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Submission: Proposal P1055 Definitions of Gene Technology

I appreciate the opportunity to participate in the consultation of Food Standards Australia New Zealand regarding the definitions for gene technology and new breeding techniques.

My concerns centre on:

- Recognition of double stranded RNA as gene technology
- Regulation proportional to risk
- Labelling
- Public confidence
- The need for food standards to take account of the broader context of food security

1. Recognition of double stranded RNA as gene technology

I support the proposal to "revise and expand the process-based definition for 'gene technology'[1] to capture all methods for genetic modification other than conventional breeding" (FSANZ Proposal 2021:9).

According to the submission from the Centre for Integrated Research in Biosafety (University of Canterbury), the use of double stranded RNA (dsRNA) is currently defined in Australia as 'not gene technology'. It seems logical that this proposal, if adopted, would capture the use of double-stranded RNA (dsRNA) as a gene technology in both countries.

Heinemann (2019) demonstrates that post-harvest treatment using the technology of *exo-ds*RNA can, through a number of mechanisms, result in *exo-ds*RNA mixing with the genetic material in the nucleus of organisms to which it has been applied (or even outside the nucleus). As such, dsRNA can act as a modifier of genes or other genetic material with the potential to create heritable changes.

Exo-dsRNA can create unintended consequences. While exo-dsRNA is used to run interference via RNAi to silence genes, it can have the opposite effect of increasing the expression of genes (Carthew and Sontheimer 2009 and Kim et al. 2009 cited by Heinemann 2019:2). Because much remains to be known about the biochemistry of dsRNA technology (as well as its environmental fate), caution should be exercised against unintended consequences. It has already been demonstrated that "the biochemistry of dsRNA-mediated gene regulation is different between plants, animals, and fungi" (Ghildiyal and Zamore, 2009 cited by Heinemann 2019:1).

Heinemann (2019) also points out that contamination may occur in the processes of conversion or isolation of dsRNA for use as exo-dsRNA. Upon entry to cells, such contaminants can result in the production of proteins that could be a source of allergens or toxins.

2. Regulation should be proportional to the risk.

The Proposal's focus on "similarity" between new breeding techniques (NBT) and conventional foods (e.g., pp. 10, 12, 13, 15, 20, 26) as a determinant of its safety lacks specification in regulating risk. "Similarity" can vary within a wide range; it does not tell us in what way similar; or whether we should

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[1] Proposal P1055 states that "gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms" (FSANZ 2021:9).

be concerned about the ways in which these products are not similar. Perhaps more importantly, it focuses on the product rather than the processes that are proliferating within our food system that could undermine its overall safety.

Heinemann et al. (2021) argue that decreasing cost and increasing accessibility of NBTs increase the chance that something can go wrong. Regulation should be proportional to that risk. The authors present a framework that regulates the technologies depending on their scale of use and level of risk and is based on critical control points. I agree with Heinemann et al. (2021) that safety will be largely affected by the scale of human intervention. I agree that consideration should be given to the regulatory framework proposed by the authors.

3. Labelling

I support the labelling of all food produced using gene technology. The Proposal states that while "labelling is based on the presence of novel DNA or novel protein in the final food, or an altered characteristic in the food. A number of exemptions to labelling may apply (e.g., the exemption for highly refined foods or ingredients)" (FSANZ 2021:9). The first category of refined ingredients (section 4.1.2) includes gelatine products. It would be dangerous to exempt gelatine from labelling. There are an increasing number of people (myself included) who, as part of acquiring the mammalian tick allergy, have a severe allergic response to gelatine, including anaphylaxis (van Nunen 2015). Gelatine products should not be acceptable in foods that are not exclusively or predominately and obviously mammalian. The inclusion of gelatine in food products should always be clearly apparent in labelling.

4. Public confidence

Although the general regulatory approach to GM food is not being reviewed as part of Proposal P1055, current regulation of GM cropping suffers serious shortcomings. These shortcomings undermine public confidence in the food standards process. A joint statement developed and signed by over 300 independent researchers calls for more rigorous assessment of GM technology and more responsive regulation with respect to transparency, safety, and labelling of GM crops (Hilbeck et al. 2015; Séralini 2020).

The evaluation of GM crops with respect to food and feed safety relies on the data provided by companies owning the genetic materials, making independent verification difficult (McIntyre et al. 2009:200; Antoniou 2013).

Still, numerous feeding trials on multiple animal species (rats, mice, rabbits, cows, chicken, fish, goats, sheep, pigs) exhibit problems with kidney and liver functions primarily, but also differences in other body organs (pancreas, adrenals, testis, uterus and pituitary); alterations to blood chemistry; slower growth rates; higher triglycerides in blood; and disturbances to the immune system (Antoniou 2013:62-65; Séralini 2014).[2] While industry and regulators have acknowledged "statistically significant differences in the function of multiple organ systems between the GM and equivalent non-GM control feeding groups" regulators have dismissed these as 'biologically insignificant' (Antoniou 2013:64). Industry studies are only short-term feeding trials (90 days). There is a need for independent long-term studies (Antoniou 2013; Séralini et al. 2014).

[2] Antoniou (2013:62,66) reports that the risks to health could be caused by *Bt* toxin; by higher exposure to herbicides through herbicide-resistant GM crops; and/or by altered plant biochemistry resulting from the mutagenic effect of the GM transformation process. Many studies have clearly demonstrated the impact on food crop composition from the mutagenic effect of GM transformations including disturbance in amino acid profiles and a newly expressed protein: zein, a well-known allergenic protein (Antoniou 2013).

5. Food Security

Finally, consideration should be given to whether GM crops have provided the advantages that have been claimed.

- GM crops have underperformed significantly with respect to yields.[3]

- GM crops have been promoted as reducing pesticide (e.g., herbicides, insecticides and fungicides). Yet weed resistance to herbicides is most closely associated with herbicide tolerant GM crops (Heap and Duke 2018).[4] In response, farmers have increased herbicide application rates, increased the number of applications,[5] and have added additional herbicides (Benbrook 2012:4). Increasing herbicides and a return to tillage jeopardises the original cost and environmental benefits provided by herbicide resistant crops (NRC 2010).

- The engineering of crops to manufacture *Bacillus thuringiensis* (*B*t) within their cells provided a short-term reduction in insecticide use. However, the technology's effectiveness has proven unsustainable. There have been three negative developments in response to *B*t GM crops:

  i) resistance and resurgence of target pests has led to on-going increases in the number of toxins embedded in the crops (Benbrook 2012 and Benbrook 2021);[6]

  ii) the rise of secondary pests[7] has resulted in the use of insecticides being substantially increased (Zeilinger et al. 2016). Secondary pests are insects that are not susceptible

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[3] After 30 years of R&D and nearly 20 years of commercialisation (Quist et al. 2013) yields of some GM crops can be highly variable, with a 10-33% gain in some places and yield decline in others (IAASTD 2009:8). In the case of GM corn, researchers in the US credit the bulk of yield gain (1996-2008) to the intrinsic yield advantage of the conventionally breed variety that the gene is inserted into and to crop management. Across all acres of corn during this period, GM technology represented 3-4% of the 28% aggregate productivity increase. In another study, yields (1961-2010) in North America were compared with those of six Western European countries with similar access to genetics (other than GM), technology, latitude and growing season. Prior to the adoption of GM technology, maize yields in the US were greater than those of the W. European countries. In the second half of this period (1986 – 2010) as 88% of maize crops in the US were converted to GM varieties, the yields in W. Europe (without GM) grew at a comparable and even slightly higher than those in the US. More striking was the advantage in 'yield-gap' (the difference between potential yield and actual yield) in W. Europe's rapeseed (canola) crops over those in Canada since the period when Canada moved to GM and Europe did not (Heinemann et al. 2014:75-77).

[4] The highest number of resistant weeds are in the USA, the second highest number are in Australia, with resistance expected to increase in terms of both the number of species and crop areas infested (Heap and Duke 2018:1047-1048).

[5] This has dramatic implications for air and water safety: "Two-thirds to 100% of air and rainfall samples tested in Mississippi and Iowa in 2007-2008 contained glyphosate" (Chang et al. 2011 cited by Benbrook 2012:5).

[6] In the US the average *B*t corn variety expresses at least 3 *B*t toxins and SmartStax GM corn expresses six different toxins - totalling more than a kilogram of toxins per 0.4 ha at contemporary corn seeding rates (Benbrook 2021).

[7] Research indicates three drivers of secondary pest outbreaks are: a reduction in use of broad-spectrum insecticides due to adoption of *Bt* crops; a reduction in the populations of natural enemies (directly through ingestion of *Bt* toxin or indirectly through consumption of pests feeding on *Bt* crops); and by secondary pests filling the newly available ecological niche once the primary pest is controlled by the *Bt* crop, as has occurred in the US, Canada, Spain and Argentina (Catarino et al. 2015).

to the *Bt* toxin and, importantly, were not originally considered a serious threat to crops. Secondary pests are now the main concern of farmers (Catarino et al. 2015; Wang et al. 2008);[8] and

iii) <u>increasing concern about the effect of the *B*t toxin on natural enemies and accumulation through the food chain</u> (Catarino et al. 2015:603). *Bt* used in GM crops is significantly different from *Bt* spray used by organic and conventional farmers (Antoniou 2012; Benbrook 2012). The differences of *B*t in GM crops is its much higher concentration, permanent presence, systemic delivery (Benbrook 2012:7; Stotzky 2004) and its lack of selectivity with respect to which insects are susceptible (Antoniou 2012).[9]

While these issues may be outside the terms of reference for determination by FSANZ, they are fundamental to weighing the risks against what was meant to be advantages of this technology. As a consumer, I want to make food choices that reflect both the safety of food production and consumption now and to know that food standards is a forward looking process, protecting the biodiversity on which future food security is dependent.

Therefore, I support:

- The proposal to "revise and expand the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding".
- Increased specificity in assessment of regulating NBTs and consideration of a framework that regulates the technologies depending on their scale of use
- The labelling of all food produced using gene technology.
- The need to secure public confidence through improved regulation of GM technology with respect to understanding, transparency and safety.
- The Proposal's recognition that a broader policy discussion is required before changes to the overall approach to GM food could be considered; and I support the initiation of such discussion, focusing on social accountability and how to control the technology's potential to cause harm (University of Canterbury submission to FSANZ 2021).

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8 Seven years after *Bt* cotton was commercialised in China, a study in 5 provinces showed the income of *Bt* cotton growers was 8% less than that of conventional cotton growers due to the higher cost of *Bt* seeds and the increased number of pesticide sprays used by *Bt* cotton growers against secondary pests, from 7 sprays/season in 1999 to 18 sprays/season in 2004 (Wang et al. 2008:117). Catarino et al. (2015:604) argue that after 10 years, all advantage of *Bt* cotton had disappeared; and, along with Benbrook (2012) demonstrate the need, when summing up total insecticide use, to include the *Bt* toxin embedded within the GM crops.

9 The same concern applies to the increased use of herbicides. A laboratory study showed uptake of the herbicides glyphosate and 2,4-D by earthworms, indicating the potential for bioaccumulation through earthworm consumption by other organisms (Lazurick et al. 2017), such as birds, frogs, turtles, snakes and other small-medium animals. Other laboratory and field studies show the effect of glyphosate (applied at nominal concentrations recommended for soya crops) on reducing earthworm reproduction and juvenile survival, and earthworm avoidance of soils treated with glyphosate (Casabe et al. 2007).

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