PSGR

Physicians & Scientists for Global Responsibility

September 8, 2024

Submission

Consultation: Proposal P1055 - Definitions for gene technology and new breeding techniques

Submitted to the:

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PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) works to educate the public on issues of science, medicine, technology (SMT). PSGR work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

3. The object of the Food Standards Australia New Zealand Act 1991 is to ensure a high standard of public health protection. The goals of FSANZ are to achieve:

(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.

Re: Second Call for Submissions: P1055 Definitions for gene technology and new breeding techniques

PREFACE

FSANZ questions revolve around an unsuitable 'regulatory outcome' that exclusively concerns the change of a proposed new definition, not whether the 'paradigm shift' proposed might impair officials to fulfill the obligations of Food Standards Australia New Zealand Act 1991 [hereafter, the Act]. Therefore, people outside the scope of questioning will be dismissed by FSANZ in their review of submissions, even if they speak to issues relevant to ensuring a high standard of health protection.

Further, PSGRNZ reluctantly considers that it is likely that FSANZ will also, as it has in the past, ignore or dismiss public input into this consultation through techniques that undermine people who discuss uncertainty and risk in relation to GMOs as they are out of scope with FSANZ chose line of questioning**.** FSANZ will then, as they have done previously, consequently dismiss and downplay themes which challenge the FSANZ new position of substantial equivalence for gene edited organisms not containing a detectable novel protein/s or detectable novel DNA. Our points follow.

· August 2018. 664 Submissions. Preliminary report: Review of food derived using new breeding techniques – consultation outcomes.

· November 2022. 1736 Submissions. The Stakeholder Feedback Summary Report. Proposal P1055 – Definitions for gene technology and new breeding techniques.

1. FSANZ has repeatedly failed to transparently disclose the balance of comment following the asking of questions in these last two NBT consultations. FSANZ does not report the number of approvals/ disapprovals from responses to the 2018 and 2021 proposal questions, and does not critically engage with expert comment or criticism.[1]

   FSANZ then contracted a University of Adelaide study[2] which conducted two online focus group with only 79 participants, where 33% considered the material to be biased in favour of gene technology. When asked about the Fact Sheet they were provided with, study participants noted they would prefer more information on risks. Participants were expected to judge different scenarios. Graphs were then designed which suggested most participants were 'generally positive' about the scenarios.

   Such in-depth work can be contrasted against FSANZ failing to disclose the weight of response when, for example, in the November 2022 review, after 1764 people participated in a FSANZ consultation.

2. FSANZ is undermining public trust when it claims to have consulted on their approach to claiming that GMOs that do not contain novel DNA or a novel protein are substantially equivalent to conventionally bred food, but do not quantify the weight of opinion, nor address issues of risk, raised by respondents.
3. This 2024 consultation is flawed in that it does not place consumer safety as a consultation outcome in a consultation that FSANZ itself states is a 'paradigm shift'. Rather FSANZ seeks approval on 'clarity' and other consultation questions that appear primarily designed to foster consent and make it difficult for people to contest the taken-for-granted as safe position of FSANZ. Such comments would likely be outside the scope and then be discounted because they have not directly responded to the submission questions.
4. FSANZ evades discussing uncertainty, risk and precaution. FSANZ has not articulated the changing nature of scientific information, nor disclosed any methodology for evaluating FSANZ's position on off-target risk from gene edited organisms.

   FSANZ has not conducted a risk assessment (RA), not methodologically reviewed the literature to ensure that their approach is unbiased. FSANZ have instead resorted to a proxy 'safety' assessment which is a distortion of regulatory RA convention.

5. FSANZ has questions relating to the 'food industry' – however this lumps industrial processed food producers working high volume, low margin products with artisan farmers, growers and producers marketing premium quality goods who lack industrial foods power, reach and turnover.

[1] E.g. discussed here: JR Bruning (September 7, 2024) Is our food safety authority failing the fairness and impartiality test? https://dailytelegraph.co.nz/opinion/is-our-food-safety-authority-failing-the-fairness-and-impartiality-test/

[2] Ankeny RA and Harms R (2021) Focus groups on consumers' responses to the use of New Breeding Techniques (NBTs) in food production. https://digital.library.adelaide.edu.au/dspace/handle/2440/137654

FSANZ does not acknowledge the price-premium when consumers recognise food is GMO-free, and the discounted prices that will be paid when consumers consider the food is tainted, or likely to be tainted with GMOs of an uncertain risk-status.

FSANZ should distinguish between conventional growers and farmers who are likely to benefit from case-by-case process-based risk assessment where GMOs are always transparently declared and industrial suppliers who will benefit from non-declaration.

6. FSANZ thus evades discussion which call attention to fundamental differences in the scale and pace of biotechnology development and the incentivisation of market release of patented GMO products that derive from stronger IP rights than developers using conventional breeding techniques can access.
7. FSANZ demonstrated in an as yet unpublished August 2, 2024 webinar that it has arrived at an internally agreed consensus position that unless a gene edited NBT contains novel DNA or a novel protein, it will be regarded as safe because any other genome alterations occur in nature (i.e. conventionally bred food products).

   It is likely, based on 2018 and 2022 summaries of feedback that FSANZ will resort to equivalent evasive tactics. These will discount public, including expert opinion**,** that contradicts FSANZ white papers which contain the reasoning which underpins FSANZ apparent internal consensus position.

8. The substantial equivalence claim is a technique historically applied by the biotechnology industry to infer that GMOs are as safe as conventionally bred foods. The technique enables regulatory authorities to avoid comprehensive risk assessment. Information and data which contradicts this viewpoint, which fails to address not only alterations at the biochemical level, but the potential for adverse off-target environmental effects, has been discounted and dismissed in the past.
9. FSANZ does not structure the questions to ascertain if respondents agree that this second round consultation will achieve the object of the Act. Their concern is narrow and unfit for policy-making.
10. FSANZ does not permit people to simply disagree with the proposed new definition, while it acknowledges that this a ‘paradigm shift’ in FSANZ’s regulatory approach to regulating and defining genetically modified organisms.
11. The questions in this consultation constrain the capacity for respondents to criticise broader claims and in-house reasoning that justify FSANZ paradigm altering regulatory approach, from process to outcomes based. The wording used does not clearly provide an avenue for the public to disagree with the new definition for genetically modified foods that would be inserted into the Code.

    By constraining question scopes to clarity on specific terms, and then shaping questions which involve asking for evidence that is difficult to access due to the absence of funding channels and policy to support such work, FSANZ have forced the public to respond in such a way that eliminates specific disagreement with their proposal and tacitly concurs with their position.

12. The text of this current consultation has been drafted so that FSANZ can claim that it has been consulted.

13. FSANZ does not permit people to talk more broadly of safety and risk. FSANZ controls the scope of response to reflect s.3(c) of the Act, but not s.3(a), (b) and (d). The questions in the consultation do not ask if the public and stakeholders consider that the intended regulatory outcome will ensure a high standard of public health protection.
14. Public health protection arises from FSANZ taking account of the full spectrum of hazard and risk. This has been 'written out' by FSANZ claiming that gene-edited food that does not result in a novel protein is not a GMO, and is therefore substantially equivalent to conventional food. FSANZ has then conducted a safety assessment as a proxy for a process-based methodological risk assessment which would follow established protocols.
15. FSANZ do not allow for uncertainty pertaining to known unknowns and unknown unknowns which may be revealed in future. Neither FSANZ nor expert communities, can know if novel proteins/metabolites are present, if genome changes are outside the consideration of the screening authority. Detection methods have a particular protein or compound in mind, and will not usually detect new substances (for example genetic contamination by foreign DNA).
16. Safety should always come first. Yet FSANZ regulatory outcome focuses on the biotechnology/GMO developer industry-friendly the definition for GM food, so that it will be easy to comply with and enforce, and is consistent. To all appearances, FSANZ hijacks the public purpose, while bending to accommodate industry/developer demands.

RESPONSE TO CONSULTATION QUESTIONS

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

This question does not address the primary object and the goals of FSANZ. Your first question should read, "Does the new definition fulfil the object and aims of the FSANZ Act 1991?"

Public opinion on FSANZ's claim of 'substantial equivalence' of GMOs (NBTs or null segregants) to non-GM food, has never been summarised, nor reasoning that contests the equivalence claim, impartially assessed by the authority. To claim that all gene edited food products not containing novel DNA or novel protein can be dismissed as having similar characteristics to conventionally-bred food and hence considered non-GM, is ignoring the published research that states the opposite.

FSANZ publications that treat NBTs as substantially equivalent to non-GM display extensive evidence of bias. Publications lead in with announcements of mutations, deletions etc. in conventional food by way of explanation. Even if mutations in NBT plants are of the type that could happen naturally, this doesn't mean it's acceptable, safe or desirable to deliberately create them rapidly on a large scale using NBT methods, without regulatory oversight. Naturally occurring mutations can be harmful, but do not occur with the frequency or on the scale of those from NBTs.

Technologies aimed at creating such mutations should be approached with great caution.

The scientific literature cited by FSANZ appears to be picked to suit a predetermined narrative.

Are officials unwilling to consider the literature[3] that contradicts their substantial equivalence claim? This includes information that suggests officials should:

(a) Examine the biochemical and physiological changes at the cellular level and gross morphology; and

(b) Consider the pace and scale of biotech release into the environment, and into food products.

The scale and pace at which biotechnology patenting is occurring,[4] presents risks that FSANZ has failed to address, even though this has been raised by submitters in previous consultations.[5]

This question fulfils 3(b) of the Act, the goal of achieving 'an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;'

This question does not ask if the new definition will ensure the best protection of public health, or if it will promote consumer confidence.

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

All gene tech foods, including NBTs, can be modified in intended and unintended ways, regardless of whether there is any novel DNA or protein present or not. DNA rearrangements and novel proteins may not be detected by usual methods.

Altered DNA methylation is an issue that needs to be seriously considered. This changes the properties of DNA. Likewise, post-translational modifications of proteins also need to be considered. If a protein folds in a different way or is modified by phosphorylation for example, it can take on new and sometimes harmful properties. Why have these factors not been considered? All foods that have been genetically manipulated need to be labelled for this reason.

The characteristics of gene technology, even from null segregants, allow people to create harm faster, even if benefits are created as well. The potential for harm increases with increased use of the technique, but safety does not. Regulations can control harm scaling of null segregants and labelling of them is essential.

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[3] Mesnage R et al (2016). An integrated multi-omics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process. Scientific Reports 6:37855. http://www.nature.com/articles/srep37855 (open access)

[4] Christoph Then, Andreas Bauer-Panskus und Ruth Tippe (June 2021) New GE and food plants: The disruptive impact of patents on breeders, food production and society https://www.testbiotech.org/wp-content/uploads/2021/06/Patents_on-new-GE.pdf

[5] **Heinemann J (2021). Submission on Proposal P1055 Definitions of Gene Technology. https://hdl.handle.net/10092/103141**

Concerns about the potential for uncontrolled spread of GMOs into the environment also need to be addressed. [6] Contamination of non-GM crops with related GM crops (via pollen or seed, for example) will result in new organisms.

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

Please see question 1b.

Novel DNA is not the only concern. Mutations and other DNA damage can occur after genetic manipulations. Unintended modifications need to be taken into account. What the cellular machinery does to repair the DNA after gene rearrangements is unpredictable and cannot be controlled.

FSANZ has not considered ongoing discussion and debate in Europe. European Commission decisions regarding GMOs have been consistently more public health protective than North American decisions.

> 'On 5 July 2023, the European Commission proposed a regulation to distinguish certain NGT plants covered by European legislation on GMOs (Directive 2001/18/EC), as they could be considered equivalent to plants produced using conventional techniques. The equivalence criteria proposed for these so-called category 1 plants have been examined by ANSES with the support of its group of experts dedicated to biotechnologies, based on the proposed regulation, its Annex I and the technical document distributed by the Commission on 16 October 2023.'[7]

The French Health Agency ANSES' then published an opinion on methods for assessing the health and environmental risks and socio-economic issues associated with plants obtained using certain new genomic techniques (NGTs).[8] Even though this is a relevant text for the 2024 FSANZ consultation, it has not been mentioned by FSANZ.

ANSES states that it is not just the size and number of the genetic modifications that is important, but also what they do, i.e. their functional consequences. Knowing the size and number of intended mutations tells you nothing about this. Based on 10 cases studies of existing NBT-derived plants, ANSES has written that 'certain potential risks appear repeatedly in these case studies' and that '[t]hese include risks linked to unexpected changes in the composition of the plant, which could give rise to nutritional, allergenicity or toxicity problems, or to medium-

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[6] **Koller F., Cieslak M., Bauer-Panskus A. (2024) Environmental Risk Assessment Scenarios of Specific NGT Applications in Brassicaceae Oilseed Plants. Preprint, https://doi.org/10.20944/preprints202402.0255.v2**

[7] ANSES Press Release December 21, 2023. Plants derived from new genomic techniques: analysis of category 1 inclusion criteria proposed by the European Commission https://www.anses.fr/en/content/plants-derived-new-genomic-techniques-analysis-category-1-inclusion-criteria-proposed

[8] OPINION of the French Agency for Food, Environmental and Occupational Health & Safety on methods for assessing the health and environmental risks and socio-economic issues associated with plants obtained using certain new genomic techniques (NGTs). January 22, 2024. French Agency for Food, Environmental and Occupational Health & Safety. https://www.anses.fr/fr/system/files/BIORISK2021SA0019EN.pdf

and long-term environmental risks, e.g. the risk of gene flow from edited plants to compatible wild or cultivated populations.

The European Food Safety Authority's GMO Panel then largely dismissed the policy-relevant context which and cautionary messaging by a key EFSA reference agencywith the GMO Panel concluding[9]:

> '...that the available scientific literature shows that plants containing the types and numbers of genetic modifications used as criteria to identify category 1 NGT plants in the European Commission proposal do exist as the result of spontaneous mutations or random mutagenesis. Therefore, it is scientifically justified to consider category 1 NGT plants as equivalent to conventionally bred plants with respect to the similarity of genetic modifications and the similarity of potential risks.'

The EFSA panel has adopted a stance very similar to that of FSANZ, writing out the concerns and uncertainty relating to NBT risk.

Neither FSANZ nor EFSA addresses potential risk of knockouts of miRNA which can impact plant development, plant architecture and alter how plants respond to environmental stimuli.[10]

FSANZ discussion covers alterations (such as deletions and insertions) in chromosomes that may be found in naturally bred organisms but there are examples which are rarely seen in plants when conventionally bred. However, some papers have not been considered by FSANZ.[11] [12] [13] Chromosomal rearrangements may be introduced intentionally or may be unintended.

The European process is far from over[14]. FSANZ should not lock in regulations that might be less stringent, weaker and less protective of health, without first waiting for European regulations to be finalised.

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

It should not, given the points made in Q 1b and 2 a.

The changes that FSANZ has made to the definitions and the exemptions around NBTs and

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[9] EFSA (June 2024) Scientific opinion on the ANSES analysis of Annex I of the EC proposal COM (2023) 411 (EFSA-Q-2024-00178).
[10] Testbiotech (2024b) NGT plants of the future: EFSA overlooked most powerful and risky applications, https://www.testbiotech.org/wp-content/uploads/2024/04/2024-04-19_presentation_Dr-Christoph-Then.pdf
[11] Liu J, Wang FZ, Li C, Li Y, Li JF (2023) Hidden prevalence of deletion-inversion bi-alleles in CRISPR-mediated deletions of tandemly arrayed genes in plants. Nat Commun. 25;14(1): 6787. https://doi.org/10.1038/s41467-023-42490-1
[12] Rönspies M, Dorn A, Schindele P, Puchta H. (2021) CRISPR-Cas-mediated chromosome engineering for crop improvement and synthetic biology. Nat Plants, 7(5):566-573. doi: 10.1038/s41477-021-00910-4.
[13] Samach A., Mafessoni F., Gross O., Melamed-Bessudo C., Filler-Hayut S., Dahan-Meir T., et al.(2023) CRISPR/Cas9-induced DNA breaks trigger crossover, chromosomal loss, and chromothripsis-like rearrangements. Plant Cell, 35(11): 3957-3972. https://doi.org/10.1093/plcell/koad209
[14] EU's food watchdog dismisses concerns over gene-edited crops proposal amid Council deadlock https://www.euractiv.com/section/agriculture-food/news/eus-food-watchdog-dismisses-concerns-over-gene-edited-food-proposal-amid-council-deadlock/

gene edited organisms will not provide consumers with adequate information to enable them to make informed choices. The public will have no knowledge about possible harmful components in their food derived from this class of GMOs.

The changes also are in direct contravention of the Ministerial Forum members. It is the duty of FSANZ, 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 Heirarchy'.

Plant, animal and microbial genomes are incredibly complex. No gene works in isolation. Entire networks of pathways are occurring and if one piece of DNA is altered, including by deletions, inversions etc., the whole cell and hence the whole organism is altered. This cannot necessarily be controlled.

Novel DNA is not the only concern. Mutations and other types of DNA damage can occur after recombinant genetic manipulations. Unintended modifications need to be taken into account. What the cellular processes do to repair the DNA after gene rearrangements/deletions/insertions is unpredictable and could result in the production of new and unexpected plant toxins, allergens or carcinogens. A minor change in molecular structure can result in a harmless plant compound becoming toxic.

We quote European organisation Testbiotech[15]:

> Several publications show that CRISPR/Cas gene scissors are a highly effective tool for knocking out genes coding for so-called micro-RNAs (miRNA). The miRNA molecules regulate various complex functions in regard to, e.g. growth, development and stress responses. Just a few changes in the genes producing miRNAs can cause profound in-depth changes in plant metabolism, involving regulatory networks of hundreds of genes. Nevertheless, EFSA has failed to consider any of these applications in its opinions on NGT plants.
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> Knock-out of miRNA genes is practically impossible to achieve with conventional breeding methods due to the genome organisation in plants. In the past, similar effects were only achieved in transgenic plants. However, CRISPR/Cas has proved to be much more efficient at targeting several miRNA genes simultaneously.
>
> The depth of intervention from miRNA genes being knocked out was shown, for example, in rice: Chinese and US researchers (Zhou et al., 2022) [16] used CRISPR/Cas to knock out two genes of a family of miRNA genes involved in growth and development as well as in plant-pathogen interaction. They observed changes in expression of 119 miRNAs and further 763 genes coding for proteins. The authors state that their results could be directly translated into the breeding practice that may face less regulatory burden than transgenic plants in

[15] Testbiotech. April 17, 2024. Press release: NGT plants: EFSA overlooked most powerful and risky applications Testbiotech warns EU Commission and Parliament of severe consequences. https://www.testbiotech.org/en/news/ngt-plants-efsa-overlooked-most-powerful-and-risky-applications/

[16] Zhou, J., Zhang, R., Jia, X., Tang, X., Guo, Y., Yang, H., Zheng, X., Qian, Q., Qi, Y. and Zhang, Y. (2022) CRISPR-Cas9 mediated OsMIR168a knockout reveals its pleiotropy in rice. Plant Biotechnol. J., https://doi.org/10.1111/pbi.13713

many countries.

Currently, transgenic plants with a knock-down in miRNAs genes have to undergo mandatory risk assessment before they are released. This would, however, not necessarily be the case for plants obtained from NGTs if the proposed EU Commission and EU Parliament plans for deregulation are accepted: the genetic changes needed to knock-out miRNA genes are a perfect match for the loopholes in the proposals for deregulating NGT plants. Consequently, NGT plants with new traits but also high risk characteristics could be released into the environment without first undergoing mandatory risk assessment.

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

No. Any food with NBTs and null segregants as ingredients should still be labelled, because of points made in Qs 1b, 2a and 2b

This biased, industry-friendly question does not permit respondents to directly talk to the incorrect stance FSANZ is taking through the substantial equivalence, and outcomes-based proposal.

We are confident that FSANZ has not invited Professor Jack Heinemann, Director, Centre for Integrated Research in Biosafety (INBI) to discuss with staff the reasoning behind the 2023 paper *Are null segregants new combinations of heritable material and should they be regulated?*[17] If staff are too busy we also have a handy podcast interview which they can listen to while in traffic.[18] This is not referenced in the 2024 paper even while it is directly relevant to the matter at hand. We quote:

'In the same way that genome editing reactions increase the efficiency (a term we prefer over the less precise term precision) of achieving a desired outcome in a target genome, they also increase the efficiency of reacting at other locations in the genome. The reactions are not actually between a lock and a key, but between molecules with a range of binding affinities (Kawall, Cotter, and Then, 2020). Although those reactions will be biased toward the characteristics of the target location and, therefore, less 'random', the secondary targets are still largely beyond our ability to comprehensively identify in advance because they are influenced by biophysical parameters at the nanoscale. Moreover, the active ingredients such as the nuclease or oligonucleotide may persist in a cell long after the cell has lost the preferred binding site. Once the primary site has been changed, the conditions shift to favour activity at secondary sites.

The issue of off-target effects has dogged gene technology since the first claims of it being more precise than other tools, including other tools of gene technology. In his 1959 Nobel lecture, Joshua Lederberg described this kind of biotechnological imaginary, calling it the ignis fatuus of genetics; 'the specific mutagen, the reagent that would penetrate to a given

[17] Heinemann JA, Clark K, Hiscox TC, McCabe AW and Agapito-Tenfen SZ (2023), Are null segregants new combinations of heritable material and should they be regulated? Front. Genome Ed. 4:1064103. doi: 10.3389/fgeed.2022.1064103
[18] JR Bruning and J Heinemann (2023) Biotechnology - Risk that scales up as efficiency increases. Heinemann on risk management & policy. https://open.spotify.com/episode/43pOIhFyKGYingZKY8Ftby

> gene, recognize it, and modify it in a specific way' (Lederberg, 1959). Considerable effort has been expended to deliver on the implications of precision—that is, precision not only in a more efficient generation of intended on-target changes as in Lederberg's description but also in the near or total absence of unintended on- and off-target changes. This has yet to be achieved.
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> …
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> In general terms, we find support for the conclusion of the Academy of Science of South Africa (ASSAf, 2016) and the Australian decision (Jenkins et al., 2021) that regulatory triggers aligned to limit the potential harm in using gene technology (which are often called process-based) have proven to be effective and flexible. That is only possible, however, if the process is concluded with a case-by-case risk assessment.
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> …
>
> Deregulation of a class of GMOs such as null segregants makes some uses of gene technology unaccountable to public oversight. Null segregants do not exist until they are proven to exist by demonstration that the final organism is reset to its non-modified parental state.'

Consideration of costs and benefits (SD2)

Q 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?

Consumers actively discount GMO, including gene edited food. Australian and New Zealand families have to date, recognised that they could avoid GMOs because of stringent labelling laws.

As consumers actively discount GMO food as they want to avoid it,[19] [20] [21] [22] [23] [24] [25] [26] consumers will now have to seek out food that specifically has a non-GMO label or that is organic.

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[19] France and USA. Stéphan Marette, Anne-Célia Disdier, John C. Beghin, A comparison of EU and US consumers' willingness to pay for gene-edited food: Evidence from apples, Appetite, doi:10.1016/j.appet.2020.105064.
[20] Japan. Akihiro Mine, Sawako Okamoto, Tomoya Myojin, Miki Hamada, Tomoaki Imamura. (2023) Willingness of Japanese people in their 20s, 30s and 40s to pay for genetically modified foods (Preprint). doi: 10.1101/2023.10.29.564581
[21] Russia. Anthony R. Delmond, Jill J. McCluskey, Mirzobobo Yormirzoev, Maria A. Rogova, (2018) Russian consumer willingness to pay for genetically modified food, Food Policy, doi: 10.1016/j.foodpol.2018.02.004.
[22] China. David L. Ortega, Wen Lin, Patrick S. Ward, (2022) Consumer acceptance of gene-edited food products in China, Food Quality and Preference. doi: 10.1016/j.foodqual.2021.104374.
[23] Vietnam. Tong, Yen Dan Khuu, Dong Toan, Truong Duc Nguyen, Phuong Duy Pham, Nhai (2021) Consumer Responses Towards Non-GM Food: Evidence From Experimental Auctions In Vietnam. *International Journal of Food and Agricultural Economics.* doi: 10.22004/ag.econ.316274
[24] Martin-Collado D et al (2022) Gene-Edited Meat: Disentangling Consumers' Attitudes and Potential Purchase Behavior https://www.frontiersin.org/journals/nutrition/articles/10.3389/fnut.2022.856491/full
[25] Koralesky KE, Sirovica LV, Hendricks J, Mills KE,von Keyserlingk MAG,Weary DM (2023) Social acceptance of genetic engineering technology. PLoSONE 18(8):e0290070. doi:10.1371/journal.pone.0290070
[26] Australia. (2022) P1055 – Consumer Survey Report Consumers' perceptions of and attitudes towards genetically modified foods. FSANZ https://www.foodstandards.gov.au/sites/default/files/2024-01/P1055%20Consumer%20Survey%20Report.pdf

It is astonishing that such considerations were not in FSANZ Cost-Benefit analysis.

FSANZ proposal will have the effect of redirecting the cost of proving safety to the consumer, as there is a cost margin in purchasing foods with non-GMO/organic accreditation.

FSANZ has failed to consider the health-based risk from unknown health impacts that families with infants and young children must take into account on a daily basis, because of the greater vulnerability of developing bodies and minds.[27] This is why families and people who are unwell may prefer GMO-free food.

The approach of FSANZ locks in the definition GMO that precludes case-by-case risk assessment and makes it easier for authorities to ignore new evidence of risk, such as allergens being produced in NBTs. [28]

For example, a protein produced by GM crops and approved for inclusion in ultra-processed foods and animal feed is the Cry1Ac toxin, a biopesticide expressed in GM Bt crops for human and animal consumption. This protein is widespread in many foods, coming from GM corn, soy or cottonseed oil, for example.

In this study, groups of mice immunised with the Cry1Ac protein developed moderate allergic reactions. Significant IgE responses were recorded and there were increased frequencies of intestinal granulocytes, IgE eosinophils and IgE+ lymphocytes.

These same groups of mice also showed colonic lymphoid hyperplasia. This condition in humans has been associated with food allergies and intestinal inflammation. Both of these health issues are widespread in populations around the world.

Cry1Ac is also able to induce anaphylaxis in mice. The same could happen in humans.

Whilst Cry1Ac is a new protein introduced by the GM process, it is a protein that is present in low levels in a non-GM form, on organic food that has been sprayed with Bt formulations. Such low levels of the non-GM bacterial form of this protein are not regarded as problematic to human health. Therefore, one can assume that the allergenicity is associated with the GM (gene-tech) process and higher concentrations of the biopesticide.

All DNA manipulations, including NBTs and null segregants, have the potential to produce unintended effects on the metabolism of the cell and the whole organism, changing biochemical and physiological characteristics.

Q 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.

FSANZ has failed to consider the economic advantage to farmers and growers that can be

[27] Barouki R, Gluckman PD, Grandjean P, Hanson M, Heindel JJ. Developmental origins of noncommunicable disease: implications for research and public health. Environ Health. 2012;11:42

[28] Santos-Vigil et al (2018) Study of the allergenic potential of Bacillus thuringiensis Cry1Ac toxin following intra-gastric administration in a murine model of food-allergy. Int. Immunopharmacol. 61:185-196

gained from New Zealand's current non-GM food production status.

FSANZ should be well aware that people generally avoid GMO food where possible, and prefer to pay more for GMO-free or non-GM food.[29] [30] [31] [32] [33] [34] [35] [36]

The failure of FSANZ to consider the economic advantage of growing non-GMO food renders the 'Cost and Benefit' analysis faulty, misleading, and unfit for purpose as a policy-document.

A regulatory situation may increase the supply of releases into the environment. ANSES noted (page 20):

> 'the supply of such plants and products may nevertheless be indirectly impacted by the regulatory situation. Indeed, changes in the regulations can influence patenting decisions, depending on whether they are perceived as flexible or rigid by biotechnology companies.'

Q 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?

New Zealand's science funding priorities direct funding towards development of innovations that will result in patents.

FSANZ disingenuously and misleadingly asks a question that is impossible to answer effectively because it merges the 'food industry' into a single entity.

We consider that in the Cost and Benefit document, FSANZ has failed to consider different stakeholders, who may be differentially affected by weaker regulations. These in turn support the biotechnology corporations whose position mirrors the FSANZ perspective.

FSANZ should be aware of the absence of long-term funding to research and assess impacts that would differentiate between, e.g., the fast-moving consumer goods (FMCG), ultra processed food sector that stands to gain the most from NBTs not being declared. Avoiding this labelling regulation would also benefit the high value nutritional compounds and products industry. These products are marketed as providing health benefits, but contain GMOs. They differ from

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[29] France and USA. Stéphan Marette, Anne-Célia Disdier, John C. Beghin, A comparison of EU and US consumers' willingness to pay for gene-edited food: Evidence from apples, Appetite, doi:10.1016/j.appet.2020.105064.
[30] Japan. Akihiro Mine, Sawako Okamoto, Tomoya Myojin, Miki Hamada, Tomoaki Imamura. (2023) Willingness of Japanese people in their 20s, 30s and 40s to pay for genetically modified foods (Preprint). doi: 10.1101/2023.10.29.564581
[31] Russia. Anthony R. Delmond, Jill J. McCluskey, Mirzobobo Yormirzoev, Maria A. Rogova, (2018) Russian consumer willingness to pay for genetically modified food, Food Policy, doi: 10.1016/j.foodpol.2018.02.004.
[32] China. David L. Ortega, Wen Lin, Patrick S. Ward, (2022) Consumer acceptance of gene-edited food products in China, Food Quality and Preference. doi: 10.1016/j.foodqual.2021.104374.
[33] Vietnam. Tong, Yen Dan Khuu, Dong Toan, Truong Duc Nguyen, Phuong Duy Pham, Nhai (2021) Consumer Responses Towards Non-GM Food: Evidence From Experimental Auctions In Vietnam. *International Journal of Food and Agricultural Economics.* doi: 10.22004/ag.econ.316274
[34] Martin-Collado D et al (2022) Gene-Edited Meat: Disentangling Consumers' Attitudes and Potential Purchase Behavior https://www.frontiersin.org/journals/nutrition/articles/10.3389/fnut.2022.856491/full
[35] Koralesky KE, Sirovica LV, Hendricks J, Mills KE,von Keyserlingk MAG,Weary DM (2023) Social acceptance of genetic engineering technology. PLoSONE 18(8):e0290070. doi:10.1371/journal.pone.0290070
[36] Australia. (2022) P1055 – Consumer Survey Report Consumers' perceptions of and attitudes towards genetically modified foods. FSANZ https://www.foodstandards.gov.au/sites/default/files/2024-01/P1055%20Consumer%20Survey%20Report.pdf

similar high value nutritional compounds and products that are known to be non-GMO.

The agricultural sectors who may be particularly concerned with NBT technologies are depicted in this diagram[37]:

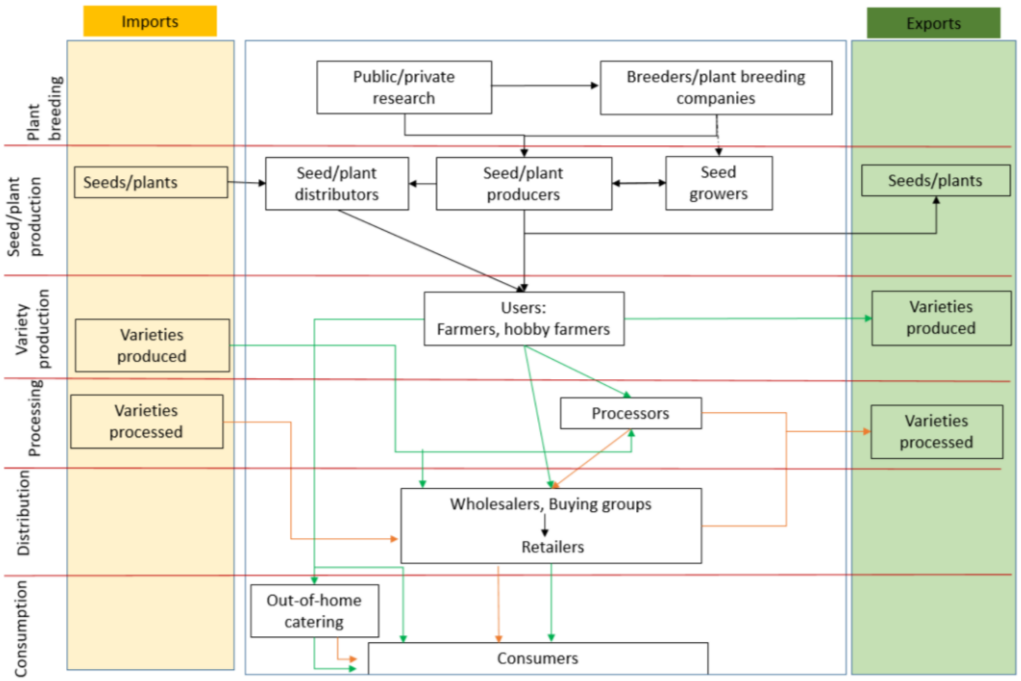
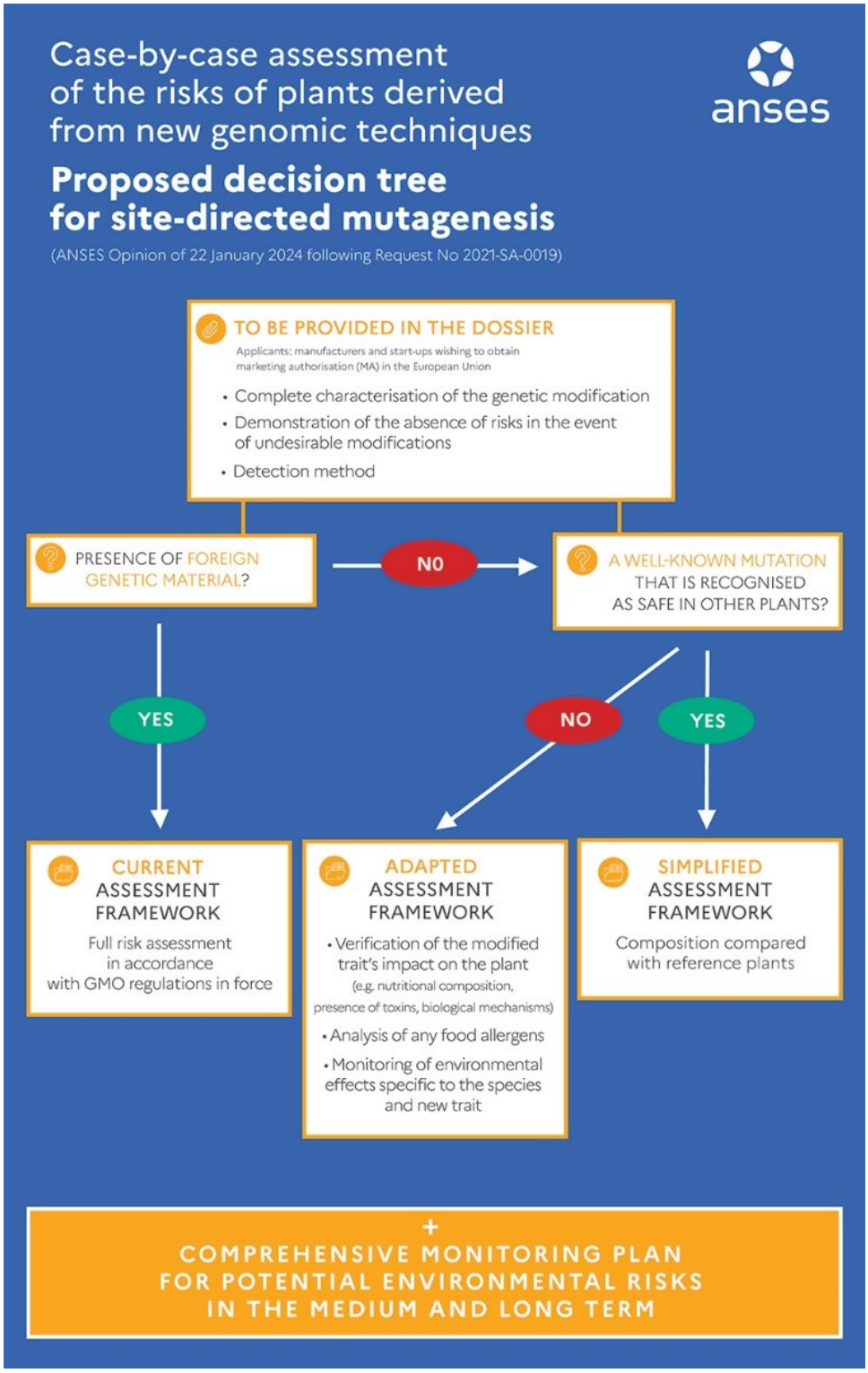


Figure 3. Conceptual diagram of the value chain for the selected varieties. The arrows show the links between the different groups of stakeholders from the upstream stage of variety production to the last link in the value chain. The black arrows represent transactions involving seeds, the green arrows transactions involving products derived directly from seeds, and the orange arrows transactions involving processed products.

[37] OPINION of the French Agency for Food, Environmental and Occupational Health & Safety on methods for assessing the health and environmental risks and socio-economic issues associated with plants obtained using certain new genomic techniques (NGTs). January 22, 2024. French Agency for Food, Environmental and Occupational Health & Safety. Page 18 https://www.anses.fr/fr/system/files/BIORISK2021SA0019EN.pdf

Q 7. Have all the major impacts to the food industry 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.



No. It is not the job of the public to provide FSANZ with studies on this topic, or any other.

It is the job of FSANZ to prove to us that their proposal will protect the health and well-being of the public and maintain "a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand.", as stated in the FSANZ Act 1991.

This is the reason that FSANZ exists - no other reason. The questions in this document do not address the most fundamental issue - food safety.

We recommend that there be broader consultation to consider the ANSES recommendation of decision-trees, which will assist to quantify impacts.[38]

[38] ANSES (July 3 2024) New genomic techniques (NGTs) : ANSES calls for appropriate regulations. https://www.anses.fr/en/content/ntg-en

ANSES provides a diagram (Figure 4)[39] to help authorities consider the value chain and how different stakeholders may be impacted in different ways:

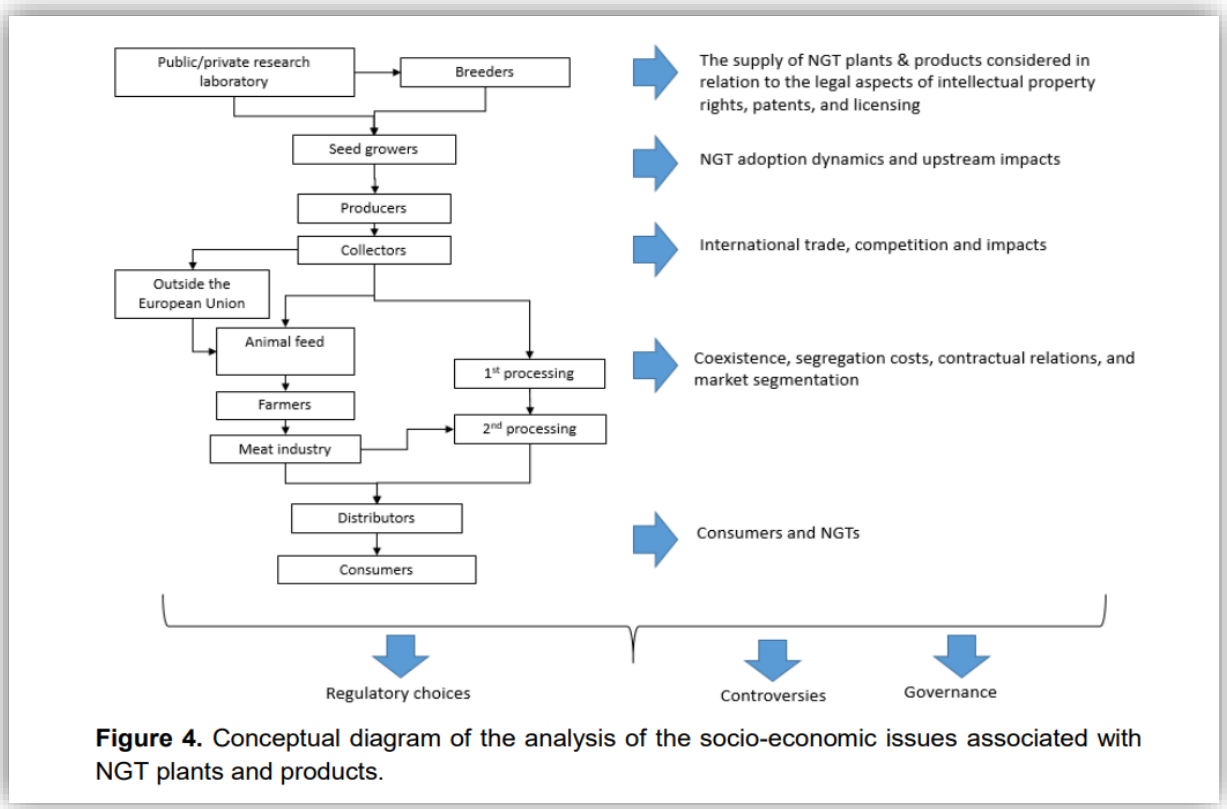


Figure 4. Conceptual diagram of the analysis of the socio-economic issues associated with NGT plants and products.

ANSES states:

> 'Figure 4 shows the main points that should be considered with regard to the economic and social impacts associated with the introduction of NGT plants and products (right-hand side of the figure). The available socio-economic literature is fairly limited and is largely made up of position papers focusing on the aims of these innovations instead of their impacts. Few empirical studies have been carried out to date.'

Q 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.

This consultation continues to repeat the same questions in different ways. There is no point to this.

How much does the healthy, clean safe food attributed to Australia and New Zealand erode over time as regulations like this pivot our standards to reflect low-bar economies such as North

[39] OPINION of the French Agency for Food, Environmental and Occupational Health & Safety on methods for assessing the health and environmental risks and socio-economic issues associated with plants obtained using certain new genomic techniques (NGTs). January 22, 2024. French Agency for Food, Environmental and Occupational Health & Safety. Page 20 https://www.anses.fr/fr/system/files/BIORISK2021SA0019EN.pdf

America, rather than stricter regulatory environments such as Europe? This cannot be clearly understood, as reputations erode slowly, and sometimes quickly, and damaged reputations can be difficult to resuscitate.

Once again, FSANZ should be providing us with studies and data to show, first and foremost, that public health and food safety are their top priority.,

There is no way we can assess impacts to the government, if the research has not been done to assess costs and benefits in such a way that it looks at the potential of long term risk. **FSANZ has also not acknowledged that uncertainty and precaution should be important considerations when public health, particularly that of vulnerable groups of people, such as pregnant mothers, infants and children, are taken into account.

The New Zealand government is incredibly focused on biosecurity. This consultation has failed to assess the risk to biosecurity. If the FSANZ claim of substantial equivalence were to be incorrect and NBTs were released into the environment, there would be a point in the future when such organisms could be deemed to present a biosecurity threat. Such a threat could be to the provenance of a related native species, or to the genetic integrity of key export crops. A change in the genetic integrity of these species could affect their capacity to be resilient in the face of any number of environmental variables.

APPENDIX

Table 3. Intended regulatory outcomes under the revised approach at 2nd CFS

Food or substance	Intended regulatory outcome
Food from an organism or cells that contains novel DNA in its genome	**GM food** unless subject to exemption
Processed food ingredients from an organism or cells that contain novel DNA in their genome	**GM food** unless subject to exemption
Food from a null segregant	**Not a GM food** (exempt)
Substances used as a food additive (FA), processing aid (PA) or nutritive substance (NS)	**Not GM food** (exempt) FA, PA and NS are subject to pre-market regulation under other parts of the Code
Food from a genome edited organism that does not contain novel DNA in its genome	**Not a GM food** May be subject to regulation as a novel food if the food is considered to have characteristics that warrant a safety assessment by FSANZ, having regard to criteria set out in subsection 1.1.2—8 of the Code
Food derived from the part of a grafted plant that does not contain novel DNA or novel protein	**Not a GM food** (exempt) May be subject to regulation as a novel food if the food is considered to have characteristics that warrant a safety assessment by FSANZ having regard to criteria set out in section 1.1.2—8 of the Code
Precision fermentation product from a microorganism that contains novel DNA in its genome	**GM food** unless subject to exemption
Cell-cultured food derived from a cell line that contains novel DNA in its genome	**GM food**
Substances used to support the growth and viability of cells or process cells in culture as part of the production of cell-cultured food	**Not a GM food** (exempt) Whether the substances are a FA, PA or NS will need to be determined on a case by case basis. FA, PA and NS are subject to pre-market regulation under other parts of the Code and are themselves exempt from the GM food definition.