Petitions Committee
New Zealand Parliament
Parliament Buildings
Wellington

3 February 2021

Tēnā koe Petitions Committee,

Thank you for the opportunity to make a more in depth submission to the Gene Editing Petition. I am writing this petition on behalf of GE Free New Zealand in Food and Environment.

We have been involved with making submissions to the Food Standards Australia New Zealand since 2004. I am aware, through my position as President of GE Free NZ in Food and Environment, that our members and many New Zealand consumers are concerned about the review of the FSANZ Act and its other bodies (FRS, Food Code) that there is a move to exempt certain food created with new breeding techniques (NBT), namely gene edited foods. In this submission we will use the term genetically engineered (GE) to cover both genetically modified (GM) and gene edited (GE) food.

Waikato University Professor Kathlene and colleagues (2020) published a survey on gene editing and genetic modification in Aotearoa/ New Zealand[i]. The survey reported that a significant majority Maori and Pakeha respondents were strongly opposed to the environmental release of all genetically engineered organisms. The survey respondents also wanted to engage in constructive discussion on how to implement a robust regulatory framework that addresses gene editing. This includes engagement in the regulatory framework around all GE food entering the food chain.

Food Standards Australia New Zealand (FSANZ) legal requirements as stated in their mission statement are:

- To protect, in collaboration with others, the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply.

<u>FSANZ Values are:</u>

- To be impartial, open and accountable;
- To use the best available sciences and evidence to guide decision-making;
- To seek, respect and be responsive to the issues raised by others;

<u>FSANZ Responsibilities are</u>

- Provide information to consumers to enable better consumer choice
- Undertake dietary exposure modeling and scientific risk assessments
- Provide risk assessment advice on imported food

This would then provide, as stated in the Objectives

a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;

c) the provision of adequate information relating to food to enable consumers to make informed choices;
d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection. (FSANZ act 1991, 18)

We would like to bring up our concerns over the carrying out of these objectives in relation to genetically modified food (GM) and food created from new breeding techniques, namely gene edited (GE) foods.

1. The reason to regulate and label all GE and gene edited food

FSANZ approval of food developed using biotechnology has been harmonized with Canada. The FSANZ harmonization with Health Canada indicates that labelling of GE food could become voluntary and certain foods developed using gene-editing techniques may be considered "not novel" and consequently no pre-market assessment through the FSANZ regulator is required[ii].

There are many studies on the gene editing of organisms[iii] that are warning of mutations, off target effects and unintended properties like the formation of new proteins. Tang et al (2018) in their research analysis of 34 CRISPR/Cas9 gene edited plants showed that the tissue culture process caused:

> "Approximately *102 to 148 single nucleotide variations (SNVs) and approximately 32 to 83 insertions/deletions (indels) per plant.*" (Tang et al, 2018) [iv].

Kosicki et al also found in their studies on mice that the repair of double stranded DNA splices from CRISPR/Cas9 caused deletions and complex rearrangements. They revealed that:

> *"DNA breaks introduced by single-guide RNA/Cas9 frequently resolved into deletions extending over many kilobases. Furthermore, lesions distal to the cut site and cross-over events were identified. The observed genomic damage in mitotically active cells caused by CRISPR/Cas9 editing may have pathogenic consequences."* (Kosicki, M, 2018)[v]

Gene editing is only 9 years old. There have been no plants or animals tested for the risk these mutations and off target effects pose. Allergic individuals face too great a risk when eating a meal stacked with multiple GE ingredients, which are sprayed with numerous pesticides.

All food sourced and produced from gene edited and transgenic food needs to be properly regulated and labelled to meet the FSANZ Act objectives.

2. The reason to require 90 day feeding trials on GE food;

A major gap in FSANZ assessments is the absence of any studies to show whether GE food is safe to eat. This is because FSANZ does not require any short or long term oral ingestion or skin prick studies on humans or animals for any GE food. There have been 90 GE food applications and there is a total absence of any *in vivo* human studies on the whole food. So, when a GE product enters the food chain, consumers are the guinea pigs. The applicants do

in some applications produce short-term animal studies on the GE food for FSANZ regulators. There is absence of consumer safety information in all GE food decisions that enter the food chain. These do not meet the risk criteria for human safety as set out in the FSANZ Science Strategy 2019-2023[vi]. This science strategy sets out the guidelines for developing biotechnology food standards. It states that the best available independent and scientifically credible evidence informs FSANZ. However, total absence of GE food studies and an assessment practice of refuting submitters' evidence further breaches their responsibilities under the Act.

How can a GE food be deemed safe for the whole population, when it is not required to undergo oral ingestion or allergy testing on the human population? In 2013 the EU introduced mandatory 90-day trial on rodents using whole food or feed called the Implementing Regulation 503/2013.[vii] As a result, the evaluation of 90-day feeding studies is now a standard part of the safety assessment of GM plants.

Testing for allergy reactions in humans was shown to be important due to unforeseen allergenic reactions. Nordlee et al (1996) conducted allergen studies on the transgenic insertion of a brazil nut gene into a soybean. The 9 subjects were allergic to brazil nuts were not allergic to soybean, however when given a skin prick test they showed strong allergy to the transgenic soybean engineered with the 2S albumin brazil nut gene. Skin prick was used, as it is too dangerous to feed these allergic subjects due to their anaphylactic reaction to the brazil nut. Nordlee did acknowledge that animal research did find that the brazil nut was not a major allergen. They went on to conclude:

> *"However, the ability of a protein to induce an IgG1 response in animals is not always a good indicator of the ability of that protein to induce an IgE response in humans...Our study shows that an allergen from a food known to be allergenic can be transferred into another food by genetic engineering."* (Nordlee (1996))[viii]

Prescott et al (2005) study showed that the alpha amylase gene from the common bean engineered into the pea caused allergies in the animals studied (mice).[ix]

Collins et al (2006) found that starch absorption was altered in pigs fed the transgenic peas.[x]

Carman *et al* (2013) ran a 5-month study on pigs fed GE soybean and mixture of double and triple stacked GE corn. The control feed was non-GE but contained a median of 0.4% GE corn and the non-GE soy contained a median of 1.6% GE soy, as this is the contamination level in the US.

> *"GM-fed pigs had uteri that were 25% heavier than non-GM fed pigs (p=0.025). GM-fed pigs had a higher rate of severe stomach inflammation with a rate of 32% of GM-fed pigs compared to 12% of non-GM-fed pigs (p=0.004). The severe stomach inflammation was worse in GM-fed males compared to non-GM fed males by a factor of 4.0 (p=0.041), and GM-fed females compared to non-GM fed females by a factor of 2.2 (p=0.034)." (Carman J, 2013)*[xi]

Zdziarski et al (2018)[xii] studies the stomachs of rats fed triple stacked GE corn (insect resistance Cry1Ab, Cry3Bb1 genes and herbicide tolerance EPSPS gene) They concluded that individually the adverse changes might not have clinical significance but collectively they might, so they pooled the findings of all the gastric mucosa findings and they concluded that

there were statistically significant adverse changes to the digestive system than control animals.

Professor Seralini and colleagues conducted a long-term life study on rats fed GE corn (NK603) tolerant to Roundup. This study found significant levels of kidney disease and liver congestion and necrosis in the GE fed rats. They also reported that:

> *"Males presented up to four times more large palpable tumors starting 600 days earlier than in the control group, in which only one tumor was noted." (Seralini et al, 2014)* [xiii]

There are more studies on the adverse effects on animal health, but only two on humans. Netherwood *et al* (2004) showed that transgenic soymeal genes survived gastric digestion[xiv]. It is concerning that FSANZ has not critiqued these peer reviewed published studies, but has specifically criticized and dismissed them.[xv] They have instead accepted the applicants' unpublished data, with no supporting studies on the human health effects of GE foods.

As there is no requirement in the FSANZ Act to have long-term oral studies on the whole GE food, neither FSANZ nor the Ministers can fulfill their responsibilities to the public. There is no scientific proof of the safety of these foods nor information for susceptible consumers like children, elderly and those who have chronic health problems. As these are not required, there is the possibility of unknown allergenic health effects and chronic risks from these foods.

Because there is no labelling to trace GE food or diagnostic tests for health professionals, it is impossible to evaluate if the GE foods are causing or aggravating existing illness. We know that common foods that are eaten regularly, like milk, wheat, peanuts, strawberries can cause severe digestive complications, even anaphylactic shock leading to death. Mandatory labelling is therefore required even if the food does not contain the allergen, but is produced in a factory that manufactures the allergenic food. Yet there is no post monitoring or requirement to label foods produced with GE. This is concerning as now there are a variety of products containing multiple GE ingredients including oils. It is even more concerning if harmonisation with Canada results in exempting gene-edited food from regulation and labelling.

3. The reason to require full assessment of pesticide residues in GE food

GE food is commonly developed to either tolerate pesticides or express insecticides.

In December 2020, the Ministerial forum approved a corn that had no nutritional benefit, it contained foreign protein genes that made it tolerant to 12 different herbicides and produced three different insecticidal CRY genes (A1192). The corn expressed an RNAi gene that when sprayed with glyphosate killed the anthers (male reproductive parts). The pesticides and novel assortment of new genetically engineered proteins were not collectively evaluated for any synergistic effects. Each transgenic protein trait was not tested from the whole corn but from the original bacteria. There were significant differences in the nutritional profile of valuable minerals and vitamins and also a rise in toxic anti-nutrients. The final approval decision read:

> *"The safety assessment of MON87429 is in Supporting Document 1 (SD1). No potential public health and safety concerns have been identified. Based on the data*

provided and other information, food derived from MON87429 is considered to be as safe for human consumption as food derived from conventional (non-GM) corn cultivars."[xvi]

4. Reasons to ensure the public can challenge GE decisions

This is a repeated statement in all FSANZ approval decision reports, and is supported by the Ministerial Forum who signs off the GE food approvals. Yet it is a dishonest and misleading statement, as there is no data on health or safety provided on the whole food, of course there would be no health and safety concerns identified. The absence of vital safety information is continually overlooked and the FSANZ Act does not allow for public submitters to ask for a review any approval decision. The application can only be reviewed if the FSANZ Authority rejects or abandons an applicant's proposal. (FSANZ Act: 143)

5. Reason for the Minister to consult with stakeholders before GE decision approvals

The FSANZ assessors and the Ministers Forum did not even question the absence of any oral risk studies on the whole food. We as consumers are unable to have a choice as to whether we want to buy this as the product is not labelled or the way the corn is processed is exempt from labelling. What is worse is the corn is not segregated so the product we buy may have a mixture of many GE corn varieties. We ask that the Ministers consult with the interested parties so they are made aware of any public submitters concerns before signing the GE food into the food chain.

We believe that the Minister for Food Safety has the ability to address all these points in the FSANZ review. We ask that the Minister advocate to –

1. regulate and label all GE food;
2. require 90 day feeding trials on GE food;
3. require full assessment of pesticide residues in GE food
4. ensure the public can challenge GE decisions;
5. consult with stakeholders before ministerial forum approvals of GM decisions

We would be happy to engage with you and talk to this submission.
Nga Mihi,
Claire Bleakley
On behalf of GE Free NZ in Food and Environment
027 348 6731

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[xvi] FSANZ Application A1192 https://www.foodstandards.gov.au/code/applications/Documents/A1192%20SD1%20at%20approval.pdf?csf=1&e=sNCryB