



GE Free New Zealand

In Food And Environment Inc.

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Re Food derived using new breeding /genetic engineering techniques - review

Dear FSANZ,

GE Free submits that Food derived from NBTs must be captured for pre-market approval under Standard 1.5.2. The definitions for 'food produced using gene technology' and 'gene technology' in Standard 1.1.2—2 must not be changed and all foods that are created through new breeding techniques must be included in the definition of "food produced using gene technology" and made subject to pre-market approval.

It is in the public interest that the new breeding techniques are acknowledged as genetically modified organisms (GMOs) and subjected to scientifically validated pre-market assessments.

As outlined in the FSANZ Code all the techniques discussed in the three outcomes are *in-vitro* techniques that alter the genome through some form of molecular genetic engineering.

As FSANZ states the key definitions in the Code are:

food produced using gene technology means a food which has been derived or developed from an organism which has been modified by gene technology.

Gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

All the techniques outlined in the three consultation questions, meet the legislative and notably the community definition of genetically modified foods.

- Outcome one: Genome contains new DNA
- Outcome two: Genome unchanged by gene technology
- Outcome three: Genome changed (genome editing)

Each option has had its genetic material altered by transgenesis, cisgenesis, intragenesis or gene editing techniques. The wording in the code regarding food produced using gene technology must not be altered to dilute or avoid regulation of the three genetic techniques in question. The European Network of Scientists for Social and Environmental Responsibility "Products of new genetic modification techniques should be strictly

regulated as GMOs”¹ report outlines and critiques in detail the reasons that these new breeding techniques need to be regulated.

In New Zealand it is accepted that *in-vitro* genome manipulations that were introduced after 1996 should be considered genetic modification techniques. (HSNO Act)

Foods created from gene technology do not have a history of being safe to eat, so should be regulated and assessed as GMOs by FSANZ.

To protect the integrity of the food system, FSANZ must be able to require comprehensive 'omics' analysis to gauge unexpected outcomes from the modifications.

All food using these techniques must undergo pre-market assessment and notified under the FSANZ Act ***Subdivision F—Modification of general procedure for developing new food regulatory measures and major variations sec 42 - 45.***

There are unknown and unintended consequences that arise when laboratory *in vitro* manipulation of animal and plant genomes are carried out.

The GM Animals report² (New Zealand) covered 15 years of GM animal experiments. These experiments used transgenesis, cisgenics, RNAi and gene editing techniques. The final milk product has not been safe for use and has been very cruel to animals, as evidenced by the gross abnormalities and deaths throughout the experiment.

The introgression, which created herbicide tolerant (HT) swedes, tolerant to chlorsulfuron, was the likely cause of the death of hundreds of dairy cows. The deaths were linked to unexpectedly high levels of glucosinolates produced by the crop³. Some glucosinolates, mainly goitrogens, can be toxic at high levels.

These toxic swedes had not been assessed or regulated, due to a loophole in regulating the techniques used. The cows deaths demonstrate the risks involved in novel crops being released commercially. It is an example of unexpected outcomes in vegetables that were considered similar to their conventional counterparts. If they had been sold as human food, there is a strong possibility that the toxic compounds could have caused illnesses and possibly deaths.

The importance of oversight that is independent of industry interests

The expert panel convened to put both this paper and the earlier “New Plant breeding techniques report 2013” are all involved in genetic modification, either in the creation, the industry promotion, or the approval of it. There is no consumer or independent scientist, who is able to give independent advice, on the panel.

¹ <https://ensser.org/wp-content/uploads/2017/09/ENSSER-NGMT-Statement-v27-9-2017.pdf>

² <http://www.gefree.org.nz/assets/pdf/GE-Animals-in-New-Zealand.pdf>

³ <https://www.stuff.co.nz/business/farming/agribusiness/69671638/ht-swede-risks-far-higher-than-other-crops>

This conflict of interest leads to comments like “genome editing, GM rootstock grafting and techniques producing null segregants are the NBTs generating the most uncertainty with respect to the definition for ‘food produced using gene technology’”.

The opinion of conflicted experts leads to unsafe long-term decisions. In the past these have led to many fatalities resulting from unexpected or overlooked harm following approvals of chemicals when regulators disregarded contrary and alternative views put to them in submissions against industry doctrine.

Answers to the questions in the consultation document.

3.1.1 - Genome contains new DNA

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, all genomes containing new DNA inserted through in vitro techniques should be captured for pre-market assessment. The European Network of Scientists for Social and Environmental Responsibility “Products of new genetic modification techniques should be strictly regulated as GMOs”⁴ report outlines and critiques in detail the reasons that these new breeding techniques need to be regulated.

3.1.2 - Genome unchanged by gene technology

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

No, these are still considered genetically modified organisms as they were derived from genetically modified organisms. Their genome has been altered through gene manipulation using in-vitro techniques. The new ‘null’ segregants have been bred from a genetically modified parent line and carry the changes recessively in their genome. There is no data to show that the expressed gene has not altered the plant deleteriously. Safety of these techniques these should be regulated for each variety and species.

3.1.3 - Genome changed but no new DNA

The new breeding techniques do alter the genome in unexpected ways affecting the plant pathways and producing unexpected mutations resulting in many off-target effects. These techniques must be regulated.

3.3 Questions - Regulatory Trigger

All new techniques should undergo regulatory oversight; all documentation of the breeding techniques used and the tolerance to chemicals should be provided. If any trigger the GM rules then the food should undergo full regulatory assessment.

3.4 Question - Other Issues

- 1. Diagnostic tools should be provided to detect the modification for clinicians to use if they want to confirm or deny any chance that the GM food could be a**

⁴ <https://ensser.org/wp-content/uploads/2017/09/ENSSER-NGMT-Statement-v27-9-2017.pdf>

cause of illness.

2. Long-term feeding studies are needed to see if any chronic effects occur from consumption of genetically modified foods, in line with EU standards.

3. All crops created from new breeding techniques involving mutagenesis, in-vitro gene editing techniques, that result in alteration of the genome or addition of DNA conferring pesticide tolerance or resistance must undergo full premarket assessment and long term feeding studies.

4. The FSANZ Code must retain its key definition without change on
***food produced using gene technology** means a food which has been derived or developed from an organism which has been modified by gene technology.*
***Gene technology** means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.*

Sincerely,

Jon Muller
Secretary GE Free NZ in Food and Environment

GE Free NZ in Food and Environment is a voluntary Organisation. We have many members in New Zealand. We support our members by writing submissions, providing information to our members and the public concerning Genetic Engineering on a local, national and International issues.