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working for a GM-free future

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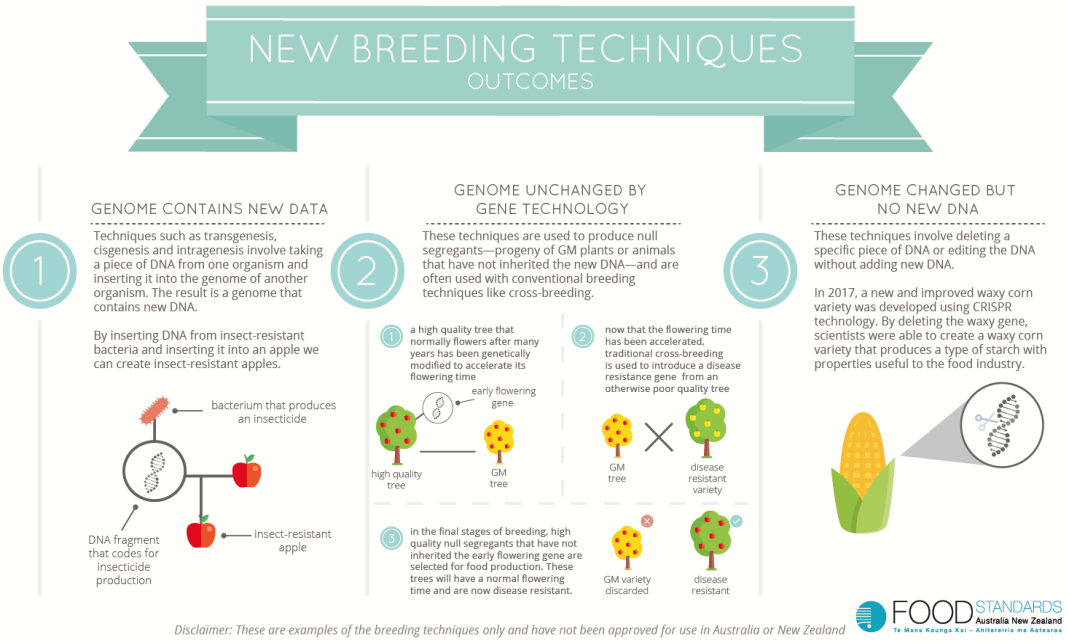
Re: Comments on FSANZ's NBT (new GM techniques) discussion document

Summary

- The conclusions of the 2012 and 2013 FSANZ workshops should be declared null and void;
- Genetic engineering science and its food products have evolved greatly since 2013;
- The workshop reports offer no scientific evidence for their findings or conclusions and are well out of date but FSANZ seeks to use them to back deregulation. Begin the process again;
- FSANZ's chosen panelists have conflicts of interest as they are associated with the global scientific establishment, and GM and agrochemical companies, that back deregulation;
- FSANZ excluded independent scientists and interested public, with a broad range of knowledge, critical views and scientific expertise e.g. public health, epidemiology, human ecology, etc;
- FSANZ fails to explain or credibly justify the reasoning and evidence for its case to deregulate;
- FSANZ secretly maneuvered, over at least the past six years, to prepare for the deregulation of foods derived from the many recently invented and new Genetic Manipulation (GM) techniques;
- FSANZ and the Food Forum amended the code, to deregulate new GM techniques and their food products which alter genomes but may not insert foreign DNA, so are not strictly 'transgenic';
- Without producing evidence, this 'consultation' seeks to move FSANZ's onus of proof onto the public, to make us justify notification, assessment, regulation and monitoring of new GM foods;
- We reject the unreasonable standards of proof that FSANZ imposes on the interested public;
- FSANZ disingenuously uses the term New Breeding Techniques (NBTs), that is industry spin;
- All submissions to this consultation should be published so the process is open and transparent;
- The Precautionary Principle sets the default position at all foods and food ingredients derived from new GM techniques being notified to FSANZ, then assessed, regulated and monitored.



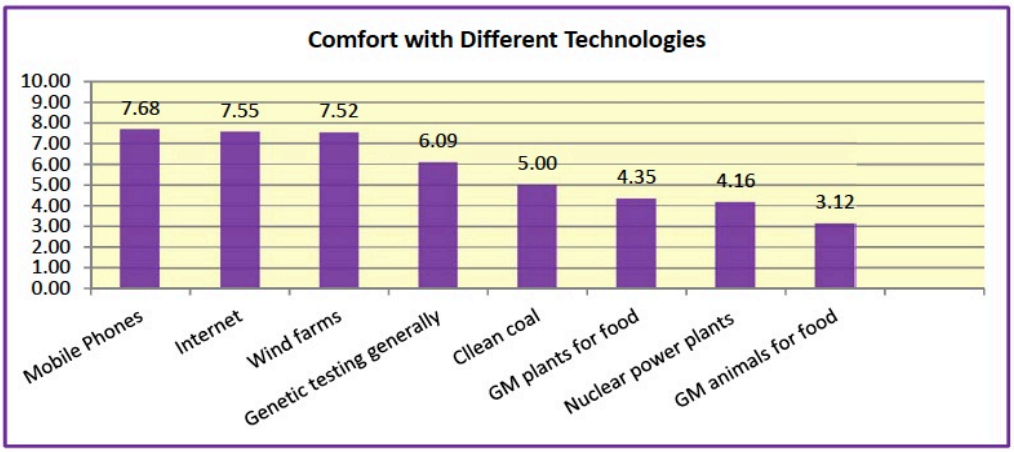
FSANZ's promotional "NBT banner"[1] purports to display and justify its proposal to deregulate many new GM techniques and their food products, exempting them from notification, assessment, regulation, approval/licensing, or monitoring. It proposes to deregulate, without scientific justification, evidence, or a history of safe use, some items in Section 1 and all in Sections 2 & 3.

1 NBT banner. http://www.foodstandards.gov.au/consumer/gmfood/PublishingImages/NBT%20banner.png

What may be in the new GM pipeline

The pipeline for organisms created using the new GM techniques (so-called gene-editing or NBTs) may soon be crowded with animals, plants and microbes designed for many purposes, including food. Yet FSANZ naively and recklessly proposes deregulation of most foods made using the new GM techniques, even in the face of many imminent intrusions into the global human food supply. FSANZ's documents and processes focus on GM plants, sidelining the more controversial animals and microbes.

Over several years, Swinburne University's Annual Technology and Society Monitor finds Australians are very uncomfortable with GM animals for food and are only slightly more disposed to eat GM plants. FSANZ and the Food Forum must be responsive to these persistent public sentiments, but are not.



[2]

Plants

In the USA new GM crops include Cibus's canola; Calyxt's "high oleic soybean"; and the Corteva Agriscience's (Dow DuPont) waxy corn, to be used in soups and salad dressings. The company says they, "will likely be the first commercial product for agriculture and potentially the first product to market for any [CRISPR] application."[3] Seventy-five farmers will grow Calyxt's soybean, created using TALEN techniques, on "over 16,000 acres" in the Midwest USA this year.[4] Other projects are at various stages in different research and development pipelines, using the bracketed new GM techniques, including,

- Corn with reduced phytate production (ZFN/SDN)
- Rice with disease resistance (TALEN/SDN)
- Non-browning white button mushrooms (CRISPR/SDN)
- Wheat with improved powdery mildew-resistance (TALEN/SDN)
- Drought and salt tolerant soybean (CRISPR/SDN)
- Alfalfa with improved nutritional content (TALEN/SDN)

Animals

If new GM techniques such as CRISPR were deregulated, Australia would be the first country to deregulate GM animals. The US Government proposes to regulate the new GM techniques used in animals, and New Zealand says it will regulate the GM techniques in all organisms.[5] Other CRISPR projects in the pipeline are proposed to:

- increase the muscle mass of animals, make farmed animals less susceptible to disease, enhance their nutritional content, or create hornless cattle, though there are hornless breeds already.[6]
- promote muscle development and body growth in sheep,[7] and to increase wool length.[8]

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2 Bruce, G and Critchley, C. The Swinburne National Technology and Society Monitor, Department of Statistics, Data Science and Epidemiology Faculty of Health, Arts & Design Swinburne University of Technology, 2015

3 Brodwin, E. A controversial technology could save us from starvation — if we let it. April 12, 2018. Presented by the Bayer subsidiary BASF. http://www.businessinsider.com/crispr-genetic-modification-agriculture-food-2018-4?IR=T

4 Calyxt Exceeds Farmer Adoption Milestone for High-Oleic Soybean Product Launch, Minneapolis-St. Paul, Minn., April 5, 2018. http://www.calyxt.com/calyxt-exceeds-farmer-adoption-milestone-for-high-oleic-soybean-product-launch/

5 Maxmen, A. (2017) Gene-edited animals face US regulatory crackdown, Nature, doi:10.1038/nature.2017.21331 https://www.nature.com/news/gene-edited-animals-face-us-regulatory-crackdown-1.21331; Smith, N. (2016). GMO regulations clarified, 5/4/16, https://www.beehive.govt.nz/release/gmo-regulations-clarified-0

6 Caplan, A L, et al. No time to waste—the ethical challenges created by CRISPR, EMBO reports, 2015.

- house GM animals even more intensively without falling ill, including pigs immune to porcine reproductive and respiratory syndrome[9] and African Swine Fever.[10] Cattle resistant to Bovine respiratory disease are also being engineered.[11]
- 'humanize' the pig genome so that pigs can be used as organ donors for humans.[12]
- produce 'customised' laboratory animals such as mice. *Nature Biotechnology* reports, "Animal model providers and contract research organizations are witnessing a boom in demand as academic, biotech and pharma clients rush to embrace CRISPR-customized animal models."[13]

Microorganisms

FSANZ does not even mention microorganisms in its two workshop reports, its Submission to the Third Review of the National Gene Technology Scheme, or this consultation document. Yet many and various microorganisms - bacteria, viruses and fungi – will probably be manipulated with the new GM techniques for a wide variety of applications in the food industry. They may soon be ubiquitous but FSANZ studiously ignores them, presumably on behalf of the global GM and science industries.

One paper suggests, "the molecular machinery from these DNA-encoded, RNA-mediated, DNA-targeting systems can be harnessed in native hosts, or repurposed in engineered systems for a plethora of applications that can be implemented in all organisms relevant to the food chain, …"[14] An annual review, "introduces CRISPR-Cas as a novel set of technologies to manage food bacteria and offers insights into CRISPR-Cas biology."[15] Another review asserts, ""The genetic manipulation of probiotic microorganisms is crucial for defining their role in intestinal microbiota and exploring their beneficial properties." and, "an overview of proposed design of advanced customized … probiotics."[16]

New GM techniques and their products must all be safety assessed

To conform with its role and functions in the Australian and New Zealand food regulation systems, Food Standards Australia New Zealand (FSANZ) should present the option of mandating the notification, assessment, regulation, approval/licensing and monitoring of all new Genetic Manipulation (GM) techniques (e.g. CRISPR, RNA interference etc.) and their food products, without exception.

Regulation is the task and public responsibility that parliaments, the law and the communities of Australia and New Zealand delegate to FSANZ. Yet FSANZ proposes instead to shirk its responsibility. Without providing any supporting scientific or other evidence, it would prematurely and recklessly deregulate most of the new GM techniques and their food products, invented in just the past five years.

Basic risk research on the new GM techniques and their living products is scarce, and they have no history of safe use. The techniques can produce unexpected mutations in Genetically Manipulated Organisms (GMOs) so FSANZ must exercise caution, as the Precautionary Principle requires.

These techniques can be used to genetically manipulate any animal, plant or microorganism, raising serious potential risks that must be assessed. But FSANZ puts the primary focus on plants, as they may prove to be a little less contentious than GM animals and the GM foods they are used to produce.

Even the safety of transgenic GMOs and food derived from them is contested, with Krimsky and many

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7 Crispo, M. et al. Efficient Generation of Myostatin Knock-Out Sheep Using CRISPR/Cas9 Technology and Microinjection into Zygotes, PLOS ONE, DOI:10.1371/journal.pone.0136690, 2015.
8 Li, W-R. et al. CRISPR/Cas9-mediated loss of FGF5 function increases wool staple length in sheep, FEBS Journal, doi:10.1111/febs.14144, 2017.
9 Whitworth K M, et al. Gene-edited pigs are protected from porcine reproductive and respiratory syndrome virus. Nat Biotechnol 34:20–22, 2016.
10 Lillico S G, et al. Mammalian interspecies substitution of immune modulatory alleles by genome editing. Scientific reports 6:21645, 2016.
11 Teluga, B P. et al. Genome editing and genetic engineering in livestock for advancing agricultural and biomedical applications, Mamm Genome, DOI 10.1007/s00335-017-9709-4, 2017.
12 Smalley, E. (2016). CRISPR mouse model boom, rat model renaissance, Nature Biotechnology, 34(9):893-894.
13 Teluga, B P, et al. (2017)
14 Selle, K, and Barrangou, R. CRISPR-Based Technologies and the Future of Food Science, Journal of Food Science, 7 October 2015. https://doi.org/10.1111/1750-3841.13094
15 Stout E, et al. Annual Review of Food Science and Technology, Volume 8, February 2017, pp 413-437. https://www.annualreviews.org/doi/pdf/10.1146/annurev-food-072816-024723
16 Yadav, R, et al. Gene editing and genetic engineering approaches for advanced probiotics: A review, 21 July 2017. https://doi.org/10.1080/10408398.2016.1274877

others correctly asserting that politics and corporate interests have had a distorting effect on honest inquiry into the health effects of GMO crops.[17]

Krimsky concludes his comprehensive analysis of the evidence on GM food safety by saying,

> "When there is a controversy about the risk of a consumer product, instead of denying the existence of certain studies, the negative results should be replicated to see if they hold up to rigorous testing. This point was made by the 300 scientists who signed a joint statement that was published in *Environmental Sciences Europe*. The statement 'does not assert that GMOs are unsafe or safe. Rather the statement concludes that the scarcity and contradictory nature of the scientific evidence published to date prevents conclusive claims of safety, or lack of safety, of GMOs.'[18] Until the twenty-six studies, or at least the best of them, are replicated and shown to be false positives, we have an obligation to treat these studies with respect and concern."

It is fundamentally unsatisfactory that Australian Regulators use 'Regulatory Science' to make key decisions. For example, when reviewing its scientific strategy, the Australian Pesticides and Veterinary Medicines Authority (APVMA) wrote,

> "What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of existing scientific knowledge and, where necessary, **assumptions to address data gaps or uncertainty**. Regulatory scientists **do not generate new lines of enquiry to answer questions**, instead relying on available information (provided by applicants or in the literature) to make a decision one way or another."[19]

This passive, selective and uncritical approach allows applicants to submit a suite of sub-standard, unpublished and un-peer-reviewed information (not scientific evidence) in support of their claims for approval. The best-guess approach of using 'assumptions' to fill data and knowledge gaps, and resolve uncertainty, is so lacking in rigor that it has no credibility. All the regulators and their regulatory systems are cast into doubt. Failure to require additional, independently generated, data to generate essential knowledge and improve confidence in regulatory decisions is irresponsible and flouts their duty to protect the public interest. FSANZ has never seriously questioned or rejected any GM application put to it.

This public 'consultation' process is a sham

We expect FSANZ to be an objective and impartial referee on disputed issues, with its regulatory activities conducted at arms length from industry. But industry views FSANZ as a service provider and exercises undue influence over its decisions. Global agribusiness, food, GM and agrochemical corporations have captured government and our regulators with their deregulatory agendas, exposing the unsuspecting populace to additional risks, hazards and costs.

Yet FSANZ presents this review of its standards on new Genetic Manipulation (GM) techniques and processes (badged as 'New Breeding Techniques') and the foods they are used to produce, as a virtual fait accompli. They focus on the proposal to deregulate as just a technocratic, short-term safety, and risk-focused exercise. Regulating these novel processes and products with the precaution required demands a long-term future and visionary focus. The new GM techniques and their food products promise to rapidly multiply, diversify, and enter our food chain by stealth.

FSANZ's consultation document whitewashes the new Genetic Manipulation (GM) techniques and their products by using the global agrochemical industry's weasel term 'New Breeding Techniques', in place of a more apt 'new genetic manipulation or genetic engineering techniques'. This misleads the public. In the 1980s the global GM industry, science and the news media also coined the contrivance 'genetically modified'. With this fiction, they sought to justify the spurious claim that laboratory Genetic Manipulation is a mere extension of conventional breeding practices invented when agriculture began thousands of years ago. Not so, as traditional breeding never could have moved a genetic trait from fish to tomatoes.[20]

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17 Krimsky, S. An Illusory Consensus behind GMO Health Assessment, Science, Technology, & Human Values, 1-32 DOI: 10.1177/0162243915598381 http://journals.sagepub.com/doi/abs/10.1177/0162243915598381

18 Hilbeck et al. No Scientific Consensus on GMO Safety, Environmental Sciences Europe, 27 (4): 1-6, 2015.

19 APVMA Regulatory Science Strategy review, 27/2/16. https://apvma.gov.au/node/19226 (Submissions unpublished)

20 A cautionary tale: Fish don't lay tomatoes, A report on the Gene Technology Bill 2000, November 2000, Commonwealth of Australia 2000, ISBN 0 642 71094 5

The Wall Street Journal now reports how the same old PR spin on GM is being used for new GM techniques and their food products, and that, "The agricultural industry is working to persuade the public to distinguish between the newer gene-edited crops and traditional GMOs."[21]

That is what FSANZ's consultation document also seeks to do. This opportunity to comment on the FSANZ position is belated and attempts to gain public acceptance and a social license for decisions made in closed workshops that FSANZ convened in 2012 and 2013. At a minimum, the advice should have been available then, for wider consultation. The workshops included no members of the informed and interested public, nor experts with the more diverse expertise needed to critically review FSANZ's advice, plans and deregulatory intentions. At the least, public health specialists, epidemiologists, human ecologists, and other independent food-focused experts, should have been on the workshop panels.

Gene Manipulators were the only experts consulted. But they have a narrow range of technical expertise and a variety of professional and commercial conflicts of interest in new GM techniques and their food products, which FSANZ sought to justify in Senate Estimates hearings.[22] This was a gross breach of due process and the results of the workshops should therefore be null and void. Yet we are now encouraged to agree with their contested advice.

> These techniques can be used to genetically manipulate any animal, plant or microorganism, all living thing in the biological universe, raising serious potential risks that must be definitively resolved. But FSANZ puts the primary focus on plants, as they may prove to be a little less contentious than GM animals and the GM foods they are used to produce.

FSANZ appears to have passively, uncritically and totally accepted the advice of the biased expert panels as FSANZ advised the Minister that,

> "We have considered the key findings of the expert panel and concur with their conclusions regarding which foods should be regarded as GM food, and which should not."
>
> "Foods derived using oligo-directed mutagenesis, zinc-finger nuclease technology used to introduce small, site-specific mutations involving one or a few nucleotides, and seed production technology are not captured by the standard and therefore do not require pre-market approval."

FSANZ has already scripted a decision to deregulate these GM techniques in food and food products. So this first public process is irrelevant window-dressing that will leave FSANZ and the Food Forum immovable on anything but minor details and beyond other official scrutiny or review.

Members of the interested public are now invited to comment on and resolve FSANZ's technical questions posed in an unreferenced document. And FSANZ does not candidly disclose that it has already developed a deregulatory agenda in two closed workshops and through in-house processes, over the past six years. Even the workshop documents contain no scientific references that would show the evidence on which they relied for their conclusions that many of the new GM techniques and their food products can now be safely deregulated.

This public process is designed merely to defend and validate FSANZ's position, already agreed with the establishment scientists who participated in the process on behalf of global GM and agrochemical industries. This approach to so-called public consultation is disingenuous, implicitly moving the burden of proof onto an unsuspecting public, to propose changes to FSANZ's pre-existing deregulatory position.

FSANZ's pro-industry bias is again reflected in the composition of the Expert Advisory Group on New Breeding Techniques (EAG NBT) it has convened to provide "expert advice on issues relevant to the review, such as the current science relating to NBTs and potential food safety issues associated with the use of NBTs," which includes several genetic scientists with personal patents and commercial interests in the new GM techniques.[23]

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https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/1999-02/gene/report/index

21 Bunge, J and Dockser Marcus, A. Is This Tomato Engineered? Inside the Coming Battle Over Gene-Edited Food: The agriculture industry, which hopes Crispr technology will transform the business, faces opponents who call it 'GMO 2.0' April 15, 2018. https://www.wsj.com/articles/is-this-tomato-engineered-inside-the-coming-battle-over-gene-edited-food-1523814992

22 Senate Community Affairs Legislation Committee, Estimates (Public), Wednesday, 1 March 2017, Canberra. Pp 123 & 124.

23 Expert advisory group members are listed here:

A common definition of GM and GMO essential

The GM regulatory system should work with a common definition of GM, GM products, GM dealings, GM techniques, and so on. But the Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Act 2016 was passed, deleting the common definitions from the Food Standards Act.

The definition of GMO in the Food Standards Australia New Zealand Act 1991 had been the same as that in the Gene Technology Act 2000, and referred to an organism (or progeny of an organism) produced using gene technology. The Act defines gene technology as,

> "any technique for the modification of genes or other genetic material."[24]

This would certainly include new GM techniques, unless specifically exempted under the Regulations. By having this definition deleted from the Act, FSANZ and the Food Forum facilitated the pre-emptive deregulation of the new GM techniques and their products, defaulting to the much weaker definition in the Food Standards Code, which defines gene technology as,

> "recombinant DNA techniques that alter the heritable genetic material of living cells or organisms".

This definition chiefly covers the old, defunct, 20th century techniques that cut-and-paste DNA between species, now largely superseded with the invention of new GM techniques over the past five years. Some of these new so-called 'gene-editing' techniques change the GMO's genome but may not introduce DNA from another organism which means they are not 'recombinant' or 'transgenic'.

Thus, the legislative changes deliberately compromised the ostensibly national, uniform GM regulatory system, creating a convenient semantic loophole that FSANZ now seeks to climb through. FSANZ wants to fabricate an uncertainty that it and the Food Forum created when they facilitated changes to the law. The 'consultation' paper claims,

> "A degree of uncertainty exists about whether foods produced using NBTs are 'food produced using gene technology' because some of the new techniques can be used to make defined changes to the genome of an organism without permanently introducing any new DNA, although it may be present in the genome initially."[25]

We reject this rationalization. FSANZ has nowhere disclosed or published any scientific evidence to support or justify its view that there are no safety concerns over food produced using new GM techniques, nor its intention to deregulate such foods. Our food regulator is not entitled to deploy this diversionary strategy, which moves the onus of proof of the need for caution onto the public. Deregulation on the basis of such contrived sophistry affronts the public interest and is intolerable.

FSANZ's mission is much broader than mere technicalities. It claims to comply with the law and acquit its legal requirements, by applying the three section 18 ("core") objectives of the Food Standards Australia New Zealand Act 1991. These principles include, "protecting and supporting the health of people in Australia and New Zealand," by making, "a positive contribution to longer term public health objectives" and considering "long-term risks when developing food standards." It shirks these responsibilities.

GM and agrochemical companies project a tsunami of GM animals, plants and microbes of all descriptions soon arriving in our environments and food supplies yet FSANZ presents the questions in its document as only short-term safety issues, ignoring its broader brief.

The food products of all new GM techniques must be labelled

FSANZ 'consultation' paper even confuses and misleads on GM label requirements when it says, "Some foods may also be required to be labelled with the words 'genetically modified', as well as other

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http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx
24 Gene Technology Act 2000, https://www.comlaw.gov.au/Details/C2011C00539
25 FSANZ Consultation paper: Food derived using new breeding techniques, 2018. P4.

additional labelling, regardless of the presence of novel DNA or novel protein in the foods. These foods are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology."

And in Application A1143 – Food derived from DHA Canola Line NS-B50027-4, Nuseed appears to accept that its canola will require labelling, as the composition of its product will be altered. The company says, "Consumers will be able to make an informed choice as a result of labelling requirements and marketing activities."[26]

However, in the FSANZ Approval report for A1143[27], the Health Department of South Australia asserts that, "Consumers should be informed of the nutritional change through mandatory additional labelling." By way of rebuttal, FSANZ claims it had, "provided rationale in the Call for Submissions against mandating an additional labelling statement that this canola line has been modified to contain DHA as an omega-3 fatty acid. … FSANZ maintains the view that additional labelling should not be mandated."

The Call for Submissions says, "Canola oil and whole seeds from DHA canola will contain an altered fatty acid profile. However, FSANZ is not proposing additional mandatory labelling."[28] Yet the document also contains this table.

Table 1: Application of labelling requirements for food derived from DHA canola

DHA canola food/ingredient	Mandatory statement
Contains novel DNA or novel protein	✓
Contains altered fatty acid profile	✓
Novel DNA or protein absent but contains altered fatty acid profile	✓
Novel DNA or protein not present and no altered fatty acid profile i.e. the same as its conventional (non-GM) counterpart	×

So exactly what is the position? As far as we know, FSANZ has no discretion to ignore a requirement to label a food with altered function, characteristics or composition, yet it further seeks to justify a 'no label' stance on GM foods by declaring that its decision not to require a label on DHA canola ingredients,

> "aligns with the approach taken for four of the five previously assessed foods that are genetically modified for the purpose of changing the nutritional profile but have no additional labelling requirement:
>
> - high oleic acid soybean line DP-305423-1
> - herbicide-tolerant high oleic acid soybean line MON87705
> - soybean line MON87769 producing stearidonic acid
> - reduced acrylamide potential and reduced browning potato line E12 (containing reduced levels of asparagine, fructose and glucose)."

Such prevarication misleads the interested public about the labelling of GM foods, especially those with novel characteristics. Absence of novel DNA and protein should not be the only de-labelling threshold.

The Food Forum should direct FSANZ to resolve the lack of clarity and rational justification for exempting the food products of new GM techniques from labelling requirements, especially where the functionality, composition, nutritional value etc. of the final foods are altered.

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26 A1143 – Food derived from DHA Canola Line NS-B50027-4.
http://www.foodstandards.gov.au/code/applications/Pages/A1143-DHA-Canola-Line-NS%E2%80%93B500274.aspx
27 FSANZ 20 December 2017 [35-17] Approval report – Application A1143, Food derived from DHA Canola Line NS-B50027-4.
http://www.foodstandards.gov.au/code/applications/Pages/A1143-DHA-Canola-Line-NS%E2%80%93B500274.aspx
28 A1143 – Call for Submissions. http://www.foodstandards.gov.au/code/applications/Documents/A1143%20CFS.pdf

Responses to FSANZ's technical questions

3.1.1 Do you agree, as a general principle, that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval?

Yes.

All old and new Genetic Manipulation (GM) techniques – so-called gene editing, GM rootstock grafting, cisgenesis, intragenesis RNA interference and null segregants and the food products derived from them - must be notified to FSANZ, safety assessed using independent evidence, approved, and monitored, before being allowed for sale into the human and animal food supplies.

All of these GM food and animal feed products – animals, plants and microorganisms - should also be labelled so that shoppers are fully informed, as the present Standard 1.5.2 requires.
A key finding of the Preliminary Report of the Third Review of the Gene Technology Review was that there are "strong arguments to support the maintenance of a process-based trigger" for the regulation of GMOs.[29] This should apply to all the new GM techniques and their products.

Should there be any exceptions to this general principle?

No. All so-called gene editing techniques – CRISPR, ZFN, TALEN, GM rootstock grafting, cisgenesis, intragenesis, RNA interference and null segregants should be included.

FSANZ should be notified of all foods derived from organisms made using the new GM techniques, and should assess and regulate them all under the Food Standard.

Even FSANZ's unreferenced 2012 report on 'New Plant Breeding Techniques' concluded that plants with GM rootstock, "may contain novel RNA and/or protein as a result of the genetic modification to the rootstock. Depending on the genetic modification, the food may also have altered composition or other characteristics," and that the panelists thought foods from such plants, "should be regarded as GM food and undergo premarket safety assessment".[30]

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

No.

If no, what are your specific safety concerns for food derived from null segregants?

FSANZ has nowhere disclosed or published any scientific evidence to support or justify its view that there are no safety concerns about such food, nor to back its intention to deregulate them. First, tell us what you and your narrowly focused, compromised, expert panels know, to level the playing field in this so-called consultation. Our food regulator is not entitled to deploy a diversionary stratagem, which moves its onus of proof of the need for caution onto the public.

The term GMO should include organisms descended or derived from all GMOs. Null segregants are the offspring of GMOs that are assumed to no longer contain any Genetically Manipulated DNA. This assumption needs validation through full molecular characterization and FSANZ assessment, to ensure there are no unintended collateral genetic changes, prior to such foods being for sale. Regulation of null segregants is consistent with the EU's regulatory approach.

FSANZ also seeks to drive its deregulatory agenda further and faster by inaccurately claiming,

29 Commonwealth Department of Health, The Third Review of the Gene Technology Scheme: Preliminary Report, 2018. P2. http://health.gov.au/internet/main/publishing.nsf/Content/011C554B9847D6F0CA258169000FCBBE/$File/thirdreview-gene-technology-preliminary-report-2018.pdf

30 FSANZ, New Plant Breeding Techniques: Report of a Workshop hosted by Food Standards Australia New Zealand, 2012. P3.
http://www.foodstandards.gov.au/publications/Documents/New%20Plant%20Breeding%20Techniques%20Workshop%20Report.pdf

"the OGTR has stated that, under the Gene Technology Regulations, null segregants are not GMOs."

While the OGTR may have expressed this view in documents informing the Technical Review of the GT Regulations, the Regulations have not been amended. Policies of the Gene Technology Scheme would require resetting before the Regulations could be amended.

3.1.3 Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis?

No.

Again, FSANZ nowhere discloses or publishes any scientific evidence to support or justify this request for an assessment of risks from foods that derive from two very different sources. This question seeks to implicitly justify FSANZ's deregulatory intentions without showing its hand. Our food regulator is not entitled to deploy this diversionary strategy, which moves the onus of proof of the need for caution onto the public.

Mutagenesis has been used to alter crop and ornamental plants since 1930[31], long before any serious regulation of such activities existed. This in no way justifies the immediate deregulation of foods derived from organisms made using new GM techniques as they have no history of use yet, let alone safe use.

If no, how are they different?

While chemical and radiation mutagenesis may increase the rate of random DNA point mutations, all GM techniques can cause DNA double strand breaks. They can sequentially be used (as in gene stacking) to make major changes to an organism's DNA that may induce unexpected mutations. Such risks justify pre-market safety assessment and approval.

Deregulating techniques such as CRISPR and its GM food products, given the large knowledge gaps regarding their risks, is inconsistent with the Precautionary Principle.

3.2 Questions - Other techniques

Are you aware of other techniques not currently addressed by this paper which have the potential to be used in the future for the development of food products?

Yes, RNA interference. FSANZ should also be aware of this technique and it is a major omission from the consultation paper.

3.2.1 Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

Yes.

The epigenetics of genetic systems are poorly understood. RNA interference (RNAi) in living systems can result in DNA methylation, gene silencing and heritable genetic changes. It may also cause "off-target gene silencing, silencing the target gene in unintended organisms, immune stimulation, and saturation of the RNAi machinery,"[32] in non-target species. And there is still a lack of scientific knowledge about these threats.[33] Foods from such sources must be assessed for safety before sale. If not banned, products made using RNAi should also be labelled as customers are entitled to this information.

31 Mutation breeding, Wikipedia. https://en.wikipedia.org/wiki/Mutation_breeding

32 Lundgren, J G, and Duan J J. RNAi-Based Insecticidal Crops: Potential Effects on Nontarget Species, BioScience, Volume 63, Issue 8, 1 August 2013, Pages 657–665, 01 August 2013. https://doi.org/10.1525/bio.2013.63.8.8 https://academic.oup.com/bioscience/article/63/8/657/266726

33 Roberts, A F, et al. Biosafety research for non-target organism risk assessment of RNAi-based GE plants, Review Article, Front. Plant Sci., 06, November 2015. https://doi.org/10.3389/fpls.2015.00958

FSANZ seeks to reassure the public that the off-target impacts of new GM techniques are predictable and manageable, by referencing a Zischewski et al (2017)[34] paper. However, the paper concerns research, not food products, and concludes, “more sensitive off-target detection methods are required.”

3.3 Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs?

Yes.

As the scientific and industrial uses of these new Genetic Manipulation techniques and processes are the genesis for such food products, a process-based trigger must be applied to ensure that all such foods are notified to FSANZ for assessment, regulation and monitoring.

New GMOs pose unique risks, so a process-based trigger remains the most appropriate and assured way to initiate their assessment.

If yes, how could a process-based approach be applied to NBTs?

The OGTR regulates all the living products of GM techniques while end product regulators are charged with regulating the products of such organisms. The new GM techniques are clearly genetic manipulation techniques, according to New Zealand’s Hazardous Substances and New Organisms Act (HSNO) 1996 so should be regulated, including RNA interference.

If a food, food ingredient, processing aid, additive, colouring or flavouring is the product of an organism created or manipulated using any of the new Genetic Manipulation techniques, FSANZ should require notification.

Are there any aspects of the current definitions that should be retained or remain applicable?

Standard 1.5.2 defines "food produced using gene technology" as "a food which has been derived or developed from an organism which has been manipulated by gene technology," and "gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms."[35] This definition clearly includes so-called ‘gene-editing’ techniques. The intent of both the Gene Technology Act and Standard 1.5.2 was to capture all new GM techniques but the amendments to the code have cast that into doubt, as discussed above.

RNA interference can also, "alter the heritable genetic material of living cells or organisms" through DNA methylation. So for clarity the definition of gene technology in Standard 1.5.2 should be amended to something like, "gene technology means in vitro techniques that alter the heritable genetic material of living cells or organisms".

Finding 8 of the Preliminary Report of the Third Review of the Gene Technology Scheme was that there were “strong arguments to support the maintenance of a process-based trigger as the entry point for the Scheme (i.e. a broad range of technologies, including new technologies, are within the scope of the Scheme).”[36]

If yes, how could a process-based approach be applied to NBTs?

Food products derived from all new GM techniques should be assessed for safety and regulated, as they are clearly GM techniques within the definitions of Gene Technology Act 2000. That definition should be restored to Standard 1.5.2 so that the national GT regulatory scheme is indeed uniform, as it purports to be.

The Gene Technology Act 2000 defines gene technology as "any technique for the modification of genes or other genetic material". This clearly includes all new GM techniques including RNA interference.

34 Zischewski et al (2017) Detection of on-target and off-target mutations generated by CRISPR/Cas9 and other sequence-specific nucleases. Biotechnology Advances 35: 95-104.
https://www.sciencedirect.com/science/article/pii/S0734975016301586?via%3Dihub
35 Standard 1.5.2 Food produced using gene technology, as at 1 March 2016.
http://www.foodstandards.gov.au/code/Documents/1.5.2%20GM%20foods%20v157.pdf
36 Commonwealth Department of Health, Third Review of the GT Scheme: Preliminary Report, April 2018, P2.

Are there any aspects of the current definitions that should be retained or remain applicable?

Standard 1.5.2 defines "food produced using gene technology" as "a food which has been derived or developed from an organism which has been modified by gene technology." It says, "gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms." This definition clearly includes gene-editing techniques. The intent of the Gene Technology Act and Standard 1.5.2 was to capture all new GM techniques. To ensure both consistency of definition and regulation the definition of gene technology in Standard 1.5.2 should be changed to that in the Gene Technology Act.

3.4 Are there other issues not mentioned in this paper, that FSANZ should also consider, either as part of this Review or any subsequent Proposal to amend the Code?

FSANZ ought to consider the potential international trade impacts of deregulating foods made using new GM techniques such as CRISPR. The European Union and many other jurisdictions have yet to make a decision on whether they will regulate the new techniques as GM. The EU and others - Nigeria[37] China[38], Japan[39] - have zero tolerance for unapproved GMOs and shipments of unapproved GM products are rejected.

A Food and Agriculture Organisation (FAO) survey of member country policies found 73% have zero tolerance for unapproved GM varieties.[40] It also found that from 2002 to 2012 trade was disrupted 200 times over unapproved GMOs in shipments. Exporters lost millions of dollars – and in some cases billions - in export earnings.

FSANZ and the Food Forum would be remiss if they ignored the trade impacts of deregulating foods made with the new GM techniques. We are out of step. Since FSANZ regulates food in both Australia and New Zealand, regulatory uniformity with our near neighbour, food exporter and trade rival is recommended and meets the requirements of the Australia-New Zealand Closer Economic Relations Trade Agreement.[41] New Zealand recently announced it would regulate all organisms created using new GM techniques as GMOs.[42]

All submissions to this consultation should be published so the process is open and transparent. All submission on applications and the applicants supporting documentation should also be published on the web.

Conclusions and Recommendations

Our submission has shown that:

- In conformity with its role and functions in the Australian and New Zealand food regulation systems, FSANZ should present the option of mandating the notification, assessment, regulation, approval/licensing and monitoring of all new GM techniques (e.g. CRISPR, RNA interference etc.) and all their food products, without exception, but it does not.
- The conclusions of the 2012 and 2013 FSANZ workshops, as well as this 'consultation' process, should be declared null and void and be restarted under new rules of engagement;
- All processes of review of the new GM techniques and their food products should now be restarted from scratch, with a broad array of independent advisors from all related disciplines;
- As the workshop reports offer no scientific evidence for their findings or conclusions they cannot be used to support FSANZ industry-aligned case for deregulation;

37 GLP, Nigeria rejects $10 million worth of unapproved GMO corn imported from Argentina, November 16, 2017. https://geneticliteracyproject.org/2017/11/16/nigeria-rejects-10-million-worth-unapproved-gmo-corn-imported-argentina/
38 Polansek, T. In wake of China rejections, GMO seed makers limit U.S. launches, Reuters, November 25, 2014. https://www.reuters.com/article/us-usa-gmo-china-insight/in-wake-of-china-rejections-gmo-seed-makers-limit-u-s-launches-idUSKCN0J90DU20141125
39 Brammer, J. Japanese GM hay rejection claim, The West Australian, Thursday, 15 October 2015. https://thewest.com.au/news/wa/japanese-gm-hay-rejection-claim-ng-ya-394200
40 FAO, The results of the FAO survey on low levels of genetically modified (GM) crops in international food and feed trade, 2014. http://www.fao.org/fileadmin/user_upload/agns/topics/LLP/AGD803_4_Final_En.pdf
41 Australia-New Zealand Closer Economic Relations Trade Agreement (ANCERTA) http://dfat.gov.au/trade/agreements/in-force/anzcerta/Pages/australia-new-zealand-closer-economic-relations-trade-agreement.aspx
42 Smith, N. GMO regulations clarified, 5/4/16. https://www.beehive.govt.nz/release/gmo-regulationsclarified-0

- FSANZ workshop reports and other documentation are long out of date as the science and understanding of genetic engineering and its food products have changed dramatically since 2013 and moved on;
- FSANZ selected panelists for its workshops and review who have serious conflicts of interest as they are associated with the global scientific establishment, and GM and agrochemical companies, that back deregulation of new GM techniques and their products for commercial gain;
- Independent scientists and the interested public, with a broader range of knowledge, critical views and scientific expertise e.g. public health, epidemiology, nutrition, human ecology, etc. were excluded from every step of the workshop and review process;
- FSANZ 'consultation' paper does not explain or credibly justify the reasoning and scientific evidence that may support its case to deregulate the new food products of the GM techniques;
- FSANZ has secretly maneuvered, over at least the past six years, to prepare for the deregulation of foods derived from the many recently invented and new Genetic Manipulation (GM) techniques;
- FSANZ and the Food Forum amended the code, to deregulate new GM techniques and their food products which alter genomes but may not insert foreign DNA, so are not strictly 'transgenic';
- Without producing evidence, this 'consultation' seeks to move FSANZ's onus of proof onto the public, to make us justify notification, assessment, regulation and monitoring of new GM foods;
- We reject the unreasonable burden of proof that FSANZ tries to impose on the interested public;
- FSANZ disingenuously uses the term New Breeding Techniques (NBTs), that is industry spin;
- FSANZ fails to mention microorganisms in its workshop reports, submission to the GT Scheme Review, or this consultation document;
- Yet many and various microorganisms - bacteria, viruses and fungi – are set be manipulated with the new GM techniques for a wide variety of applications in the food industry, and may soon be ubiquitous in the human food supply;
- FSANZ and the Food Forum must not ignore microorganisms in this or other reviews;
- A review is needed to disclose the presence of GM microbes and their products in the food supply now, and the future intrusion of microbes made or altered with the new GM techniques;
- FSANZ and the Food Forum must be responsive to negative and persistent public sentiments about GM animals and plants in the food supply;
- The Food Forum should direct FSANZ to resolve the lack of clarity and rational justification for exempting the food products of new GM techniques from labelling requirements, especially where the functionality, composition, nutritional value, etc. of the final foods are altered;
- The Precautionary Principle sets the default position at all foods and food ingredients derived from new GM techniques being notified to FSANZ, then assessed, regulated and monitored;
- All submissions to this consultation should be published so the process is open and transparent;
- We call on FSANZ to also publish all the submissions made to it, as it is unfair to merely cherry pick key concerns and dismiss them with lame rebuttals, in the Final Approval report for each application;
- Any background documents that applicants submit with their applications should also be published online.

Researched and written by Bob Phelps, Executive Director, Gene Ethics, April 2018.

GMFAA and its constituents also support this submission.
http://www.gmfreeaustralia.org.au