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Kia ora FSANZ,

We thank Food Standards Australia New Zealand for inviting responses to this proposal.

We do **not** support the proposed definitions and exemptions of genetically modified food as proposed in P1055. GE Free NZ is concerned over the new definitions and exemptions regarding New Breeding Techniques and gene editing.

We object to the unethical approach taken through the P1055 process which has pre-empted and marginalised consumer submissions by predetermining the broad outcome (by leaving labelling 'out of scope.' The public have an expectation and legislated right to have information to choose food for their dietary health. This can only be achieved through labelling of NBTs.

Food Standards Australia New Zealand (FSANZ) is charged with an effective, transparent and accountable regulatory framework that gives the public confidence in the dietary information on the foods they eat.

FSANZ proposal document (P1055) has contravened the legislation and duty of care toward the public. It has not consulted with major stakeholders like the Organic or industry sector to consider the impacts of P1055 on their business.

Until now FSANZ, has respected Consumer preferences and the importance of disclosure for consumer choice, not just as a matter of 'safety'.

FSANZ used to recognise the value of process-based risk assessment as stated here:

December 2019. Final report: Review of food derived using new breeding techniques.

FSANZ notes that

> *"process-based definitions for triggering pre-market approval of GM foods have been widely adopted around the world. In terms of their advantages, such definitions can provide a simple and clear way to signal the regulatory status of certain products and make regulations more predictable... Capturing products on the basis of the process used can also provide an effective mechanism to prevent regulatory gaps in coverage and ensure comprehensive risk assessments are applied equally to all products derived using a specific technology." (p. 17/29)*[1]

[1] Review of Food derived from New Breeding Techniques. FSANZ ,December 2019. https://mta-sts.foodstandards.gov.au/sites/default/files/consumer/gmfood/Documents/NBT%20Final%20report.pdf?utm_source=substack&utm_medium=email

FSANZ have unilaterally reversed the consumer guarantee *"…to ensure comprehensive risk assessments"* that has been fundamental to legitimise FSANZ's "duty of care."

Question 1a. Is the new definition for 'genetically modified food' clear? If not, which parts of the definition could be clearer.

Answer: No

We support the wording in the code-

1.1.2 ***gene technology*** means recombinant genomic techniques that alter the heritable genetic material of living cells or organisms.

And suggest the FSANZ Act.

1.5.2 '***food produced using gene technology*** means a food which has been derived or developed from an organism which has been modified by gene technology.
and
gene technology means recombinant genomic techniques that alter the heritable genetic material of living cells or organisms.

The wording as regards the definition for a genetically modified food in 3.2 is contradictory

(1) (a)(iv) *"genetically modified food (GMO) that is derived from an organism or cells containing novel DNA"* contradicts

(2) (a) *"null segregant (NS) organism, cell/s descended from an organism that contain novel DNA."*

The wording is ambiguous and implies that a GMO is a null segregant and in this context should not be regulated. This may be FSANZ's deliberate intention, but this will give the industry and consumer a false and misleading understanding on the regulatory meaning of exempted NBTs and could lead to NBT food entering the food chain that endangers public safety.

- There should be no exemption on NBT foods developed by recombinant techniques.
- There is no oversight for how FSANZ will verify NBT foods exempt from pre-market assessment.
- All foods from recombinant new breeding techniques (NBT) must be submitted to FSANZ for consideration as to their safety and status?
- FSANZ must require developers to submit safety evidence in order to ensure that the exempt NBT foods are adhering to the public safety requirements. This includes - pesticides residues, absence of novel DNA, "omics" tools to identify new undetected changes to the genome, that may cause allergies or health risks.

Question 1b. Will the new definition for 'genetically modified food' produce the intended regulatory outcomes, as described in section 3.2 and Table 3?

Answer: No,

These definitions for exempt NBT-derived foods are not in the public health interest and do not give adequate information on the product.

We do not accept that a food from a genome edited organism (GE) that does not contain novel DNA being defined as **"Not a GM food".**

We acknowledge that FSANZ considers some NBT characteristics may warrant a safety assessment. Though FSANZ has never required *in vivo* safety assessments, we regard *in vivo* independent safety assessments as essential before the release of exempted NBT foods onto the market.

It is unclear what tools FSANZ will require to be used to ensure that the exempted NBT foods are adhering to the public safety requirements for pesticide residues, absence of novel DNA, labelling, and new undetected changes to the genome. Any or all of these may result in the production of toxins and allergens.

Table 3 notes -*"Food derived from the part of a grafted plant that does not contain novel DNA or novel protein is* ***Not a GM food."***

This is unclear as to whether the grafted plant was

a. a non-GMO scion that was grafted onto a GMO rootstock or
b. a GMO scion the was grafted onto a non-GM rootstock or
c. a GMO rootstock that had a different GMO plant grafted onto it.

The heritable GM rootstock or scion may have changed the food in an unpredicted and undetectable way having potentially adverse dietary implications. Even the simplest SDN1 and SDN2 techniques have been shown to have unintended genomic changes that for susceptible consumers could cause anaphylaxis or allergies.

- All Exempt NBT foods have to undergo *in vivo* independent safety assessment before entering the market.
- All foods from NBT's, regardless of their percentage in the food, must be labelled as GMO, to meet the consumer demand for disclosure of gene technology being used.
- FSANZ's proposal to end case-by-case assessment will have a negative impact on consumer confidence in the quality and safety of food produced, processed, and sold.
- Surveys show that the international and national public want the right to know if food is a product of gene technology.
- It is wrong for FSANZ to impose predetermined outcomes on the consultation process. FSANZ has predetermined and ignored submitters in round 1 by exempting GE foods that are described as "non-GMO". Changing terminology does not render a food safe and betrays the consumer with disrespect of their right to choose.
- Foods produced from the GM process new breeding techniques (NBTs) should be regulated with no exemptions.

Question 2a. Is the new definition for 'novel DNA' clear? If not, which parts of the definition could be clearer?

Answer: No,

The definition is not clear is does not consider the potential for cis-genic organisms to change their DNA composition or structure, or to produce unwanted outcomes even when novel DNA is not detected. Gene technology processes (existing and future techniques) can create novel changes to genome deletion in the same way as intragenic or transgenic techniques.

Dr. Kawall as published in Frontiers said that

> *"Comparing all genomic alterations or allelic combinations generated by CRISPR/Cas9 generally as identical to naturally occurring variations is a misleading oversimplification."* [2]

The presence of novel DNA is not an adequate scientific basis for assuming safety or for determining unintended outcomes. Even without extant novel DNA, the processes can nevertheless still have safety implications.

Question 2b. Will the new definition for 'novel DNA' produce the intended regulatory outcomes, as described in section 3.3 and Table 3?

Answer: No

The definition does not cover the unintended mutations and foreign proteins that might be created in the process of creating a NBTs or gene editing. These concerns have been raised by Professor Heinemann and colleagues who write–

> **"***Changing the nature, kind and quantity of particular regulatory-RNA molecules through genetic engineering can create biosafety risks. While some genetically modified organisms (GMOs) are intended to produce new regulatory RNA molecules, these may also arise in other GMOs not intended to express them."* (Heinemann J.A *et al*, 2013)

In FSANZ 2nd call for submission Proposal P1055 on code definition of "novel DNA" states – *"(a) a person has inserted into the genome of an organism, cell/cells…"* (sec:3.3, p.25)[3] The term "Person" is incorrect as it implies that any person can create a NBT without any expertise or training, and it would be acceptable to FSANZ. Also, a machine could be used to undertake this process, and would that then exempt the NBT from regulation?

Question 3. Do you believe additional clarifying information would be helpful to accompany the proposed the new definitions? If yes, what additional information would be most helpful?

Answer: Yes,

Food Standards Australia New Zealand (FSANZ) is to achieve the following goals:

> *"a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand"* (FSANZ Act, sec3)

The Ministerial Forum, as referred to in the Policy guideline on Food labelling to support consumers to make informed healthy choices[4].

The FSANZ Act was written to protect consumers from the food risks arising from genetic modification. Policy also recognises the importance of maintaining consumer choice as a dietary-related matter of importance to the public.

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[2] https://www.frontiersin.org/journals/plantscience/articles/10.3389/fpls.2019.00525/full?utm_source=substack&utm_medium=email

[3] https://consultations.foodstandards.gov.au/fsanz/p1055/user_uploads/p1055-2nd-call-for-submissions-report.pdf

[4] Policy guideline on food labelling to support consumers to make informed healthy choices (foodregulation.gov.au)

Dr Zhang l., *et al* (2012a), published in *Nature Cell Research*, have shown that dsRNA molecules can enter the blood stream from GE food and can alter gene expression. Food are now being sprayed with RNA pesticides. (Zhang et al, 2012a) [5]

Dr Zhang H., *et al* published in *Insect Science*, found that the

> *"Production of intended dsRNA molecules may also have off-target effects due to silencing genes other than those intended… further study on dsRNA uptake mechanisms based on the knowledge of insect physiology and biochemistry is needed."* (Zhang et al, 2012b)[6]

Professor Heinemann's research "A comparative evaluation of the regulation of GM crops or products containing dsRNA suggested improvements to risk assessments" , [7] published in the *Environmental International Journal*, recommends a process to adequately assess the hard to detect unanticipated off-target adverse effects safety of GMOs from gene editing techniques before they are released or commercialized includes the following:

(1) bioinformatics to identify any likely, unintended targets of the dsRNA in humans and other key organisms;
(2) experimental procedures that would identify all new intended and unintended dsRNA molecules in the GM product;
(3) testing animal and human cells in tissue culture for a response to intended and unintended dsRNAs from the product;
(4) long-term testing on animals; and possibly
(5) clinical trials on human volunteers. (Heinemann J.A et al, 2013)

Through this time FSANZ has ruled out the need for *in vivo* GM testing. We consider this unscientific and a dereliction in its "duty of care." It is recognised that animal testing is an acceptable way to study the effects that might occur if extrapolated to people. FSANZ has ignored and dismissed any GM health effects that have been detected in animals. They have instead allowed untested genetically engineered food into the food chain. This has released untested and potentially unsafe GE foods that have not been subject to monitoring but have been exempted from labelling due to their ultra processed nature, into the food chain.

This undermines consumer trust and confidence in the decisions made by FSANZ. It is also causing consumer distrust of all foods possibly derived from GMOs, affecting manufacturers and retailers.

- Consistent and uniform enforcement of labelling regulations is important to ensure consumers have choice with access to accurate labelling information.
- The Process used to produce food is important to consumers. FSANZ must accept GE food labelling is about reflecting consumer choice, perception and ethical values, including Te Ao Māori.

[5] Zhang, L., Hou, D., Chen, X., Li, D., Zhu, L., Zhang, Y., ... & Zhang, C. Y. (2012). Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. *Cell research*, *22*(1), 107-126.
[6] Zhang, H., Li, H. C., & Miao, X. X. (2013). Feasibility, limitation and possible solutions of RNAi-based technology for insect pest control. *Insect science*, *20*(1), 15-30.
[7] Heinemann JA, Agapito-Tenfen SZ, Carman JA.(2013) A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environ Int. 55:43-55. doi: 10.1016/j.envint.2013.02.010. Epub 2013 Mar 20. PMID: 23523853.

- Consumers choose foods for a variety of reasons. Food labels are essential to inform consumers' choice of foods to eat, and surveys are definitive that foods from NBT processes are a matter for consumer choice, not to be denied by FSANZ.
- FSANZ has failed repeated requests for clarification on the expectations for developers to self-assess NBT foods that do not require FSANZ pre-market assessment. How are they to be evaluated for compliance and safety? What Insurance cover will be provided by commercial insurers to close the risk-gap that FSANZ's assumption of substantial equivalence opens up?
- All foods produced from New Biotechnologies (GMO and Gene Edited) must be labelled, regardless of the level of percentage in product, in line with the FSANZ objective for accurate labelling consumer information to allow choice.
- All foods produced from New Biotechnologies (GMO and gene edited) must ensure disclosure of Gene Edited products to farmers and consumers for the right to choose**.**

1. **Question 4: Do you have any information (e.g. studies or data) that may be able to quantify the impacts to consumers that may arise from the proposed changes?**

   Answer: Yes, we have additional information.

   FSANZ is charged with **"the provision of adequate information relating to food to enable consumers to make informed choices."**

   The proposed changes by FSANZ to the definitions and the exemptions around NBTs and gene edited organisms will not provide consumers with adequate information to make informed choices. This is a dereliction of duty to the public.
   The changes also are in direct contravention of the Ministerial Forum members. It is their duty as set out in their Policy Principles to ensure that "the physical product should include information to provide consumers the opportunity to identify foods that contribute to healthy dietary patterns…within the Food Labelling Hierarchy". [8]

   FSANZ is a regulatory body set up to protect public health through the food system it is incumbent on the FSANZ to provide the studies and data for submitters to comment on. In previous submissions we have provided data and independent peer reviewed studies to show that under laboratory trial conditions the survival of the transgene, and / or serious adverse health effects were found.

   Additional papers (see below) show significant differences in products from gene technology processes that makes FSANZ's claim of equivalence untenable except as an intentionally political not scientific view as FSANZ claim.

   The submitted published studies have been dismissed (as published on the FSANZ site "Response to a feeding study…"). The many research scientistswho published findings that

[8] https://www.foodregulation.gov.au/sites/default/files/2023-09/policy-guideline-on-food-labelling-to-support-consumers-to-make-informed-healthy-choices.pdf

showed harm, instead of being considered have been ignored and defamed [9.10, 11, 12, 13,]. Yet there have been no contra studies to show that the information was incorrect

All these independent peer reviewed published studies show that there is potential for harm. It is incumbent on FSANZ to protect consumer health and look further into the studies, and not rely on unpublished industry studies. Rather than say without foundation that "FSANZ considers such toxicological studies in rodents to be unsuitable for testing whole GM foods" FSANZ must require testing on humans if animal model is not considered suitable.

FSANZ has presented no information on how they will evaluate possible major impacts from the proposed approach, and how they are going to conduct or retire developers to conduct assessment and monitoring of exempt NBTs. Excuses that FSANZ have no enforcement role are unacceptable as this deliberately subverts the capacity of those government agencies that do have that responsibilities to execute their duties.

Nor has FSANZ considered the serious chromosomal damage that occurs from the Site Directed Nuclease SDN1 and SDN2 gene editing techniques (as presented below).

The consumer requires regulatory oversight on any NBT/GE product and process that has no history of safe use. Claims that NBTs are 'substantially equivalent' to traditional foods, that have a history of safe use, are immaterial given scientific evidence of potential differences in NBT processes that demand evaluation. It has been found that GE and the technological manipulation of NBTs cause unexpected mutations.

Henry et al (2018), *Methods Molecular Biology,* found in **Detection of Chromothripsis in Plants that -**

> *"Chromothripsis, or chromosome shattering, occurs after chromosomes missegregate, are pulverized and subsequently repaired erroneously, leading to highly complex structural rearrangements. In plants, chromothripsis has been observed as a result of mitotic malfunction connected with the incomplete loss of haploid inducer chromosomes during uniparental genome elimination." (*Henry et al 2018*)*[14]

Dr. Wu *et al* analysis in the *Journal of Plant Biotechnology,* found that Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)–CRISPR-associated protein 9 (Cas9)-based methods had many off target mutations in transgenic rice [15]

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[9] https://www.foodstandards.gov.au/consumer/gmfood/seralini

[10] https://www.foodstandards.gov.au/consumer/gmfood/Response-to-a-feeding-study-in-rats-by-Zdziarski-et-al

[11] https://www.foodstandards.gov.au/consumer/gmfood/Response-to-Dr-Carman-27s-study

[12] https://www.foodstandards.gov.au/consumer/gmfood/Response-to-a-feeding-study-in-goats-by-Tudisco-et-al

[13] https://www.foodstandards.gov.au/fsanz-response-study-linking-cry1ab-protein-blood-gm-foods

[14] Henry IM, Comai L, Tan EH. Detection of Chromothripsis in Plants. *Methods Mol Biol*. 2018;1769:119-132. doi: 10.1007/978-1-4939-7780-2_8. PMID: 29564821. https://link.springer.com/protocol/10.1007/978-1-4939-7780-2_8

[15] Wu Y, Ren Q, Zhong Z, Liu G, Han Y, Bao Y, Liu L, Xiang S, Liu S, Tang X, Zhou J, Zheng X, Sretenovic S, Zhang T, Qi Y, Zhang Y. (2022) Genome-wide analyses of PAM-relaxed Cas9 genome editors reveal substantial off-target effects by ABE8e in rice. *Plant Biotechnol J*. 20(9):1670-1682. doi: 10.1111/pbi.13838.

Samach et al (2023)[16] published in *The Plant Cell* designed methods to detect the loss of heterozygosity (LOH) in somatic cells, enabling the study of a broad range of Double Stranded Breaks (DSB) -induced genomic events. Their research found CRISPR/Cas induced "DNA breaks that triggered Chromosomal loss and Chromothripsis like rearrangements" even at the most basic SD1 breaks.

Weisheit *et al.* in the *Journal of Cell Reports*, detected deleterious effects in NBT/ gene edited plants that may have adverse dietary implications. [17]

Drs Koller and Cieslak review in *Frontiers in Bioengineering and Biotechnology,* concluded that

> *"unintended genetic changes caused by NGT processes are relevant to risk assessment. Due to the technical characteristics of NGTs, the sites of the unintended changes, their genomic context and their frequency (in regard to specific sites) mean that the resulting gene combinations (intended or unintended) may be unlikely to occur with conventional methods."(Koller F., & Cieslak M.,2023)* [18]

Dr Lazar (2024) team, published in *Nature Genomics* study found

> *"recent studies on CRISPR/Cas have shown that it can have unintended effects such as structural changes. However, these studies have not yet looked genome wide or across data types. Here we performed a phenotypic CRISPR–Cas9 scan targeting 17,065 genes in primary human cells, revealing a 'proximity bias' in which CRISPR knockouts show unexpected similarities to unrelated genes on the same chromosome arm. This bias was found to be consistent across cell types, laboratories, Cas9 delivery methods and assay modalities, and the data suggest that it is caused by telomeric truncations of chromosome arms, with cell cycle and apoptotic pathways playing a mediating role…This previously uncharacterized effect has implications for functional genomic studies using CRISPR–Cas9*. (Lazar *et al* 2024)[19]

Dr. Ahmad (2019) in his published research in *J. Cellular Physiology*, reported that –

> *"Despite its [CRISPR/Cas] popularity, the technology has limitations such as off-targets, low mutagenesis efficiency, and its dependency on in-vitro regeneration protocols for the recovery of stable plant lines. Several other issues such as persisted CRISPR activity in subsequent generations, the potential for transferring to its wild type population, the risk of reversion of edited version to its original phenotype particularly in cross-pollinated plant species when released into the environment and the scarcity of validated targets have been overlooked."* (Ahmad N., *et al*, 2019)[20]

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[16] Samach A., Mafessoni F., Gross O., Melamed-Bessudo C., Filler-Hayut S., Dahan-Meir T., Amsellem Z,, Pawlowski W., Levy A., (2023) CRISPR/Cas9-induced DNA breaks trigger crossover, chromosomal loss, and chromothripsis-like rearrangements, *The Plant Cell*, Volume 35, Issue 11, Pages 3957-3972, https://doi.org/10.1093/plcell/koad209

[17] Weisheit, I. *et al.* (2020) 'Detection of deleterious on-target effects after HDR-mediated CRISPR editing', *Cell Reports*, 31(8), p. 107689. doi:10.1016/j.celrep.2020.107689 .

[18] Koller F. and Cieslak M (2023), A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment. *Front. Bioeng. Biotechnol.* 11:1276226. doi: 10.3389/fbioe.2023.1276226

[19] Lazar, N.H., Celik, S., Chen, L. *et al.* High-resolution genome-wide mapping of chromosome-arm-scale truncations induced by CRISPR–Cas9 editing. *Nat Genet* **56**, 1482–1493 (2024). https://doi.org/10.1038/s41588-024-01758-y

[20] Ahmad N, Rahman MU, Mukhtar Z, Zafar Y, Zhang B. A critical look on CRISPR-based genome editing in plants. J Cell Physiol. 2020 Feb;235(2):666-682. doi: 10.1002/jcp.29052. Epub 2019 Jul 10. PMID: 31317541.

The change to the definitions allows new and untested, unlabelled whole foods that may have undetected mutations that are toxic or allergenic into the food chain without any proof of safety for the consumer. Health professionals also do not have the information given to them to diagnose the cause if there is an unintended outcome of unregulated / developer self-regulated use of gene technology. Due to the hidden nature of the exempt NBT foods This would lead to the potential for an untraceable serious health event, that might be overlooked and misdiagnosed, as there are no diagnostic tools or antidotes available for health practitioners to use.

Though FSANZ state they have no enforcement role, this creates a moral responsibility on FSANZ as an arm of government serving the public interest. The lack of labelling information has a direct impact on consumer rights and ensuring public health and safety.

2. **Question 5: Have all the major impacts to consumers from the proposed approach been identified in the consideration of costs and benefits. Please provide evidence (where possible) to support the inclusion and magnitude of other impacts.**

Answer: No

The information is presented above in Q:4 these could have major impacts on consumer and industry costs. Further, Professor Heinemann and colleagues have raised concerns over the

> *"Transcription will produce new RNA molecules that might be able to form dsRNA because of complementarity or internal base-pairing causing stem-loop structures to form. This may lead to intended and unintended off-target gene silencing in the GMO or in organisms that eat the GMO." (Heinemann J. et al, 2013)*[21]

EU retailers considering issues for regulation of NBTs have signalled the risk of increased food costs to consumers. The increased costs are associated with the unfair imposition of verification onto producers and retailers of non-GMO food that will be associated with maintaining integrity and traceability to meet consumer demand. As cited in *Fortune Business Insights* the global non-GMO food market was projected to grow to $895.36 billion in 2024. There is an economic cost to losing the traceability of exempted NBT products, seriously affecting market share and the capacity to meet industry growth in non-GMO food.[22]

The EU retailers also highlight patents on NBT foods as potentially adding costs that will end up increasing price of food to consumers.

These matters need to be subject to proper economic modelling and analysis by FSANZ for the P1055 proposal.

FSANZ's preliminary cost/benefit overview has not considered the real market demand and sought instead to justify ignoring or imposing such costs in favour of aligning with overseas regulators guilty of the same betrayal of their citizens and consumer expectations for regulation of NBTs and the right to choose.

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[21] https://www.sciencedirect.com/science/article/pii/S0160412013000494?via%3Dihub

[22] Non-GMO Food Market Size, Share & Industry Analysis, By Type (Cereals & Nuts, Fruits & Vegetables, Meat & Poultry Products, Beverages, Dairy Products, Processed Food, and Others), Distribution Channel (Hypermarkets/Supermarkets, Specialty Stores, Online Retail Stores, and Others), and Regional Forecast, 2024-2032 https://www.fortunebusinessinsights.com/non-gmo-food-market-106359

The FSANZ view that the expansion of availability of NBT foods has benefit for consumers is hypothetical and not proven as the market demand for non-GMO food is proven.

The denial of labelling is unethical and unacceptable and breaches the consumer right to know if gene technology has been used. This is irrespective of any assumption by FSANZ that a NBT food is deemed safe or not.

Health of the public is not predicated on cost benefit if the exempted product is dangerous. Who will be benefited by the exemptions? New Zealand /Aotearoa is a small island nation with no history of genome edited or NBTs as part of the diet. FSANZ has approved many varieties of GM foods but limited in the species. These are highly/ultra processed and denatured, as soy isolates and oils, and often end up in animal feed rather than branded products in supermarkets. It is important to have disclosure labelling as it allows the market to operate in terms of the right to choose.

Just because FSANZ considers that it is a *"Reduced regulatory burden will lead to increased production efficiencies and profits for GM and NBT foods and ingredients getting to market"* and that "*GE and NBTs are not well understood by the public."* There is no , there is no justification to exploit the lack of knowledge by pushing the artifice of 'substantial equivalence' and exempting NBTs from regulation without the requisite dietary safety research. This is enabling FSANZ to progress essentially unethical and anti-consumer proposals, as set out in P1055, based on a serious lack of "duty of care" for public information and choice in relation to personal values, Te Ao Māori and dietary health.

FSANZ writes –

> *"Providing a clear and predictable pathway to market is important because new technologies, such as NBTs, although not widely available, could be useful tools that may contribute to more sustainable food production, climate change resilience and mitigation, cheaper food and innovative food products which benefit the food and agriculture sectors, where eventually consumers will benefit from these products of innovation."*

"Could" is the operative word and in no way justifies the trade-off of the consumer right to know that FSANZ is seeking to extinguish in P1055.

To date these projected benefits have not been proven. Given FSANZ's repeated rebuttal of questions of testing methodologies and enforcement as matters outside its role - clarification is needed on why FSANZ is citing in its proposals these implied consumer benefits and hopes for sustainability, and climate resilience. What do they have to do with P1055 for public and consumer safety, other than as a cover for justifying the removal of regulation expected by the public, and to remove labelling of NBTs needed to allow consumers to exercise choice?

- We do not accept that the balance of costs and benefits of Gene Editing deregulation are in the public interest.
- We do not accept that the FSANZ has acted morally or ethically by its predetermination to remove labelling and monitoring from the proposed NBT approach and make it out of scope for consultation
- FSANZ is the agency set up to primarily protect public health and provide information, including for GM/NBT foods even if deemed to be 'safe'
- We require businesses and companies using whole foods or ingredients derived from NBTs to show evidence that there are no unexpected changes from the NBT process.

- FSANZ must state what tools and data must be assessed to evaluate NBT products and provide a clear statement for developers that "unexpected and off-target changes can occur from existing and future gene technologies and must (i.e Mandatory) be assessed.
- Experts in the Insurance Industry must be used to assess and cover real-world risks that FSANZ has decided are too small to be regulated by FSANZ assessment.
- P1055 transfers risks (all be they deemed negligible by FSANZ) to the developer and to the consumer. FSANZ must advise developers that the intended self-assessment under P1055 for what are deemed low-risk products still creates a risk that warrants commercial Insurance.
- Labelling, testing and information must be enforced and verified before NBT foods are put on the market. Process is important to consumers for reasons other than just safety, and FSANZ know that. To deliberately subvert this and deny consumer choice is unconscionable and threatens trust in the regulator, and to increase costs to consumers of accessing non-NBT food.

3. **Question 6. Do you have any information (e.g. studies or data) that may be able to quantify the impacts to the food industry that may arise from the proposed changes?**

FSANZ proposal document (P1055) has contravened the legislation and duty of care toward the public. It has not consulted with major stakeholders like the Australian and New Zealand Organic or food industry sector to consider how they will manage the impacts of P1055 on their business. European producer and food enterprises called for mandatory labelling requirements writing "The organic and non-GMO industries in particular feel that their very existence is at risk" (2023)[23]

FSANZ quotes that *"it is challenging to predict the benefits…and how it might incentivize innovation"*. FSANZ is acting as an industry body by weighing its considerations around how to incentivize innovation.

The EU retailers (above) have signalled a transfer of costs from innovation Developers to consumers and existing non-NBT producers that must be independently evaluated and is unacceptable if it increases the cost of food as they predict.

FSANZ is charged with the protection of public health and should not be weighing up and offsetting the benefits to industry over the public/ consumer.

As reported in Dr. Ahmed publication there are many considerations to be evaluated outside the direct interpretation of novel DNA which is not fit-for-purpose as a definition triggering risk assessment. It is up to industry to produce research data on the safety of its patented innovation for the consuming public and for FSANZ to assess the NBT in the light of public health and protection.

- Companies producing food from NBTs must identify them to allow enforcement of regulations. FSANZ has no enforcement role, but by pushing P1055 without clear statements on expected testing and traceability methodologies and mandatory

[23] European enterprises call for rigorous labelling of NGTs https://www.ohnegentechnik.org/en/press/articles/european-enterprises-call-for-rigorous-labelling-of-ngts

identification disclosure by developers, is subverting the capacity of other regulators to do their job.

- Regulations must ensure disclosure of gene edited products to farmers and consumers for the right to choose**.** Maintaining traceability and disclosure is vital to underpin the integrity of food systems into the future, with safety implications that FSANZ may yet be able to identify given its beliefs in 'substantial equivalence' are not science-based.
- Deregulation of GE risks imposing unacceptable increased costs to maintain the integrity of non-GMO food on producers, exporters and consumers.

4. **Question 7. Have all the major impacts to the food industry from the proposed approach been identified in the consideration of costs and benefits?**

Answer: No

FSANZ is charged with **"an effective, transparent and accountable regulatory framework within which the food industry can work efficiently."**

Due to the past rejection of the evidence presented by submitters and the inability of submissions to be heard on matters of public interest, people are losing confidence and faith in FSANZ's decisions around GMOs. The regulatory framework is not considered effective, transparent or accountable for its decisions, which, according to FSANZ, cannot be challenged.

Provenance and process are important to consumers and the lack of honesty and transparency proposed by FSANZ will undermine trust. This will affect industry, and potentially drive ups costs of food to consumers because of additional efforts required by food producers to secure their supply chain.

There are many surveys on consumer views on GE. Primary Purposes survey, June 2024, found continued regulation of NBT food to important consumers. The survey found

- When given some context about areas of potential gene technology use, 14% said they would like to see regulations eased, 45% that further exploration should be cautiously undertaken on a case-by-case basis, and 29% said that New Zealand food production should be completely free of genetic technology

- Majorities (59-62%) were also moderately or very concerned about some of the potential risks (food safety, long-term environmental impacts and animal welfare) [24]

The responsibilities of FSANZ have been corrupted to benefit the food industry and an agenda of innovation over consumer preference for existing foods with a history of safe use and made with processes that meet consumer values, including Te Ao Māori.
To ensure trust, transparency and accountability, it is essential that labelling of all whole and processed foods that are NBT/GE is mandatory. Such labelling provides necessary information to allow consumers to choose what foods they want to eat.

[24] Public perceptions of genetic technologies in New Zealand food production systems https://static1.squarespace.com/static/5991327b9f74563f03253a11/t/66832f576083fc1c428cadeb/1719873382191/Public+percpetions+of+genetic+technologies+report+June+2024.pdf

- We do not accept that the balance of costs and benefits of Gene Editing deregulation are in the public interest.
- There must be a requirement for businesses or companies using NBTs to show evidence that there are no unexpected changes from the NBT process, and to have commercial Insurance to provide confidence in the face of at-scale commercialisation of NBTs.
- Labelling, testing and information must be enforced and verified before NBT foods are put on the market.

5. **Question 8. Have all the major impacts to government from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence such as studies or data to support the inclusion and magnitude of other impacts.**

Answer: No

FSANZ is charged with

> *"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, sec 3)*

To do this FSANZ can lead in ethical regulation that meets the public's clear expectations and does not have to be acquiescent to jurisdictions that deny the scientific evidence of the potential for risk from NBTs, nor the unethical denial of consumer choice.
The Government has enacted legislation requiring FSANZ is to protect public safety by means of an effective, transparent and accountable regulatory framework around NBTs (GMOs). NBT foods have no history of safe use and exempting them from regulations will reduce safeguards that are currently in place to protect the health of consumers, and the right to choose. This leads to socialised costs to the public via Government for any public health impacts from NBTs used by commercial developers.

It is the duty and function of FSANZ to require a register of all food created from NBTs.

To ensure traceability and public trust that NBTs are safe, and that consumers have a right to choose based on personal preference, foods from NBT processes must undergo rigorous long-term *in vivo* feeding trials before being allowed to enter the food chain.

Foods made from NBT ingredients must be disclosed as made with gene technology (existing and future) regardless of whether there is modified novel DNA/protein in the final product.

- Exports of non-GE food have an economic advantage with growing market demand this will increase Government revenue. The Global market for NON-GMO food is growing (projected ACGR 11.9 % to 2032)
- Deregulation of GE risks imposing increased costs inequitably, to maintain the integrity of non-GMO food on producers, exporters and consumers impacting the affordability of food and Government revenue.
- The agencies of Government with enforcement responsibilities must be enabled to fulfil their role to enforce labelling, regular robust post- monitoring and 'identity preservation' documentation on commercial producers and processors, including for 'low' risk (SDN1, SDN2) NBT foods, to ensure public safety and information.

Summary:

- We oppose the new terminology on the definition of genetically modified foods.
- All Exempt NBT foods have to undergo *in vivo* independent safety assessment before entering the market.
- All foods derived from NBT's, regardless of their percentage in the food, must be labelled as GMO.
- Long-term testing of NBTs, and requirements for methodologies and data needed to assess safety must be enforced.
- Require developers to submit safety evidence using "omics" tools in order to ensure that the exempt NBT foods are adhering to the public safety requirements. This includes - pesticides residues, absence of novel DNA, to identify new undetected changes to the genome, that may cause allergies or health risks.
- Diagnostic tools for Health professionals must be developed and verified before NBT foods are put on the market.
- We require businesses and companies using whole foods or ingredients derived from NBTs to show evidence that there are no unexpected mutations or genome changes from the NBT process, and to have commercial insurance against unintended mistakes.
- All food produced through NBTs, including those FSANZ intends to exempt, must be labelled and not the subject of patents that will increase cost burdens for farmers, producers and consumers.
- Companies must be required to notify and identify food produced from NBTs to allow enforcement of regulations and traceability which underpins local and international consumer trust in food safety and quality.
- There must be disclosure of products produced with gene editing processes to farmers and consumers for the right to choose**.**
- FSANZ's proposal to end case-by-case assessment will have a long-term and increasing negative impact on consumer confidence in the quality and safety of food produced, processed, and sold.
- Surveys show that the international and national public want the right to know if food is a product of gene technology, even if FSANZ say they are stupid and don't deserve to be respected in their demand for the right to choose.
- FSANZ has predetermined the outcome of this process and ignored submitters concerns by exempting GE foods that are to be described as "non-GMO", when they are products of gene technology.
- Changing terminology is deliberately misleading and unethical in terms of the consumers' right to know and, does not render a food safe just because it is assumed to be similar to food with a long history of safe use and consumer preference.
- Foods produced from the GM process new breeding techniques (NBTs) should be regulated with no exemptions.

We support the submissions of PSGR(NZ), INBR, Soil and Health, Gene Ethics and OANZ.

Ngā mihi,

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