FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Preliminary report

Review of food derived using new breeding techniques – consultation outcomes

August 2018

Contents

About this preliminary report

This report provides a summary of views expressed by submitters in response to the Food Standards Australia New Zealand (FSANZ) *Consultation paper: food derived using new breeding techniques* (released for public comment on 15 February 2018).

Selected quotes from some submissions are included to reflect the range of views expressed. All submissions are available on our website.

Acknowledgement

FSANZ wishes to acknowledge the time and effort that submitters have put into preparing their submissions.

Executive summary

In June 2017, FSANZ began a review of the Australia New Zealand Food Standards Code (the Code) to consider how it should apply to foods derived using new breeding techniques (NBTs). The primary focus of the review has been on definitions in the Code that determine what foods are captured as food produced using gene technology and are therefore subject to pre-market safety assessment and approval. The key questions for FSANZ are whether the definitions in the Code remain fit for purpose, given the rapid pace of technological change, and whether requiring a pre-market safety assessment for foods derived from NBTs is justified in terms of risk.

A consultation paper addressing these questions was released for public consultation from February– April 2018. In total, 664 submissions were received from a wide range of stakeholders (Appendix 1). The submissions show there are diverse views about food from NBTs. FSANZ has analysed the submissions and has identified seven key outcomes from the consultation. These are listed below, and described more fully in Section 2 of this report.

The submissions will be used to help inform FSANZ's decision about what the next steps should be. It is anticipated a final report, including recommendations informed by the consultation process, will be released in early 2019.

Key outcomes from the consultation

Outcome 1: Views are divided on the risks or safety of food derived from NBTs and the need for pre-market safety assessment.

Outcome 2: Significant concerns remain for some submitters about the safety of genetically modified (GM) foods in general.

Outcome 3: A commonly held view is that changes to the definitions for '*food produced using gene technology'* and '*gene technology'* are required to improve clarity about what foods derived using NBTs are captured for pre-market assessment and approval.

Outcome 4: Many submitters desire more alignment between the Code and other regulatory schemes in Australia and New Zealand so there is consistency in outcomes between what is regulated as a genetically modified organism and what is regulated as a food produced using gene technology.

Outcome 5: Views are divided on whether the use of a process-based definition should continue or a more product-based approach should be adopted, with a variety of reasons being provided for or against either approach. Some submitters have suggested that a hybrid approach, incorporating both process and product-based elements, may be more appropriate.

Outcome 6: Labelling of GM foods continues to be an important issue for many submitters who wish to exercise purchasing choice. These submitters also want GM labelling applied to food derived using NBTs.

Outcome 7: A number of submitters consider that the harmonisation of regulatory approaches to NBTs, both domestically and internationally, is the best way to facilitate trade, deliver certainty, and provide the agricultural sector and consumers with access to innovative products.

1. Background

1.1 Purpose of review

Food Standards Australia New Zealand (FSANZ) is reviewing the Australia New Zealand Food Standards Code (the Code) to consider how it applies to food products of new breeding techniques (NBTs).

Specifically, the review is considering the definitions for '*food produced using gene technology*' and '*gene technology*', specifically:

- whether the current definitions remain fit-for-purpose given the emergence of newer genetic modification (GM) techniques
- whether subjecting NBT-derived foods to pre-market safety assessment and approval is justified in terms of risk.

The review is not considering labelling issues, nor will it directly result in changes to the Code. When the review is complete, FSANZ will decide whether to prepare a proposal to amend the Code. Any subsequent proposal to amend the Code will be a separate process involving additional public consultation.

FSANZ established an Expert Advisory Group on New Breeding Techniques (EAG NBT) to assist with the review[1]. This group has been providing advice on issues, including the current science, potential food safety issues and stakeholder concerns associated with NBTs.

1.2 Public consultation

As part of the review, a consultation paper[2] was released for public comment from February–April 2018. The purpose of the consultation was to seek views from a broad range of stakeholders on some of the specific issues and questions raised by the review.

To help consider the issues, FSANZ grouped NBTs according to the types of outcomes they produce in the genome of the organism from which the food for sale would be obtained:

1. Genome contains new DNA
2. Genome unchanged by gene technology (null segregants)
3. Genome changed but no new DNA (genome editing).

Questions were asked about each of these categories as well as more general questions about the definitions and other relevant issues (see Appendix 2 for the full list of questions). The key outcomes from the consultation in relation to these questions are summarised below.

[1] A list of EAG members is available from http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx

[2] *Consultation Paper: Food derived using new breeding techniques*, available from http://www.foodstandards.gov.au/consumer/gmfood/Documents/Consultation%20paper%20-%20Food%20derived%20using%20new%20breeding%20techniques.pdf

2. Key outcomes

2.1 Risk and safety

Some submitters stated there is sufficient risk and/or uncertainty about safety to justify pre-market safety assessment of all NBT-derived food products. Part of the concern expressed by these submitters relates to the relatively short period of time the techniques have been in use and that the evidence base in relation to their safety is considered insufficient. Reviews commissioned by other governments were cited by submitters to support these concerns[3]. These submitters also do not believe there is any legitimate distinction to be made in terms of outcome or risk between NBTs and older GM techniques. Many of these submitters also continue to have concerns about the safety of GM foods in general.

In contrast, other submitters point to the safety record of GM foods, arguing the current pre-market safety assessment approach is not commensurate with risk. One of the concerns expressed by this group of submitters is that pre-market assessment and approval will be extended to foods derived using NBTs, which they consider pose the same or less risk than foods derived using conventional breeding approaches. These submitters argue for a more risk-based approach and would like certain categories of foods, including in some cases existing GM foods, to be excluded from pre-market assessment and approval. Some of these submitters also noted that food derived using NBTs is already regulated under food law which requires that all food be "safe and suitable".

A number of other submitters, while comfortable with the current regulatory approach to older GM techniques, believe there may be justification on a risk basis for excluding some categories of NBT foods and/or subjecting them to more simplified forms of safety assessment (i.e. using a risk-tiering approach). Some of these submitters consider that case-by-case consideration may still be appropriate for certain categories of foods.

"NBTs are still not fully understood and/or their consequences fully known. Therefore, it is essential that any application to use NBTs in the production of food for humans and animals should be considered on a case-by-case basis, as is the present situation." – *Consumers' Association of South Australia*

"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." – *Gene Ethics*

"It is too soon to draw an arbitrary distinction between the organisms created by some GM techniques and not others, especially when the monitoring and testing through to final consumption has not been done." – *FOODwatch*

[3] For example Eckerstorfer et al (2014) New plant breeding techniques and risks associated with their application, available from https://www.researchgate.net/publication/273141996_New_Plant_Breeding_Techniques_and_Risks_Associated_with_their_Application

"In fact, the risk of safety issues arising with GM and NBTs is not higher than with other unregulated breeding tools. For GMOs, this has been demonstrated in the last twenty years of GMO regulation." – *Simplot Plant Sciences International*

"We should defer to the collective wisdom of the overwhelming consensus of scientific opinion and the vast number of peer-reviewed scientific papers that have produced the evidence that GM foods are safe, and that the same situation applies to foods produced using NPBTs." – *Joint submission from Adjunct Professor Paul Brent and Adjunct Professor Andrew Bartholamaeus*

"The problem for regulators is that the use of recombinant DNA is a far more precise means to that end than mutagenesis, with fewer potential risks, but regulations commercially compel the latter over the former. It is against this background that the AFGC recommends FSANZ be very cautious about extending the current regime in Standard 1.5.2 to breeding techniques outside its current scope.**" –** *Australian Food and Grocery Council*

"MPI considers that in assessing the risk from any NBT that the benchmark should be the outcomes of conventional breeding techniques. Where a NBT results in an outcome for the genotype and phenotype that would not significantly differ from the capabilities of conventional breeding techniques then there is not a risk basis to support additional regulation of food from the resulting organism." – *Ministry for Primary Industries*

Outcome 1: Views are divided about the risks or safety of food derived from NBTs and the need for pre-market safety assessment.

Outcome 2: Significant concerns remain for some submitters about the safety of GM foods in general.

Genome contains new DNA

Some submitters stated that the introduction of new DNA, irrespective of source, poses a potential risk to food safety and therefore that pre-market safety assessment should continue to be required.

Other submitters did not agree that food from organisms with new DNA should automatically be captured for pre-market assessment. They argued the introduction of new DNA does not necessarily pose any additional risks over and above that of conventional breeding and that continuing to capture foods derived from these techniques is not commensurate with risk. Some of these submitters made risk distinctions between different types of foods on the basis of the source of the new DNA. For example, a number of submitters consider foods derived from cisgenic or intragenic organisms to have a risk that more closely resembles foods derived using conventional breeding. Submitters in this group argue these types of foods could be considered for exclusion from pre-market safety assessment, or alternatively that their lower inherent risk should be reflected in the data requirements for their safety assessment. Some of these submitters also raised issues with FSANZ's use of the term 'new DNA', arguing that the term is confusing in relation to cisgenesis for example where the introduced DNA will not be new to the species.

A range of views were expressed about food derived from GM rootstock grafting. Some submitters consider that all food from GM rootstock grafting should be subject to pre-market assessment as they consider the risks to be the same as transgenesis, irrespective of whether the food contains novel DNA or protein or has altered characteristics. Rather than focussing on potential exceptions, one submitter suggested the adoption of a more streamlined regulatory approach that focussed on the GM rootstock so that approved rootstocks could be used generally with any scion. Other submitters argued that some foods from GM rootstocks could be excluded from pre-market requirements, although for different reasons. Some thought foods should be excluded if novel protein is absent from the edible part of the food crop whereas others thought pre-market assessment should only be required where the food has altered characteristics. There were also submitters who considered food from GM rootstocks to be akin to food from null segregants (see below), arguing both should be excluded from pre-market assessment because of the absence of novel DNA.

"Whenever and wherever a new piece of DNA is inserted into the genome, pre-market safety assessment and approval for any food for sale from it should be required. There should be no exceptions." – *Consumers' Association of South Australia*

" MPI agrees that food derived from organisms containing new pieces of DNA should be regarded as GM food and therefore captured for pre-market assessment and approval. The presence of new DNA from intragenesis and cisgenesis is likely to present an identical risk profile to transgenic food, which is already captured for pre-market approval." – *Ministry for Primary Industries*

"As a general principle, I agree that it is reasonable to capture foods derived from organisms that contain recombinant DNA from species that would not normally be able to share DNA in nature for pre-market safety assessment and approval." – *Dr Brian Jones*

"The Academies would support exceptions from pre-market safety assessment and approval for technology applications with a long history of safe use. Exemptions should be considered for low risk GM foods, in particular foods where the modified gene is not present in the edible part of the food crop." - *Joint submission from Australian Academy of Technology and Engineering and Australian Academy of Science*

"The lower inherent risk from cisgenic or intragenic traits should be reflected in the data requirements for these products. In all cases data requirements for new food products should take into account the history of safety use of traits, and be commensurate with the level of potential risk." – *Simplot Plant Sciences International*

"Our Institute believes that where there is no foreign DNA present in the material to be consumed as food – i.e. the genome has been changed by gene editing but with no new DNA added, it is a null segregant or where it is produced from a scion grafted on a transgenic rootstock – that there is no compelling public safety benefit to be gained from additional pre-market assessment beyond that required generally of all foodstuffs." – *Plant and Food Research*

Genome unchanged by gene technology (null segregants)

Submitters who supported excluding food from null segregants argue that because the introduced DNA is no longer present due to segregation, the organisms are identical in terms of food risk to those obtained through conventional breeding. Some of these submitters however suggested that as part of any exclusion there should be a procedure in place to verify that an organism is a complete or true null segregant.

Submitters who were opposed to excluding food from null segregants are concerned unintended changes may have occurred as a result of the introduced DNA, or that additional insertions of DNA may still be retained by the final organism used for food. They consider a pre-market safety assessment is essential to determine this.

"Null segregants as described in the Consultation Paper contain no modified genetic material and are biologically and biochemically indistinguishable from unmodified organisms. The idea that null segregants might be "contaminated" by the involvement of gene technologies earlier in their development is not scientifically supportable." – *Joint submission from Australian Academy of Technology and Engineering and Australian Academy of Science*

"Food from null-segregant organisms should not automatically be excluded from pre-market assessment and approval. Although progeny are selected that have not inherited any new DNA and do not display the GM trait, it is unclear whether there could be other unintended outcomes. For example, if the GM parent was produced using NBTs, it may be difficult to distinguish GM progeny from non-GM progeny unless specific markers are used. Also, it may also be possible for GM progeny to be mistakenly released as null segregants." – *Fonterra Co-operative Group Limited*

"There may be a need for some verification to be provided that all the GM components in the parent organism have been removed during segregation but this is easily achieved these days using Next Generation Sequencing or other molecular diagnostic technologies." – *Commonwealth Scientific and Industrial Research Organisation*

Genome changed but no new DNA (genome editing)

A range of views about the need for pre-market assessment and approval were provided for this category, as well as detailed technical arguments and evidence. Submitters who supported subjecting all foods derived from genome edited organisms to pre-market assessment argue that genome editing is fundamentally different in terms of risk to older mutagenesis techniques used as part of conventional breeding. The main concern for many of these submitters is potential off-target changes that may be introduced as a result of a double-stranded break being introduced at other than the intended site, or other unexpected changes that may occur during repair of the double-stranded DNA break. Some submitters are also concerned that the use of these techniques is still in its infancy and that it is difficult to predict how such techniques may be applied in the future. The fact that the consultation paper focussed on plants and animals, without mentioning microorganisms, was particularly noted by some submitters. Some submitters also questioned the legitimacy of making a conclusion about risk for a whole category of products without first undertaking product-specific or case-by-case risk assessments. In addition, some submitters consider that chemical and radiation mutagenesis techniques should also be subject to pre-market assessment and approval, arguing they do not have a history of safe use and can also potentially result in hazardous outcomes.

Other submitters however were of the view that genome editing techniques are no different, in terms of outcomes, to what can be achieved using random mutagenesis techniques (using chemicals or radiation, and in some cases somaclonal variation) which they argue have a long history of safe use in food production. They consider that comparison of outcomes with conventional breeding should be the benchmark for deciding what foods should or should not be captured for pre-market assessment and that there is no legitimate risk basis for singling out similar genome edited products for pre-market assessment simply because of the process used. In support of the relative safety of these techniques and the products they produce, many of these submitters also highlighted the precision of genome editing techniques in comparison to older mutagenesis techniques, the extensive use of screening and selection which is standard for any breeding programme, as well as the greater

understanding of genomes that exists today.

In addition to these two views, other submitters acknowledged that not all genome edited products would be similar to existing conventional foods and that there may be some food products that will warrant pre-market assessment by FSANZ. There were also submitters who argued for an approach where food products could be triaged according to their characteristics and potential risk, and then regulated and assessed accordingly.

"While chemical and radiation mutagenesis can increase the rate of random DNA point mutations, gene editing techniques cause DNA double strand breaks and can be used sequentially to make dramatic differences to DNA. They are also prone to additional unexpected mutations. They therefore carry both different and greater risks and warrant pre-market safety assessment and approval." – *Friends of the Earth*

"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" – *Gene Ethics*

"It is bogus to suggest that gene editing would be done and the immediate lines would be released without testing. The trait would be studied and understood before the task of gene editing would be undertaken and the modification assessed under laboratory and field conditions before commercial release. It would be far better understood than any natural or induced mutation." – *Dr Brian Duggan*

"The perceived lack of history of safe use for modern breeding tools in comparison to tools grouped under "conventional breeding methods" is counterbalanced by the significantly improved knowledge about the genomes today and the precision that the tools bring to the breeding process compared to earlier tools." – *Bayer Crop Science*

"We suggest a formalised Food Safety Risk Assessment (FSRA) matrix to classify food produced using gene technology via initial screening and ranking regarding food safety risk of (a) unlabelled food produced using gene technology entering the market (e.g. failure to identify null segregant in production), and/or (b) case-by-case considerations of unintended effects of genetic modifications. Such FSRA for pre-market assessment/approval could be based initially on documentation provided as per FSANZ Application Handbook (2016) part 3.5.1 (Foods produced using gene technology). If ranked-risk is assessed as above a predefined quantitative/semi-quantitative threshold, further assessment by FSANZ … would be warranted." – *Queensland Department of Health*

Other techniques

There were mixed views about whether there are other techniques not addressed by the consultation that should also be subject to pre-market assessment and approval. Some submitters, while not naming any particular technique, expressed the view that any new technique should be captured. Other submitters referred to specific techniques, particularly DNA methylation (which was used as an example in the consultation paper[4]), but differed in their views about whether derived foods should be captured. There were also submitters who suggested that FSANZ should conduct regular science-based reviews as new techniques will continually emerge, noting that the Code needed to be sufficiently flexible to deal with the raft of new developments expected in the future (see also discussion on regulatory trigger below

[4] Page 13 of the FSANZ Consultation paper: Food derived using new breeding techniques.

in Section 2.2).

"Methylation is a process of altering genetic expression and hence should be regarded as a form of genetic modification. Furthermore, methylation techniques may result in methylation of other, non-target sections of DNA, thereby changing the expression of other genes in unintended ways. In addition, as the FSANZ Discussion Paper states, methylation can result in changes to DNA expression that can be inherited by subsequent generations. Consequently, food derived using methylation techniques should be subject to regulation and undergo pre-market assessment." – *Public Health Association of Australia*

"Agcarm submits that food derived via DNA methylation techniques is not regulated as these changes can already readily be induced in traditional breeding. When it comes to other techniques, these need to be assessed on an individual basis using sound risk assessment criteria." – *Agcarm*

"As new techniques will continue to arise, it is important that FSANZ remains technique neutral and flexible otherwise they will be practising in a constantly outdated regulatory environment. Utilising the food product characteristics as the driver for a pre-market assessment will help to future proof FSANZ to work in the rapidly developing scientific space." – *Dow AgroSciences*

2.2 Regulatory issues

Clarification of definitions

While views about risk are divided, there appears to be reasonable consensus that greater clarity is needed in terms of what foods are captured for pre-market assessment and approval. In this respect, a number of submitters consider that the definitions in the Code for '*food produced using gene technology*' and '*gene technology*' are no longer fit for purpose.

Not all submitters agree however that greater clarity is required or that the definitions need to be changed. Some submitters consider that FSANZ has applied an overly narrow interpretation of the current definitions. In their view, food from NBTs is clearly captured by the definitions, and no changes are required.

A number of submitters made specific suggestions about how the current definitions could be revised to provide greater clarity and/or to exclude particular food categories, using either a product or process approach or a combination of both.

A common issue raised by many submitters was the need for greater consistency and harmonisation of definitions—both within Australia and New Zealand, as well as internationally. For example, a number of submitters suggested that the definitions in the Code be brought into alignment with the Codex definition for modern biotechnology[5] which they consider to be more encompassing of new technologies. Other submitters suggested that FSANZ should harmonise its definitions with those in the *Gene Technology Act 2001* or the *Hazardous Substances and New Organisms Act 1996*, including in some cases their respective regulations, so that consistent regulatory outcomes are achieved in terms of what foods and organisms are captured for pre-market approval. In relation to this point, some submitters also suggested that FSANZ not take any action to change Code definitions ahead of other reviews addressing the *Gene Technology Act 2001* and its regulations currently ongoing in Australia.

[5] http://www.fao.org/3/a-a1554e.pdf

"The definition in the code for *gene technology* needs to be modernised to fit with NBTs." – *Professor Andrew Allan*

"The NFF is supportive of the review's objective to clarify definitions and bring food standards regulations in line with scientific developments. The NFF recognise that a range of new technology has been developed that creates ambiguity as to what constitutes GM, and the NFF is supportive of FSANZ clarifying these definitions in line with other Australian government regulatory reviews on this issue." – *National Farmers' Federation*

"The definitions for 'food produced using gene technology' and 'gene technology' in Standard 1.1.2—2 must not be changed and all foods that are created using new breeding techniques must be included in the definition of 'food produced using gene technology' and made subject to pre-market approval." – *GE Free New Zealand*

"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." – *Friends of the Earth*

"The Food Authority considers it important to ensure clarity and consistency around the consideration of what constitutes gene technology in Australia and therefore proposes that specific consideration of what technologies when applied to food require pre-market safety assessment according to Standard 1.5.2 of the Australia New Zealand Food Standards Code (the Code) be delayed until the OGTR and the Commonwealth Department of Health gene technology review processes have concluded." – *New South Wales Food Authority*

Outcome 3: A commonly held view is that changes to the definitions for 'food produced using gene technology' and 'gene technology' are required to improve clarity about what foods are captured for pre-market assessment and approval.

Outcome 4: Many submitters desire more alignment between the Code and other regulatory schemes within Australia and New Zealand so there is consistency in outcomes between what is regulated as a GMO and what is regulated as a food produced using gene technology.

Process or product-based regulatory trigger

Submitters who favour all foods from NBTs being subject to pre-market assessment and approval were more likely to support continuing with a process-based definition. These submitters consider food risks to be very much linked to the process or technique used. If a product-based definition were to be adopted they are concerned that potentially unsafe foods will enter the food supply without any scrutiny. Other submitters also cautioned that a move to a product-based approach to regulatory capture would put FSANZ at odds with how others regulate such products and that this could have potential negative consequences for Australian and New Zealand food exporters.

Those submitters who support excluding certain categories of products from pre-market assessment and approval were more likely to support moving to a more product-based definition for NBTs, and in some cases the whole GM food category. These submitters consider the current process-based approach does not deliver appropriate risk-based outcomes in terms of what is captured for pre-market assessment and approval and also potentially acts as a deterrent to innovation.

In terms of future proofing, some submitters argued that adopting a product-based definition, focussing on risk, would be the best way to address the continual and rapid emergence of new technologies. In addition, some submitters also believe it is important to have flexible and agile regulatory processes to respond to new and innovative technologies.

"Irrespective of what might be the best approach in technical terms for securing food safety, an astounding feature of the proposed move from process-based to product-based regulation is that it represents a departure from international norm (as defined by Codex) and the practice of the great majority of food regulators, without serious analysis being offered." – *Sustainability Council*

"Fonterra considers that a process-based definition is not appropriate as a trigger for pre-market approval. The details of the breeding technique used may help to identify any hazards as part of the pre-market safety assessment, but should not, in itself, be used as a predictor of the need for a pre-market safety assessment and approval." – *Fonterra Co-operative Group Limited*

"The potential regulation of new breeding techniques must be proportionate to the risks involved, and if current regulation is not also proportionate across different means of achieving the same outcome, that regulation becomes an arbiter of science and process, rather than outcomes, in effect trying to look into a crystal ball to determine which food production techniques are to be (unregulated) 'winners' and which are (regulated) 'losers'." – *Australian Food and Grocery Council*

Outcome 5: Views are divided on whether the use of a process-based definition should continue or a more product-based approach should be adopted, with a variety of reasons being provided for or against either approach. Some submitters have suggested that a hybrid approach, incorporating both process and product-based elements, may be more appropriate.

2.3 Other issues

Consumer information and labelling

Labelling for informed choice was raised by many submitters. A common concern is that if foods from NBTs are excluded from pre-market approval they will also escape the GM labelling requirements under the Code. For these submitters pre-market approval not only ensures that foods are subject to case-by-case safety assessment, it also provides the means to impose GM labelling, which they consider important for making informed purchasing decisions once GM foods enter the food supply.

Other submitters stated that FSANZ should consider whether existing labelling requirements need to be amended to ensure consumers are provided with adequate information in relation to all approved GM foods, including food derived from NBTs.

"It is essential that all forms of genetic modification including CRISPR and ZFN are subject to regulatory control and are thoroughly tested for safety and unwanted effects before being approved for use. In the case of GM food material including ingredients, labelling of the GM content should be mandatory, to give consumers the choice of purchasing or not. There are various justifiable reasons for people to avoid GM food: many are unconvinced of their safety and lack of long-term effects, others find GM techniques abhorrent in principle." – *Mr Rodney Stace*

"The genetic change to the organism may itself be of ethical concern and provision of consumer information through traceability and labelling may need to be considered. For example, the development of hornless cattle in the USA addressed animal welfare concerns regarding dehorning, and the characteristics of the meat are identical; however, consumers may still want to make an informed purchase." – *Fonterra Co-operative Group Limited*

"It is acknowledged that labelling is outside the scope of the current consultation paper. However, any subsequent proposal to amend the Code may need to consider whether labelling requirements should also be amended to allow consumers to make informed choices." – *Queensland Health*

Trade, harmonisation and innovation

The need to harmonise regulations within Australia, between Australia and New Zealand as well as internationally, as well as the possible negative effects on international trade if countries have different regulatory measures for NBTs, were strong themes. Many submitters were also concerned about the negative effects that over-regulation of NBTs may bring, particularly on innovation and uptake of the technology.

"It is important that FSANZ consider the potential international trade aspects if it deregulates food produced using new GM techniques such as CRISPR. Key export markets such as the European Union have yet to make a decision on whether they will regulate these techniques as GM and have zero tolerance policies for unapproved GMOs." – *Friends of the Earth*

"We would like to see the Australian and New Zealand governments to push for harmonisation of the regulation of these techniques internationally, to reduce regulatory hurdles and to provide the best environment for Australian and New Zealand innovation in plant breeding. Inconsistent policies make research collaborations difficult, have a negative impact on the commercial seed trade as well as trade in agricultural products, will limit the range of new varieties for farmers and new products for consumers, and will hamper global innovation and agricultural development." – *Australian Seed Federation*

Detection

The ability to detect or otherwise analytically distinguish between foods from NBTs and the products of conventional breeding was raised by a number of submitters. While the potential challenges for compliance and enforcement were noted by some submitters, other submitters do not consider this to be a legitimate reason for deciding whether or not to capture foods for pre-market safety assessment and approval. Other non-analytical approaches for ensuring compliance were noted by some submitters, as well as potential future improvements in analytical methodology.

"Furthermore, considerable complexities for the trade could occur where it may not be possible to detect products which have been derived from the application and use of new breeding technologies." – *Grain Trade Australia*

"The notion that the products of certain new GM techniques cannot be reliably detected is simply false. There is no technical barrier to developing reliable detection tests." – *Sustainability Council*

"We note that some of the foods produced using NBTs cannot be distinguished from conventional foods using currently available analytical techniques. We comment that enforcement using testing should not be the basis of decisions to exclude or include these foods from the definition, as it may be possible to develop other measures, where warranted, to determine if a technique was used to produce the food (such as food production records or traceability methodology)." – *Ministry for*

Primary Industries

"The development of further protocols (including advances in the robustness of whole genome sequencing) and techniques may allow for better, cheaper and more reliable detection of small changes (e.g. one base pair changes) in genome edited organisms. These include 'BATCH-GE', a bioinformatics tool for batch analysis of DNA sequence data and spectroscopy methods for differentiating between genome-edited and conventionally bred plant varieties." – *Friends of the Earth*

Outcome 6: Labelling of GM foods continues to be an important issue for many submitters who wish to exercise purchasing choice. These submitters also want GM labelling applied to food derived using NBTs.

Outcome 7: A number of submitters consider that the harmonisation of regulatory approaches to NBTs, both domestically and internationally, is the best way to facilitate trade, deliver certainty, and provide the agricultural sector and consumers with access to innovative products.

3. Next steps

FSANZ is now in the process of considering possible options and timing for progressing the NBT work beyond the review, including whether to prepare a proposal to amend the Code.

A final report, including recommendations informed by the consultation, is anticipated to be published in early 2019.

Appendix 1: Table of submitters

Sector	Name	
Government (4)	Victorian Departments of Health and Human Services & Economic Development, Jobs, Transport and Resources (joint submission) New Zealand Ministry of Primary Industries Queensland Department of Health New South Wales Food Authority	
Community (630)	Consumers Association of South Australia GE Free New Zealand Auckland GE-Free Coalition Soil & Health Association of New Zealand Sustainability Council of New Zealand	MADGE Australia Inc. Gene Ethics FOOD Watch 28 private individuals (2 as a joint submission) 594 web form campaign submissions
NGOs (3)	Friends of the Earth Australia Friends of the Earth New Zealand Public Health Association of Australia	
Research (4)	Australian Academy of Science & Australian Academy of Technology and Engineering (joint submission) CSIRO La Trobe University Institutional Biosafety Committee Plant and Food Research	
Industry (17)	Australian Food and Grocery Council AusBiotech European Seed Association Grain Trade Australia Ltd Grain Growers Ltd Dow Agrosciences Australia Ltd Bayer Crop Science Australian Seed Federation Simplot Plants Sciences (SPS) International	CropLife Australia Association of Manufacturers & Formulators of Enzyme Products Fonterra Co-operative Group Limited Enzyme Technical Association Food Technology Association of Australia Inc. New Zealand Food and Grocery Council Recombinetics Inc. NZ BIO
Agriculture (5)	Pastoralists and Graziers Association of Western Australia New Zealand Association for Animal Health and Crop Protection New Zealand Plant Breeding and Research Association National Farmers' Federations New South Wales Farmers	
Other (1)	MOD New Zealand	

Appendix 2: Consultation questions

Question 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? Should there be any exceptions to this general principle?

Question 3.1.2: Should food from null segregant organisms be excluded from pre-assessment and approval? If yes, should that exclusion be conditional on specific criteria and what should those criteria be? If no, what are your specific safety concerns for food derived from null segregants?

Question 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? If no, how are they different? If yes, would this apply to all derived food products or are there likely to be some foods that carry a greater risk and therefore warrant pre-market safety assessment and approval?

Question 3.2: 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? Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval? Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

Question 3.3: Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs? If no, what other approaches could be used? If yes, how could a process-based approach be applied to NBTs? Are there any aspects of the current definitions that should be retained or remain applicable?

Question 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?