

## **Submission to FSANZ on Proposal P1055**

### **Definitions and the Need for Continued Regulation of current and future New Breeding Techniques (NBTs)**

#### **From: Auckland GE-Free Coalition (AGEFC)**



Thank you for the opportunity for the public to make a submissions on definitions and potential exemptions.

AGEFC is a community network concerned with the regulation of powerful gene technologies in the public interest.

This submission highlights findings from the FSANZ research on the need to heed, respect and deliver on the public expectations for NBT regulation, (which is similar to expectations for other genetically engineered products).

#### **AGEFC:**

- Support the precaution and direction provided to FSANZ by INBI. (Centre for integrated Research on Biosafety, University of Canterbury)
- Oppose any exemptions of NBTs - current or future gene editing.
- Ask that public expectations be respected not sidelined or ignored in favour of industry.
- Ask that public expectations be met for tools like safety testing, genomic sequencing and omics to be required in methodologies for safety assessment and approval.
- Ask that NBT products must be registered.
- Ask that products from NBT be labelled to allow consumer choice.

Auckland communities and whanau are ethnically and culturally diverse and are a broad representation of people and community values in Aotearoa New Zealand.

The FSANZ research on public attitudes to NBTs shows there are commonalities across the publics of many countries in terms of expectations of food safety regulators.

**FSANZ's *NBT Focus Group* and *NBT Literature Review* show shared public expectations for regulation, in common across the range of people's views (and across the range of levels acceptance of the benefits and risks presented by gene technologies).**

- The qualitative and quantitative data (quoted further below), indicate there is a shared expectation of regulation to ensure safety, traceability, labelling and consumer choice, including of NBTs.

- The FSANZ consumer/public attitudes reports highlight significant doubt that anything has changed in the public demand for regulation of all products of gene editing and genetic engineering.
- These public expectations remain essentially consistent for NBTs and do not legitimate exemptions from safety regulation for any NBT.
- The regulation of NBTs provides a social 'license to operate' and the basis for public confidence that the system is functioning.
- To quote from the FSANZ NBT reports:

<https://www.foodstandards.gov.au/code/proposals/Documents/NBT%20focus%20groups%20final%20report.pdf>

*“FSANZ consumer research of concepts featured potential benefits but little recognition of risks which participants cited themselves. **Even for most the most acceptable concepts “Many participants highlighted the need for testing** in order to avoid side effects for humans, the plants and the environment, and non-human animals” (page 22)*

*“ (That for non-experts), **foods produced by NBTs will never be ‘equivalent’** to foods produced by traditional breeding techniques and are viewed along a continuum with foods produced using other forms of genetic modification rather than as distinct from them or obviously preferable.”*

*“Although NBTs might in principle involve less change than genetic modification from the point of view of those who are experts in these fields, **other factors matter to non-experts even within applications of NBTs**. Relatedly, the type of product seems to matter to participants’ views on NBTs’*  
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**FSANZ are warned in its own reports *not to fall into the mistaken belief that academic and industry assumptions show a higher level of consumer acceptance of deregulated NBT/ GE products.***

- The FSANZ reports find that public expectation of regulation remains relevant for NBTs as it does for 'earlier' genetic engineering.
- The research also warns against certain 'expert' and 'specialist' perspectives being used to subvert or dismiss public concerns to further the interests of industry.
- This is especially problematic when FSANZ has chosen to approve all applications for GMOs on the basis of rejecting submissions providing independent science, warnings for precaution, and admonitions for further research before deployment.
- Trust in FSANZ as regulator is reliant on public confidence that citizens' expectations are not compromised by FSANZ's other priorities for enabling trade and commercial innovation.

## **Public Trust and Confidence in FSANZ must be regained.**

- There is a public perception that FSANZ are overly reliant on industry data and meeting industry objectives, and ignore independent peer-reviewed science that is inconvenient to industry objectives. An independent audit of FSANZ is needed to establish if this has been the case, and to guide a rebalance by FSANZ back to the public interest.
- In the NBT discussion document FSANZ considers the GMO foods approved into Australia and New Zealand are overwhelmingly safe. This is fortunate if it is the case, but there is an absence of evidence from consumption monitoring or other data.
- The limited existing assessment undertaken by FSANZ of products of gene technology falls short of requiring safety testing of novel foods and is reliant largely on applicants' own data.
- This has resulted in habitual approvals by FSANZ of GM foods against scientific submissions and ignoring peer reviewed data showing a need for further research or to decline an application.
- Flawed decisions weaken public perceptions of FSANZ and risk FSANZ being seen to be captured by industry or to prioritise international trade over properly delivering on the public expectations of precaution and testing in regulation.

### **Examples of approvals that demonstrate flaws in FSANZ that are likely to undermine public trust in FSANZ:**

- *Example: Hi-Lysine Corn*  
FSANZ rejected safety concerns that by-products from Hi-Lysine corn could be harmful if accidentally released into the human food chain and heated for consumption. (Hopefully, no accidental contamination of human food will ever occur)
- *Example: Golden Rice*  
FSANZ justifies its safety approval as technically correct but the outcome of the approval is non-sensical. The US FDA found the product cannot claim any efficacy to address Vitamin A deficiency, which was its intended purpose. (Nonsensical outcome: It doesn't actually work, but its approved safe for sale)
- *Example: Round-up Resistant Crops (multiple)*  
FSANZ makes no recognition of the negative impact of increased exposure for consumers to residues of glyphosate based herbicides (GBHs) as a result of higher levels of spraying. Independent peer-reviewed science on cancer (EU) and tumor risks demonstrated in animal models (Seralini) are ignored. (Nor is FSANZ managing or monitoring impact on public health from the combined interaction of different agri-chemicals in people's diets.)
- However, FSANZ regulation has a positive if it helps chill risk-taking by applicants for other potentially harmful gene technology products that would otherwise go ahead.

## FSANZ's reports warn of the need for building public trust in FSANZ with regulation of NBTs.

*(Source: NBT Focus Group and NBT Literature Review - (italics/bold added)*

These results represent a moderate to low belief in the ability to effect change in the Australian/New Zealand food systems, with less confidence found amongst New Zealanders. ***This result is worth exploring in a more detailed study focused on sources of distrust and understandings of food system regulation and oversight, given these low levels of trust in reporting and resolution procedures.***

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***Over a third are unsure of the FSANZ fact sheet briefing's credibility and observe a promotional bias towards gene technology.***

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***The increase of knowledge created in the research also has as an outcome an increased demand for governments to regulate such new technology ( Fig 4.6.1)***

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For example, according to one participant: 'It feels to me like people have already been doing a lot of research and testing and whatever it is will go ahead anyway whether we like it or agree with it, or not.' This type of comment also could be argued to align with some of the findings in the trust metrics which showed that ***participants did not think that they were likely to have effects on the food regulatory system or related matters.***

The ***relatively large increases in desire to have government regulation of new technologies following discussions about NBTs including specific applications related to the food supply*** indicates a growing awareness amongst participants of the importance of regulation and potentially how it could relate to some of the ***concerns expressed by them, such as the need for longer-term data, controls over potential abuses of these technologies for unethical purposes, and the need for research on and tracking of environmental and other impacts.***

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Key repeated themes with regard to the questions raised and the information desired by participants included clarity on *longer-term effects* of applications on the organisms in question, the environment, humans, and the resulting food products. In addition, there were frequent requests for *more evidence of safety* and the ***need for long-term testing*** in conjunction with applications of these technologies. There were some discussions about the ***need to ensure that such technologies could be reversible, and that conventional varieties would not be adversely affected or would be maintained in parallel to these new applications in part as an insurance policy and also to maintain biodiversity.*** Finally, there were concerns about whether these applications would result in increased costs for farmers or consumers.

...

In addition, the discussions particularly on the specific application scenarios revealed that many of the themes in the comments from those negatively disposed to NBTs, as well as many of the questions posed by those ***across all of the segments (negative, neutral, and positive), are similar to those found in the literature on attitudes toward other, older gene technologies, such as GM, such as need for reassurance about safety through long-term independent testing and monitoring.*** This finding is ***in contrast with what is often assumed in some regulatory approaches*** and in the scientific literature, namely that NBTs are clearly less invasive and more precise, and therefore likely to be much less problematic for the public than older types of genetic modification.

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## From the Systematic Literature review...

(Source)

<https://www.foodstandards.gov.au/code/proposals/Documents/NBT%20Literature%20Review.pdf>

The literature that does exist currently suggests attitudes and behavioural responses to NBTs are **slightly** more positive than toward older forms of genetic modification (GM), and slightly more negative than toward food produced using traditional breeding techniques.

- This relatively more positive attitude could be due to the 'more targeted' and 'less distant' nature of NBTs compared with more 'random' and 'distant' GM techniques; **it could also be a result of the framing biases of the research thus far conducted.** P5.

### 4.2.3 Understanding of NBTs

**Key finding: In the absence of information, non-experts don't conceptually separate NBTs from other technologies.** P19

### 4.3.4 Importance of attitudes toward NBTs

**Key finding: The literature has suggested attitudes to NBTs are more positive than GM, but it is not yet clear if this finding is reliable.**p25

*(It) is unclear whether this is because people perceive this themselves or because this is the information that has been provided to them in studies or the way in which the studies have been framed. This point is critical: optimism about NBTs appears implicit in some of the literature explored in this review (see for example Ferrari et al 2021, Barrangou 2020, Wolter and Puchta 2017, De Marchi et al. 2019). Hence findings about positive attitudes may not be entirely well founded.*

### 4.4.1 Behavioural responses to NBTs in Australia and New Zealand

Key finding: As with work on attitudes to NBTs, the literature on behavioural responses to NBTs in Australia and New Zealand is spotty; **indications do suggest a discounting of NBT-derived food, but not as much as GM food.** p26

**Similarly, the possibilities of being faster, cheaper, and easier might resonate with supporters of NBTs such as Barrangou (2020), but will these supposed advantages trump over developing processes for the discussion, engagement, monitoring, and regulation that many consumers may well demand? It is worth recalling Cornick et al.'s finding (2017) that the intervention most likely to change the minds of those who considered GM too risky were long term (i.e., 10 year) studies of safety.** P31

Others point to **the key role played by labelling as a communication intervention.** Bartowski and Baum (2019) note that this strategy can be closely coupled with deliberation (discussed below), in what they term an 'exit-voice' framework. Here deliberation allows 'voice', and labelling allows those reluctant to consume food produced by NBTs to 'exit' the market. **Bechtold (2018) argues that food labelling and consumer choice should be considered as institutions to "support communication about values and to broaden the perspective on the agricultural use of genome editing and its products". Labelling, in this case, could "stagger the processes of deliberation allowing for cautious governance of the new breeding technologies"** (see also Bechtold et al. 2018; Carson 2019).

"While some research has suggested consumers appreciate the potentially 'targeted' nature of NBTs (see Debucquet et al. 2020), and producers appreciate the potential for 'simpler', 'faster', 'cheaper' and 'untraceable' pathways to produce GM organisms,<sup>8</sup> others have suggested that these key aspects may present critical communication challenges. (NOTE 8: **These facts are applauded throughout the wider literature on NBTs, particularly in editorials and opinion pieces, and appear evident in the 'optimism bias' discussed in section 4.3.4** (see other examples in Barrangou 2020, Wolter & Puchta 2017).

**Context – FSANZ must recognise the Emerging risks in NBT/Gene Editing becoming cheap, easy and open for many users who may not be as competent as others.**

- A new scale of risk is created by an environment of easy, cheap gene editing where competency and risk-taking are even more in need of oversight and regulation.
- The changing environment of Gene Editing as 'cheap', 'fast', 'easy' (and official assumptions that they are precise and without safety relevance) is expanding the range of risk
- Commercial pressure for innovation is creating a new level of risk appetite for NBTs to be rapidly deployed and costs reduced by exempting them from regulatory oversight, safety evaluation, tracking/labelling, and liability.
- FSANZ's own consumer-citizen reports show this commercial risk appetite is NOT shared by the public.
- The public do not want these risks to be ignored or transferred from the producer/manufacturer to the consumer, farmers or the environment.
- Public Trust and confidence is necessary, with lessons in the Covid 19 response for the importance of independent regulation, testing, rapid genome sequencing, clinical trials and monitoring.
- FSANZ proposal to rely on producers to screen products for undesirable qualities is wholly inadequate and makes the future food system vulnerable.
- Gene Editing NBTs are promoted as more targeted than mutagenesis but should also be recognised to potentially much more disruptive of key parts of a genome than mutagenesis. NBTs provide the capacity to override preserved areas of the genome that are (for some reason) resistant to damage through mutagenesis.
- Use of NBTs may expand beyond current professional developers with an expansion of risk as less competent and less responsible users apply Gene Editing as it becomes ubiquitous, 'cheap' and 'easy'.
- However tools for FSANZ to properly regulate are also cheaper and easier - including genome sequencing and Omics, and data management for product registers.
- A mandatory register of products from NBTs processes will support Intellectual Property systems, downstream tracking and research across government and civil society to monitor and understand the impact of novel introductions into the existing varied gene pool.

**Similarity of a product of NBT to a conventional bred product is inadequate for FSANZ to justify exemption of the NBT product.**

- Gene Editing techniques are new and rely on cell processes of gene repair that are not yet fully understood. FSANZ and industry point of view is that Gene Editing is precise and controlled. By nature of the techniques being used, this cannot always be the case, with

unexpected outcomes from the NBT processes.

- FSANZ believe the use of a Gene Editing process is irrelevant for safety purposes if the end product is 'the same', concluding that current and future NBT products require no additional oversight. This view is flawed and ignores important lessons from current peer reviewed science on unpredicted and off-target effects in the gene repairs in NBTs.
- Unexpected genomic changes may have occurred and any exemptions would leave safety implications beyond scope. Such off-target outcomes cannot be assumed always to be negligible for safety and must be considered by FSANZ, even if a product is on the surface similar to a natural product.
- FSANZ should keep 'process' as their trigger and should not exempt any more NBT products from risk assessment by simply 'redefining' the inconvenient as 'not gene technology' (as lead to FSANZ exemption for SDN-1)
- FSANZ should keep a more expansive process-based trigger reject the exemptions, (and not use the flawed USDA definition which undermines this)
- **Taking account of the public/ citizen/ consumer values and expectations, we reject FSANZ's belief that NBTs with outcomes 'similar to nature' are reason enough to ignore the potential for unexpected off-target gene editing process itself and for exemption.**

### **FSANZ Must Learn the Right Lesson from the Commercialisation of Gene Edited Polled Cattle. The lesson is to check gene edited genomes before, NOT after an approval.**

- FSANZ's consultation document mentions but fails to grasp the importance of finding unexpected changes such as those in Gene Edited Polled Cows. These were found *after* commercialisation.
- FSANZ are missing the lesson if they assume future errors can be similarly 'fixed up' afterwards.
- FSANZ is wrong to accept such risks (based on hope of *later remediation to remove the unwanted genetic material* as with the cows..)
- The lesson for food safety is that the PROCESS must trigger oversight for unexpected changes. This is important for food safety where issues cannot be remediated or are only identified after commercial release as a risk to public health.
- Future NBTs may also have different process and potential disruptions of genomes and also cannot be exempted from regulation.
- FSANZ has erred in approving all previous applications for GMO foods as 'overwhelmingly' safe, without requiring safety testing. (Although the limited current FSANZ safety process may still have given a degree of protection for public health by motivating applicants to avoid the worst /harmful products for approval. Exemptions must not be made that weaken this even further).

## **The Tools for FSANZ Regulation of Gene Editing are ALSO getting cheaper, faster, easier, and must be integrated into its process.**

- As gene editing is becoming cheaper, quicker, ('anyone can do it'), and so are the tools for regulation becoming cheaper for FSANZ and less onerous on applicants.
- Regulation is a cost of business that reassures the public of the integrity of the food system, especially as novel technologies are emerging.
- Regulation of NBTs and other GE/GM products is also a vitally important moderator of commercial risk-taking as innovative gene techniques exposes the public, commons or the environment to 'costs'.
- The benefits for genomic sequencing and omics as a standard practice in truly effective NBT/ GE/GMO regulation is detailed in the INBI submission.

## **Trade agendas, Industry views and limited technical specialist views must not dominate and demean the public expectation for Regulation of NBTs in FSANZ's current review and process.**

- FSANZ's Trade considerations and enabling industry/convenience should not trump the overarching importance of regulation that meets the needs of the citizen-consumer in Australia, New Zealand and in export markets overseas.
- Australia and New Zealand food exports are reliant on consumer impressions and our 'brand' reputation internationally. Safe food is of the utmost importance as an economic asset. Deregulation of gene editing in some countries should not be used as a trade-lever against Australia and New Zealand to prevent continuing regulating NBT and other products of gene editing to the high standards the public expect.

## **Recommendations: required action by FSANZ for inclusive definitions and no exemptions for NBTs for future food safety and public confidence:**

- FSANZ must prioritise consumer-citizen needs and the expectations that your own research shows for the baseline for acceptable regulation, safety testing, labelling and monitoring.
- Definitions should not allow exemptions from any NBTs from safety oversight and exemption from being listed on a register.
- FSANZ's previous exemption of SDN1 products should be reversed.
- Use of NBT *processes* should trigger safety oversight of all Gene Editing products, including those superficially similar to conventional breeding.
- NBTs as defined in FSANZ's proposal must not be given exemptions and must be subject to case by case safety evaluation.
- NBT product approval methodologies should require the use of tools such as genome sequencing and Omics as a basis for genuine safety assessment and approval by FSANZ of all products of gene technology.
- Products of NBT, other new gene editing and other GM technologies must be required to be listed on a *register*.

Thank you. Please keep AGEFC informed.