelling requirements imposes costs on Australian and New Zealand food producers who must deal with the risks of product rejection due to even trace contamination of conventional foods by imported ingredients.

It also imposes risks on the public through the abandonment of food safety assessment procedures that are the international standard, and without an adequate basis for this.

To the extent there any public benefits, they seem unlikely to be qualitative gains in the food supplied that could not be delivered by means conforming to current food safety standards. So the question immediately arises: why would such a tradeoff be entered into by a regulator if this were the case? If the claim is instead that consumers will benefit from access to cheaper food, where is the evidence to date that IP holders have been willing to freely deliver to consumers, economic rents secured by patents over GM food ingredients that they can otherwise continue to hold, and what is the evidence in support of a change in future?

Overall, there is no coherent rationale for the proposal beyond offering a regulatory discount to developers, while the costs are externalised (transparency, safety and supply chain responsibilities) to food producers and the public. We believe the new breeding techniques should continue to be covered under the regulations.

Sustainability Council of New Zealand
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