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

Final report

Review of food derived using new breeding techniques

December 2019

Contents

Foreword

Since the food regulations for genetically modified (GM) food were established by FSANZ 20 years ago, there has been a steady emergence of new techniques for genetic modification. Given the continued emergence of such techniques is inevitable, it is important our regulatory systems are agile and able to support innovation, while at the same time continue to protect public health and safety now and into the future.

In June 2017, FSANZ commenced a review to consider the definitions for GM food and whether these are fit for purpose since the emergence of a range of new techniques for genetic modification – so called new breeding techniques or NBTs.

While this final report signals the conclusion of that review, it does not conclude FSANZ's work on this matter. FSANZ will shortly announce the commencement of a new process to consider how the definitions for GM foods should be amended.

The final report should be read in conjunction with the following documents:

- *Consultation paper: Food derived using new breeding techniques* (February, 2018)[1]
- *Preliminary report: Review of food derived using new breeding techniques – consultation outcomes* (August, 2018)[2]

Acknowledgements

FSANZ wishes to acknowledge and thank all those who contributed to this review. This includes:

- *Expert Advisory Group on New Breeding Techniques* whose advice and constructive feedback helped inform the development of the consultation paper;
- *Submitters* who contributed their valuable time to preparing submissions in response to the consultation paper; and
- *Reviewers* who provided helpful suggestions on the various review documents.

[1] Consultation paper: Food derived using new breeding techniques

[2] Preliminary report: Review of food derived using new breeding techniques – consultation outcomes

Glossary

Term	Description
Cell and tissue culture	A technique where plant or animal cells are grown in the laboratory.
Cisgenesis	Transferring genes between organisms of the same or a cross-compatible species.
Conventional breeding	A traditional method of developing new traits in plants or animals not involving gene technology.
Cross-breeding	The mating or cross hybridisation of different breeds or varieties within the same species.
DNA	DNA, or deoxyribonucleic acid, is the hereditary material for most living organisms. DNA is present in cells as two strands (double stranded) composed of a series of nucleotides.
Double-stranded break	When both strands of the double-stranded DNA molecule are severed.
Gene technology	A method that alters the DNA of living cells or organisms using recombinant DNA techniques. May also be called GM techniques.
Genetic modification	The process of altering the DNA of an organism.
Genetically modified organism (GMO)	An organism whose genome has been modified using gene technology.
Genome	The complete set of genetic material in a living cell or organism.
Genome editing	A technique which can be used to make specific changes at targeted locations in the genome of an organism.
GM food	Food derived from organisms that have been modified using gene technology.
Indel	An **in**sertion or **del**etion of nucleotides into or from the genome of an organism.
Intragenesis	Transferring a new combination of DNA into a related organism.
Mutagenesis	A way to induce changes to DNA.
New breeding techniques (NBTs)	A wide range of new techniques used to modify the genomes of plants, animals and microorganisms.
Nucleotide	The basic structural unit of DNA. For all living organisms, there are four types of nucleotides in DNA: adenine (A); guanine (G); cytosine (C) and thymine (T).
Null segregant	Progeny that have not inherited an introduced gene.
Point mutation	A change to a single nucleotide in DNA.
Recombinant DNA techniques	Recombining or joining DNA from two different sources.
GM rootstock grafting	Joining the vegetative (upper) part of a compatible plant variety to the rootstock of a GM plant.
Scion	The vegetative upper part of a plant that is joined to a rootstock.
Trait	A distinguishable characteristic belonging to an organism.
Transgenesis	Transferring DNA from unrelated organisms.

Executive summary

The *Australia New Zealand Food Standards Code* (the Code) contains definitions that determine what foods are food produced using gene technology and therefore subject to pre-market safety assessment and approval.

Over the last decade, a variety of new breeding techniques (NBTs) have emerged that are increasingly being applied to the production of food. The emergence of these techniques has generated uncertainty about the regulatory status of derived food products, specifically whether such foods would be considered food produced using gene technology and therefore require an application to FSANZ for pre-market approval.

In June 2017, FSANZ commenced a review of the Code to consider how it should apply to food derived using NBTs (NBT foods). The key questions the review was seeking to answer were:

- whether the definitions for '*food produced using gene technology*' and '*gene technology*' remain fit for purpose given the emergence of NBTs

- whether a pre-market safety assessment of NBT foods is justified based on risk.

A public consultation undertaken in February – April 2018 showed there are diverse and sometimes strongly polarised views about NBT foods. Following consideration of the submissions FSANZ identified seven key outcomes from the consultation.

While many submitters believe the definitions in the Code should be revised to improve clarity, views are divided on the type of definitional trigger that should be used and whether some foods could be excluded from pre-market scrutiny. A number of submitters expressed concern about the safety of NBT foods, and GM foods in general, as well as a strong preference for all NBT foods to be labelled as GM foods. A number of submitters were also in favour in greater alignment of definitions both domestically (i.e. those used in Australia for genetically modified organisms) as well as internationally. These outcomes and a summary of the submissions received were published in a preliminary report in August 2018.

Since the preliminary report was released, FSANZ has given further consideration to the two key questions above, taking into account the diverse views provided in submissions as well as the scientific evidence. FSANZ also undertook additional targeted consultation with key stakeholders in the government, public health, research and industry sectors.

In relation to the definitions themselves, FSANZ has found some of the wording to be ambiguous in the context of NBTs and it is this ambiguity that is responsible for the current uncertainty. Also, because the current definitions focus on a single technology and do not reflect the diversity of techniques now in use, they are now considered to be outdated.

FSANZ has also made a preliminary analysis of whether pre-market approval of NBT foods is justified based on risk. In considering this question, FSANZ has noted that NBTs may be used to produce a variety of different outcomes in terms of the food and that in some cases these outcomes may be similar if not identical to outcomes achieved using conventional breeding methods. There may therefore be a case for excluding some NBT foods from pre-market safety assessment if they are equivalent in terms of their characteristics to conventional food. The case for exclusion is strongest in relation to food derived from null segregant organisms but the equivalence argument may also be made for some foods derived through genome editing, GM rootstock grafting and cisgenesis.

FSANZ notes however that submitters were divided on whether or not foods should be excluded from pre-market scrutiny, with many expressing concern about the possibility that NBT foods could enter the food supply without any oversight by FSANZ. What constitutes an appropriate level of oversight is a question that will need to be further considered by FSANZ.

The key review findings are:

1. the definitions in the Code for '*food produced using gene technology*' and '*gene technology*' are no longer fit for purpose – they lack clarity, are outdated and do not reflect the diversity of techniques now in use

2. there may be a case, based on risk, for some NBT foods to be excluded from the requirement for pre-market safety assessment

3. divergent views exist among submitters about the acceptability and risk of NBT foods and how best to regulate them.

To determine the most appropriate way forward, and having regard to the prevailing uncertainty about the regulatory status of NBT foods under the Code and the need to future proof against further technology development, FSANZ considered three available options – maintain the *status quo* (do nothing), consider non-regulatory approaches, or amend the definitions in the Code.

This report concludes that the only viable option to effectively address the current regulatory uncertainty, as well as future proof the Code, is to amend the definitions. Maintaining the *status quo* by not addressing the problem will only further exacerbate the regulatory uncertainty. Non-regulatory approaches, such as providing guidance on how to interpret the current definitions in the Code, are also not considered a viable option as they do not provide legal certainty and would not address new and emerging genetic technologies.

In terms of amending the current definitions, submitters were divided about whether to retain a process-based definition or adopt an outcomes-based approach that includes the use of more product-based definitions. FSANZ notes there are advantages and disadvantages to both approaches that will need to be further considered.

The primary objective in amending the definitions however should be to improve clarity, which could be achieved with either approach. Another important objective will be to ensure foods are regulated in a way that is commensurate with the risks they pose.

On this latter point, FSANZ acknowledges there are different views among stakeholders about the risks posed by NBT foods and therefore what level of regulation would be regarded as "commensurate with risk". In moving forward it will be important for FSANZ to engage in as wide a discussion as possible with stakeholders and the broader community to ensure any potential regulatory changes take into account the diverse range of views that exist. An important component of this will be to explore ways to raise awareness in the community about GM and NBT foods.

Recommendations

Recommendation 1: FSANZ prepare a proposal to revise and modernise the definitions in the Code to make them clearer and better able to accommodate existing and emerging genetic technologies.

Recommendation 2: As part of the proposal, FSANZ give consideration to process and non-process based definitions and the need to ensure that NBT foods are regulated in a manner that is commensurate with the risk they pose.

Recommendation 3: Throughout the proposal process FSANZ will ensure there is open communication and active engagement with all interested parties and also explore ways to raise awareness about GM and NBT foods.

Next Steps

In line with Recommendation 1, FSANZ will prepare a proposal to amend the definitions in the Code for '*food produced using gene technology*' and '*gene technology*'. This work will commence as soon as practicable in 2020. FSANZ will continue to engage with stakeholders in the lead up to and throughout the proposal process and will communicate any relevant updates through the FSANZ webpage[3].

[3] https://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx

1. Introduction

The review was initiated to consider how the Code applies to food products derived using NBTs (NBT foods).

Definitions for '*food produced using gene technology*' and '*gene technology*' were considered and the review examined whether:

- the current definitions remain fit for purpose given the emergence of NBTs
- a pre-market safety assessment of NBT foods is justified based on risk.

The review did not consider issues related to labelling, i.e., it did not consider the current approach to GM food labelling, or the specific requirements in the Code that relate to GM food labelling.

The outcomes of this review have not changed any aspect of the Code that relate to food produced using gene technology, including mandatory labelling requirements.

The purpose of the review was to investigate whether there is a case for FSANZ to prepare a proposal to amend the Code. Any subsequent proposal to amend the Code will be conducted as a separate process according to requirements set out in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and will include further rounds of public consultation.

2. Review findings and recommendations

During the consultation FSANZ asked a number of questions (see Appendix 1) that relate to the following broad themes:

- the current definitions and whether they remain fit for purpose
- the safety of NBT foods and the need for pre-market safety assessment
- the definitional trigger that should be used for NBT foods.

Other themes also emerged through the consultation process, such as GM food labelling and international harmonisation. The submissions also showed there are many different views and perspectives that exist among stakeholders in relation to NBT foods and GM foods in general.

FSANZ's findings in relation to the above and subsequent recommendations are discussed below.

2.1 Current definitions

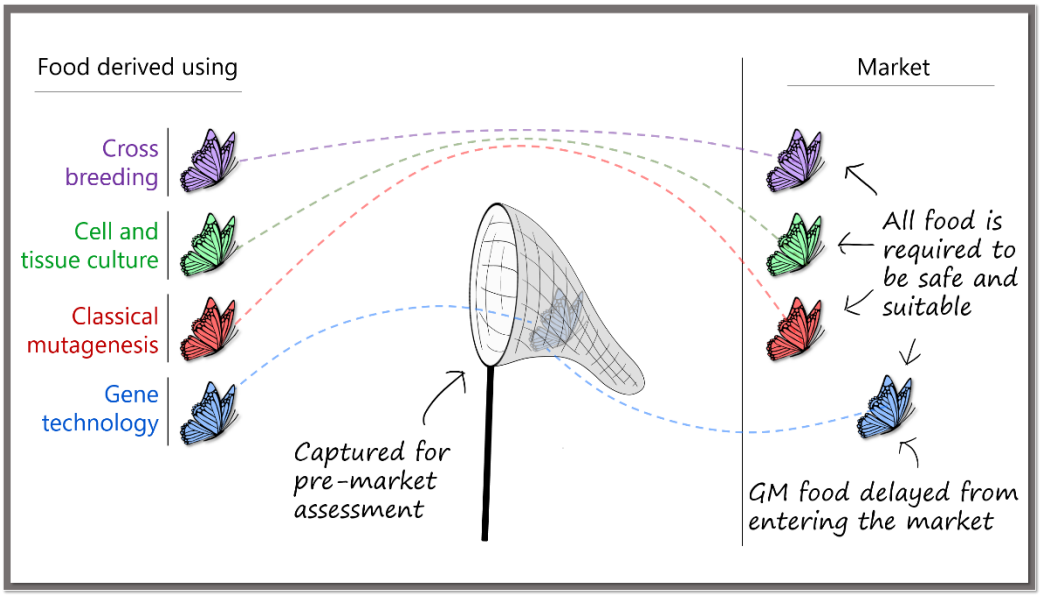
The need for clear definitions was the issue that generated the most agreement among submitters. Not all submitters agreed however that the definitions need to be changed. Some submitters consider an overly narrow interpretation of the current definitions has been applied and that NBT foods are clearly captured.

2.1.1 History and purpose of the definitions

The current definitions in the Code were put in place 20 years ago. They were intended to capture the types of GM food products that existed at the time. That is, food from transgenic organisms which had been developed using recombinant DNA techniques. The definitions were also intended to clearly exclude food derived using conventional breeding methods, such as traditional cross-breeding, cell and tissue culture techniques and classical mutagenesis. The definitions therefore created a clear dichotomy between GM foods and food derived through conventional breeding methods (Figure 1).

Since the transgenesis technique typically involves randomly inserting foreign DNA from unrelated organisms, it is easily distinguished from other types of genome modifications achieved using conventional breeding methods. Derived foods were perceived at the time to be a potentially greater source of risk compared to conventional foods, primarily because of concern about unintended effects arising from the random insertion of foreign DNA, as well as the potential for transfer of harmful characteristics, e.g. an allergen. For this reason it was considered appropriate to single out these types of foods for additional regulatory oversight in the form of pre-market assessment and approval, noting that under food law all food is required to be safe and suitable.

Figure 1: Effect of the current definitions in the code



2.1.2 Clarity and applicability of current definitions

The main reason for commencing the review was because of the uncertain regulatory status of NBT foods under Standard 1.5.2 – Food produced using gene technology of the Code. Food that comes within the scope of Standard 1.5.2 is required to undergo pre-market assessment and approval before it may be sold. To be subject to such requirements a food must meet the definitions for '*food produced using gene technology'* and '*gene technology*':

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

FSANZ has considered the wording of these definitions and has identified two aspects that are a source of uncertainty in relation to NBTs. The first is the ambiguous nature of the wording "derived or developed from" in the definition of '*food produced using gene technology*', and the second is the absence of a definition for the term "recombinant DNA techniques" in the definition for '*gene technology*'.

The ambiguity surrounding the meaning of "derived or developed from" is relevant to foods derived from genome editing, grafting and null segregant organisms (see Appendix 2). For example, it is unclear how "derived or developed' from should be interpreted in the case of a null segregant that has not itself inherited a genetic modification introduced using gene technology but is nonetheless descended from an organism that has been modified using gene technology.

The above wording could be interpreted as either including or excluding food derived from null segregant organisms but a broader interpretation, which would be consistent with the views of some submitters, is that food derived from null segregants is currently captured by the definition for '*food produced using gene technology*'.

The absence of a legal definition for “recombinant DNA techniques” makes it unclear whether certain NBTs are considered to be ‘*gene technology*’. A common scientific understanding of the term however is that it refers to the recombining or joining of DNA from two different sources. In practice, “recombinant DNA techniques” in the definition for ‘*gene technology*’ has resulted in foods derived primarily from transgenic organisms being captured for pre-market assessment and approval. The applicability of the term “recombinant DNA techniques” to some of the genetic modifications introduced using genome editing is unclear, particularly as there is no recombinant DNA that remains in the final food producing organism.

Finding 1: The definitions in the Code for ‘*food produced using gene technology*’ and ‘*gene technology*’ are no longer fit for purpose – they lack clarity, are outdated and do not reflect the diversity of techniques now in use.

2.1.3 Addressing the problem

Having determined that the current definitions are no longer fit for purpose, FSANZ considered different approaches that could be used to address the problem including whether there were any non-regulatory options that could be effective instead of amending the Code, as well as the potential impacts of doing nothing, i.e., maintaining the *status quo*.

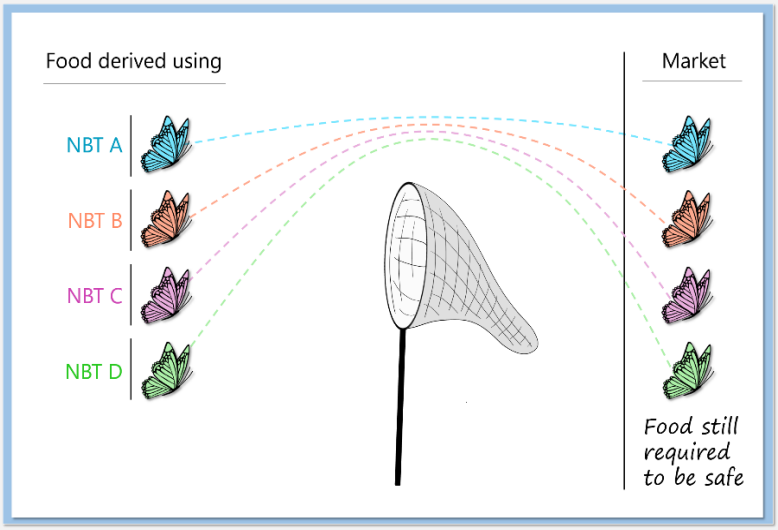
The non-regulatory options that FSANZ investigated as part of the review included the development of guidance or alternatively a code of practice to clarify the interpretation of the current definitions in the Code. It is unlikely that such approaches would be effective at addressing the problem because they would not provide any legal certainty. Legal certainty is important for product developers so they know the regulatory pathway to market for their product and is also important for enforcement agencies to enable them to determine if a food is compliant with the Code. Legal certainty also provides reassurance to the community that food law is being appropriately implemented and enforced.

The other disadvantage with non-regulatory options such as guidance is that it would only apply to the current definitions, which FSANZ has already determined are outdated and do not reflect the current diversity of techniques now in use. If FSANZ were to adopt an approach that maintained the current definitions, there is a risk that some foods will be deemed to be outside the scope of the current definitions even though a pre-market safety assessment may be justified.

In certain instances, particularly where viable non-regulatory options exist, maintaining the *status quo* and not introducing any amendments to the Code may be a reasonable option to consider, at least in the short term or as an interim measure. However in this case the continuing regulatory uncertainty may lead to a number of negative impacts (see Box 1).

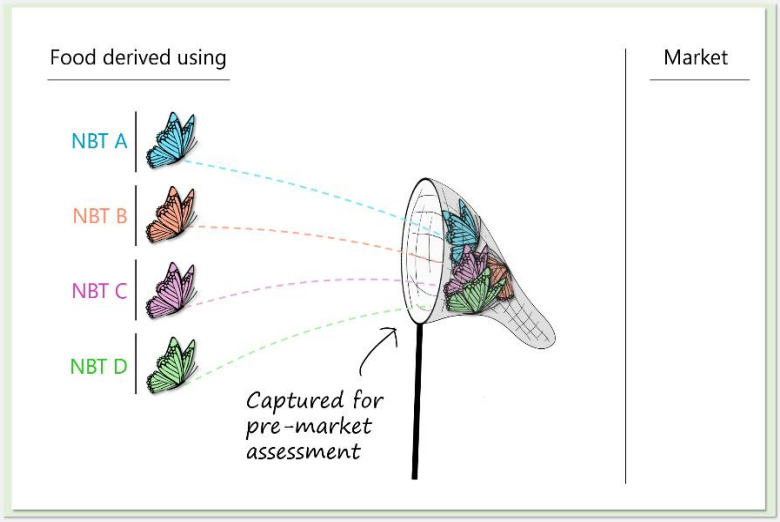
Box 1 | Possible scenarios if the current definitions remain unchanged

These scenarios are each associated with particular costs/disadvantages for consumers, food developers, regulatory authorities and society. These scenarios are non-mutually exclusive and for every given NBT each food developer could interpret the code differently. This could result in inconsistencies in the way such food is regulated.



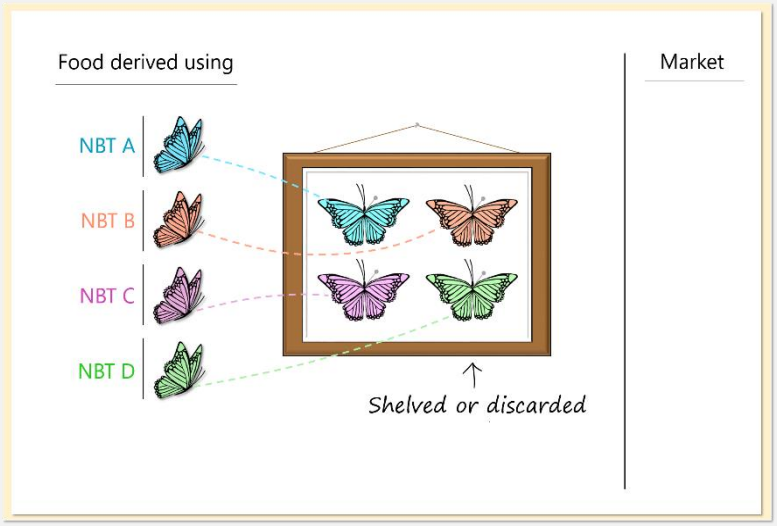
Scenario 1. *Non-compliant NBT foods might enter the market place.*

Food developers might incorrectly believe their product does not require pre-market scrutiny. Possible risks to public health and safety.



Scenario 2. *An increase in applications to FSANZ.*

Food developers might incorrectly believe their product requires pre-market approval and submit an application to FSANZ. There are cost implications for both product developers as well as FSANZ.



Scenario 3. *The development of NBT products might be abandoned.*

Possible negative impacts on innovation because developers are uncertain about the regulatory pathway for a particular NBT food.

For example, there may be potential health and safety risks to the community if, as a result of the uncertainty, some developers incorrectly believed their product did not require pre-market approval. Conversely, developers may decide to err on the side of caution and submit products to FSANZ for assessment and approval that do not actually require pre-market approval under the current definitions, creating additional work for FSANZ. A third potential impact is that developers may refrain from investing in a product or abandon a product's development because of uncertainty about the regulatory requirements.

In this context FSANZ has also considered possible impacts of delaying further work on the definitions, given the work that is now being undertaken in Australia to implement the recommendations of the Gene Technology Scheme (GTS) review[4], including further consideration around definitions.

The risks of maintaining the *status quo* and doing nothing are the same as the risks of deferring further work until the GTS review recommendations are implemented. Neither are considered to be a viable option

Recommendation 1: FSANZ prepare a proposal to revise and modernise the definitions in the Code to make them clearer and better able to accommodate existing and emerging genetic technologies.

2.2 The need for pre-market safety assessment

2.2.1 The current approach to GM foods

Under Standard 1.5.2 – Food produced using gene technology, GM food must first be approved and listed in Schedule 26 of the Code before it may be sold in Australia and New Zealand. Approval is contingent on the outcome of a pre-market safety assessment.

Standard 1.5.2 came into effect in 1999 and was intended to capture all GM food for pre-market safety assessment irrespective of potential risk. This was considered justified because of the uncertainty that existed at the time regarding gene technology, i.e., it was a relatively new technology, few examples of GM foods existed, there was limited regulatory experience assessing such products as well as little empirical evidence of safety.

The main reasons for adopting Standard 1.5.2 were so that:

- the community could be assured about the safety for human consumption of food produced using gene technology and be confident in the food supply
- industry could have confidence that the regulatory framework will be clear and enable it to be innovative and internationally competitive
- consumers could have access to accurate information on the use of foods produced using gene technology including labelling where appropriate.

The approach fulfilled community expectations at the time that all products of gene technology be subject to regulatory scrutiny because of the perception of increased risk.

[4] More information is available on the Australian Government Department of Health website.

2.2.2 Food derived using NBTs

NBTs encompass a wide variety of new techniques for the modification of genomes. These techniques may result in a variety of different outcomes, both in terms of changes introduced to the genome as well as changes to the characteristics of a food. Therefore, the risk associated with NBT foods will vary according to the outcomes produced.

One of the key questions for the review was whether there is sufficient justification in terms of risk to subject all NBT foods to pre-market safety assessment or whether there are certain foods, or categories of foods, that could be excluded from such scrutiny.

Views among submitters were mixed in relation to this question. Some submitters argued that because the techniques are still relatively new there is insufficient evidence of safety of derived foods and also that there is no scientific basis for making a risk distinction between NBTs and older GM techniques.

Other submitters argued not only for the exclusion of certain categories of NBT foods but also for the exclusion of some existing GM foods, stating that such food poses the same or less risk as food derived using conventional breeding methods. A number of other submitters were comfortable with the current regulatory approach to older GM foods but considered there may be justification either for some categories of NBT foods to be excluded or for them to be subjected to a simplified safety assessment.

In the case of GM foods, FSANZ notes that safety is determined by comparison to a conventional counterpart food which is the benchmark for what is considered safe[5]. This type of comparison may also be applied to NBT foods.

The rationale for this approach is that if the characteristics of NBT foods are similar or the same as a conventional food, the NBT food can be considered to have the same benefits and risks as food already in the food supply. This would be a relevant consideration in determining whether a NBT food should be subject to additional regulatory scrutiny in the form of a pre-market safety assessment.

As a preliminary analysis, FSANZ considered the different types of NBT foods to determine if there was potential for some NBT foods to be similar to conventional foods in terms of their characteristics (see Appendix 2). The outcome of this analysis is that:

- food derived from null segregant organisms will be identical to conventional food
- food derived from cisgenic organisms may be similar to food derived through cross-breeding
- some food derived from GM rootstock grafting will be identical to conventional food
- some food derived using genome editing will be equivalent, if not identical, to conventional food, including that derived using classical mutagenesis methods.

More robust analysis and further consultation will be required before FSANZ makes any conclusions about the equivalence of some NBT foods to conventional food.

[5] *Foods derived from modern biotechnology* (Codex 2009), page 7.

FSANZ notes that submitters were divided on whether any foods should be excluded from pre-market scrutiny, with a number of submitters expressing concern about the possibility that NBT foods could enter the food supply without any oversight by FSANZ. What constitutes an appropriate level of oversight is a question that will need to be further considered by FSANZ and the broader food regulatory system.

Finding 2: There may be a case, based on risk, for some NBT foods to be excluded from the requirement for pre-market safety assessment.

Finding 3: Divergent views exist among submitters about the acceptability and risk of NBT foods and how best to regulate them.

Unintended changes

One of the prevailing concerns about GM foods, which flows through to NBT foods, is the potential for unintended changes to occur. A number of submitters consider that a pre-market safety assessment is essential for all GM and NBT foods to guard against the occurrence of unintended changes, which they consider to be the major source of risk.

FSANZ has been undertaking GM food safety assessments for the last 20 years and has examined a large amount of data and information as part of those assessments. While concern about unintended changes in GM foods persists, the accumulated evidence does not support the hypothesis they are inherently harmful or a major source of risk to the consumer.

The occurrence of unintended changes is not peculiar to gene technology but may also occur when conventional breeding methods are used[6]. The evidence to date indicates that gene technology is no more likely than conventional breeding to produce unintended changes[7]. It may also be argued that because techniques such as genome editing are more targeted or directed, the likelihood of unintended changes occurring is much less compared to other genetic modification methods including conventional breeding. FSANZ is aware of only very rare instances where unintended changes from conventional breeding has resulted in a potential food safety concern[8]. It is also important to emphasise that the fact a change is unintended does not make it any more likely to be harmful. An unintended change may be harmful, neutral or advantageous with respect to the final product and whether it is likely to be harmful is independent of the genetic modification method used.

2.3 Regulatory approach

2.3.1 Definitional trigger for pre-market assessment

In recommending that the definitions in the Code for '*food produced using gene technology*' and '*gene technology*' be amended, one of the key considerations will be to determine what type of definitional trigger would be appropriate. That is, whether to continue to rely on

[6] For more information see Schnell et al (2015) A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. *Transgenic research* 24:1-17.

[7] FSANZ Application Handbook (1 July 2019), page 36.

[8] For more information see page 12 of Channapatna S. Prakash (2001) The Genetically Modified Crop Debate in the Context of Agricultural Evolution. *American Society of Plant Physiologists* 126: 8–15.

process-based definitional triggers or change to more product-based definitions. To assist in the decision-making, it will first be important to identify what the key objectives should be for amending the definitions.

The primary objective of any amendment to the definitions should be to provide greater clarity about what foods require pre-market assessment and approval and what foods do not. Clear definitions provide legal certainty which benefits all stakeholders.

To avoid further periods of uncertainty as new technologies continue to emerge, as well as frequent reviews of definitions, another important objective should be to adopt a definition that better accommodates current and future technology developments. Genetic technologies are in a constant state of evolution and the pace of change is also likely to increase over time. In the face of such technological advances, the Code needs to be flexible and forward thinking while remaining focussed on managing legitimate food-related health risks.

The other important objective will be to adopt a definition that results in NBT foods being regulated in a manner that is commensurate with the risks they pose. Regulation can have benefits by minimising risks to public health and safety but excessive regulation may stifle innovation and deter investment in the technology without providing any added public health protection. In the case of NBT foods, a case exists that pre-market approval should only be required where justified according to a reasonable expectation of greater risk compared to existing conventional foods.

FSANZ acknowledges there are different views among stakeholders about the risks posed by NBT foods and therefore what level of regulation would be regarded as “commensurate with risk”. In moving forward it will be important for FSANZ to engage in as wide a discussion as possible with stakeholders and the broader community to ensure any potential regulatory changes have regard to the diverse range of views that exist.

In summary, FSANZ proposes the objectives for revising and modernising the definitions in the Code should be to:

- improve clarity about what foods are captured for pre-market approval
- better accommodate new and emerging genetic technologies
- regulate NBT foods in a manner that is commensurate with the risks they pose.

Process-based and product-based definitions

One of the key questions for FSANZ to consider in contemplating an amendment to the current definitions in the Code is whether to continue with a process-based definitional trigger, or change to a more product-based approach. Product-based definitions are focussed on the outcome of the genetic modification, including the product characteristics, rather than the process or specific technique used to achieve the outcome.

In considering the responses from submitters on the relative merits of process-based and product-based definitions, FSANZ notes that views were divided.

A number of submitters were in favour of continuing to use process-based definitions as they see this as the most effective way to capture all NBT foods for pre-market safety assessment and approval. Some submitters also consider that a process-based definition would be more consistent with definitional triggers used elsewhere and that this would be better for trade.

Other submitters were more in favour of product-based definitions as they consider this type of definitional trigger is more likely to deliver risk-based outcomes in terms of what foods are captured and would also be more effective at future proofing the Code.

FSANZ notes that process-based definitions for triggering pre-market approval of GM foods have been widely adopted around the world. In terms of their advantages, such definitions can provide a simple and clear way to signal the regulatory status of certain products and make regulations more predictable in terms of outcome[9]. Capturing products on the basis of the process used can also provide an effective mechanism to prevent regulatory gaps in coverage and ensure comprehensive risk assessments are applied equally to all products derived using a specific technology.

The main disadvantage of process-based definitions is that they can quickly become outdated and therefore require periodic review and potentially need amendment as technology changes. Also, because some NBTs can result in foods that are identical or equivalent to conventional foods, a further disadvantage of process-based definitions is that they can result in identical products being regulated differently.

The advantage of product-based definitions is that they may be better able to accommodate a diverse range of technologies because of their focus on outcome, rather than process. It may also be argued that the use of product-based definitions allows regulations to be applied in a way that is commensurate with the level of risk. In terms of potential disadvantages, specific guidance may need to be developed to ensure implementation is effective, and such definitions may also have reduced compatibility with process-based regulatory systems.

In considering an amendment to the definitions in the Code, it will be important for FSANZ to weigh up the advantages and disadvantages of both types of definitional trigger, as well as consider which approach will best enable FSANZ to meet the three key objectives as outlined above.

Recommendation 2: As part of the proposal, FSANZ give consideration to process and non-process based definitions and the need to ensure that NBT foods are regulated in a manner that is commensurate with the risk they pose.

2.3.2 Alignment of definitions with other regulatory schemes

The gene technology regulatory landscape in Australia and New Zealand is complex and the relevant legislation and regulations, including definitions, for genetically modified organisms (GMOs) and food produced using gene technology were developed independently from each other.

Many submitters to the consultation consider it is important for there to be alignment of definitions to avoid inconsistencies between what is regulated as a GMO and what is regulated as a GM food. Some submitters were also wary of FSANZ making any changes to definitions before the outcomes of other reviews addressing the *Gene Technology Act 2000* and its regulations are known.

In considering this issue, FSANZ believes it may be necessary to take a more pragmatic approach, and notes that despite the differences in current definitions in relevant legislation

[9] For more information see Eckerstorfer *et al* (2019) Plants Developed by New Genetic Modification Techniques-Comparison of Existing Regulatory Frameworks in the EU and Non-EU Countries. In *Frontiers in bioengineering and biotechnology* 7:26.

and regulations in both Australia and New Zealand, consistent regulatory outcomes have been achieved in terms of what is regulated as a GMO and what is regulated as a food produced using gene technology.

One of the important issues to consider in attempting to align definitions for example between the Code and the *Gene Technology Act 2000* (GT Act) and its regulations is their respective purposes. The objectives of the GT Act, and the risks to be managed, are significantly broader than those of the Code, and more specifically Standard 1.5.2, which was put in place specifically to manage risks associated with the consumption of food produced using gene technology.

Another important consideration is the lack of alignment in definitions between the GT Act and its regulations (as recently amended)[10] and in New Zealand, the *Hazardous Substances and New Organisms Act 1996* (HSNO Act). As the provisions in the Code for food produced using gene technology apply to food sold in New Zealand it would be difficult to develop a revised definition that would align with both the GT Act and the HSNO Act.

A final consideration is that the potential risks to human health and the environment of a GMO may be very different to that of derived food. Hence it may not be justified or appropriate for the Code to capture all foods derived from organisms captured as GMOs under either the GT Act or the HSNO Act.

It may be more practical to focus on the alignment of regulatory outcomes, rather than definitions, and to also consider the extent to which alignment of outcomes is appropriate given the different risks to be managed. This is something that will require further consideration during the next phase of the work.

2.3.3 International harmonisation of regulatory approaches

Many submitters stressed the importance of international harmonisation of regulations. If regulations are not harmonised there is concern about possible negative impacts on trade and market access.

FSANZ notes that internationally there is no single consensus on the regulatory approach to NBTs and derived foods with a number of different approaches being adopted around the world[9]. These approaches generally fall into three main types:

- countries that are revising existing definitions (e.g. Australia)
- countries that are applying existing regulatory frameworks to NBTs (e.g. New Zealand, Canada, European Union, United States, Japan)
- countries that are implementing supplementary legislation for NBTs to support existing regulatory frameworks (e.g. Argentina, Brazil).

Some of these countries continue to rely on process-based definitions, whereas others are applying more outcomes-based approaches.

The international situation in relation to the regulation of NBTs remains fluid, with little likelihood of harmonisation in the near future. Whether the absence of harmonisation will

[10] Information about the amendments to the *Gene Technology Regulations 2001* is available from the OGTR website.

impact trade is unknown at this stage as there are very few NBT food products that have been commercialised and traded between countries. FSANZ will continue to monitor international developments and will have regard to these during the next phase of the work.

2.4 Other relevant matters

2.4.1 GM food labelling

GM food labelling was not included in the scope of this review. Nevertheless, FSANZ recognises that the ability to exercise informed choice when purchasing foods containing GM ingredients is important to consumers. This was a dominant theme that came out of the consultation.

During the GTS review, stakeholder dissatisfaction with GM food labelling was noted. Much of this dissatisfaction appears to be because many consumers had not encountered any foods that were labelled and had assumed (incorrectly) that GM food labelling was not mandatory. Market research undertaken in Australia recently indicates consumer knowledge about GM foods is limited, particularly in relation to the number and type of GM foods in the food supply[11]. At present there are no whole GM fruit or GM vegetables in the food supply. Most GM foods enter our food supply as ingredients (e.g. oil, flour, starch) in imported processed foods.

Current approach to GM food labelling

The policy approach and requirements for GM food, including its labelling, were developed 20 years ago and have not been changed. Under that approach food produced using gene technology is required to undergo pre-market safety assessment before being approved for sale. Approved food produced using gene technology is also subject to mandatory labelling requirements. Mandatory labelling was adopted not for safety reasons but rather to assist consumers to make an informed choice.

The approach to GM food labelling is product based[12]. That is, labelling is required based on the presence of novel DNA or novel protein in the final food or if the characteristics of the food have been changed in a meaningful way (an altered characteristic) (Figure 2). A number of exemptions to mandatory labelling apply that are either product based (e.g. the exemption for highly refined foods or ingredients) or based on other practical considerations (e.g. unintended presence).

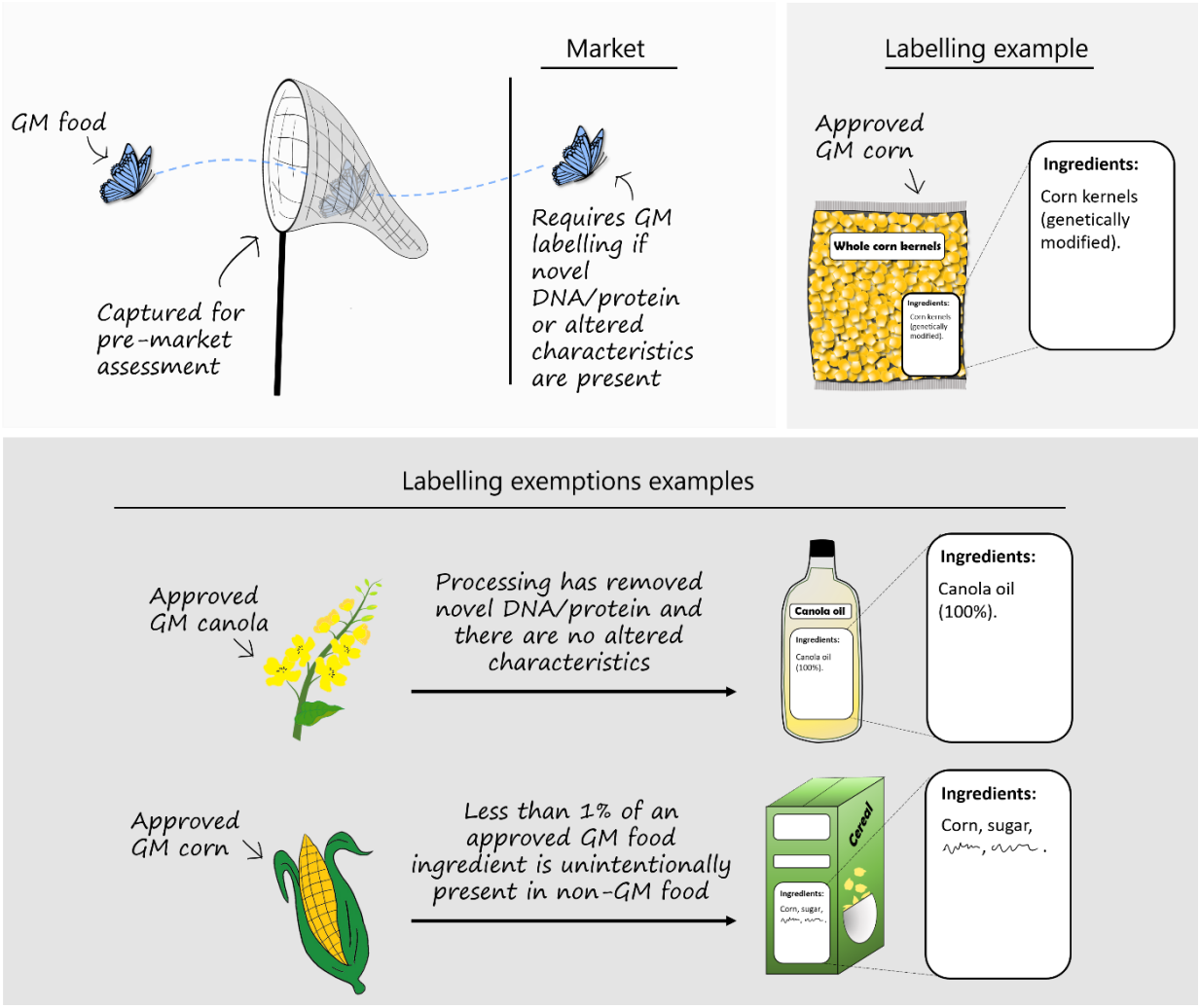
The labelling approach to GM foods was reviewed as part of *Labelling Logic: Review of Food Labelling Law and Policy* in 2011[13]. In response to that review, the Legislative and Governance Forum on Food Regulation considered the existing labelling provisions for GM food to be appropriate.

[11] More information is available on the Australian Government Department of Health website.

[12] More information is available on the FSANZ website.

[13] More information is available on the Food Regulation website.

Figure 2: Labelling requirements



Further consideration of definitions

In undertaking further work on NBT foods, including consideration of possible amendments to definitions, FSANZ does not intend to review the GM food labelling requirements. The GM food labelling requirements will therefore remain as they are and will continue to apply to approved food produced using gene technology.

FSANZ acknowledges the continued interest among stakeholders in GM food labelling and the importance of the definitions in determining what foods may be subject to those requirements.

As part of any future proposal, and consistent with the s18 objectives of the FSANZ Act, FSANZ will need to consider potential implications for consumer information arising from any amendments to definitions.

In addition, and having regard to the limited knowledge in the community about GM foods and their labelling, FSANZ will explore ways to raise awareness among consumers about GM foods and how labelling is applied.

2.4.2 Participation in the proposal process

In moving forward with a proposal to amend the Code, a key consideration will be to ensure the community is kept well informed about the process and opportunities for input and that FSANZ continues to engage in a transparent way.

FSANZ considers openness and transparency to be vital to this work given the diversity of views on gene technology, as well as the limited understanding in the community about NBTs[14]. FSANZ notes a multidisciplinary panel of experts, who carefully considered the implications of NBTs for New Zealand, has encouraged wide engagement with the community to help bridge this gap in understanding[15]. FSANZ acknowledges that feedback on public attitudes and ethical views are an important component of this engagement.

Such engagement will allow FSANZ to develop revised definitions that are informed by the science and consistent with community values and expectations. Engagement may not however always result in an outcome that is favourable to all members of the community but this is part of the democratic process of decision making.

Recommendation 3: Throughout the proposal process FSANZ will ensure there is open communication and active engagement with all interested parties and also explore ways to raise awareness about GM and NBT foods.

3. Next steps

The review was undertaken in accordance with section 113 (s.113) of the FSANZ Act. The publication of this report signals the conclusion of the review.

As soon as practicable after the conclusion of the review, FSANZ intends to prepare a proposal to amend the Code. Proposals to amend the Code are undertaken in accordance with specific provisions in the FSANZ Act, including various statutory criteria that FSANZ must have regard to in its assessment of proposed amendments to the Code.

For the next phase of the work, FSANZ will therefore need to consider how best to progress the recommendations, the scope and timing of any proposal, and the regulatory options for amending the definitions in the Code. Throughout this next phase FSANZ will continue to engage with stakeholders (through public consultation as well as other means) and communicate any relevant matters.

[14] More information is available on the OGTR website.

[15] More information is available on the Royal Society Te Apārangi website.

4. Background

4.1 How we conducted the review

The review was conducted over a two and a half year period and included a number of stages as outlined below in Figure 3. A key part of the review was the public consultation undertaken in February – April 2018. The consultation paper was developed with the assistance of an Expert Advisory Group on New Breeding Techniques[16] and a preliminary report was released in August 2018. Further consideration of submissions and the key consultation outcomes, as well as additional targeted consultation undertaken over the last 12 months, were used to inform the key findings and recommendations.

Figure 3: Steps taken in the review

[16] More information on the Expert Advisory Group on New Breeding Techniques is available on the FSANZ website.

4.2 Relationships to other reviews

Two other reviews conducted in Australia have coincided with the FSANZ review of food derived using NBTs. Those reviews are:

- the Technical Review of the *Gene Technology Regulations 2001*, conducted by the Office of the Gene Technology Regulator (OGTR), which was concluded in April 2019 and resulted in amendments to the *Gene Technology Regulations 2001*[17]

- the Third Review of the National Gene Technology Scheme, conducted by a collaboration of Commonwealth, state and territory officials on behalf of all Australian governments, which was concluded in October 2018[18].

While these reviews have also considered new technologies, they are separate and independent of the FSANZ review. The outcomes of these reviews have not changed any parts of the Code that relate to food produced using gene technology.

4.3 Terminology

The term new breeding techniques or NBTs has been used throughout the course of the review and associated documents.

NBTs refers to a wide range of new techniques used to modify the genomes of plants, animals and microorganisms and includes such techniques as genome editing, GM rootstock grafting, cisgenesis, intragenesis and techniques producing null segregants (see Appendix 2). The term NBT has been widely adopted around the world and is used to distinguish the newer techniques from older methods of genetic modification. FSANZ acknowledges that not all stakeholders agree with this distinction and the use of such terminology.

[17] Information about the OGTR's Technical Review of the *Gene Technology Regulations 2001* is available from the OGTR website.

[18] Information about the Third Review of the National Gene Technology Scheme is available from the Australian Government Department of Health website.

Appendix 1: 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?

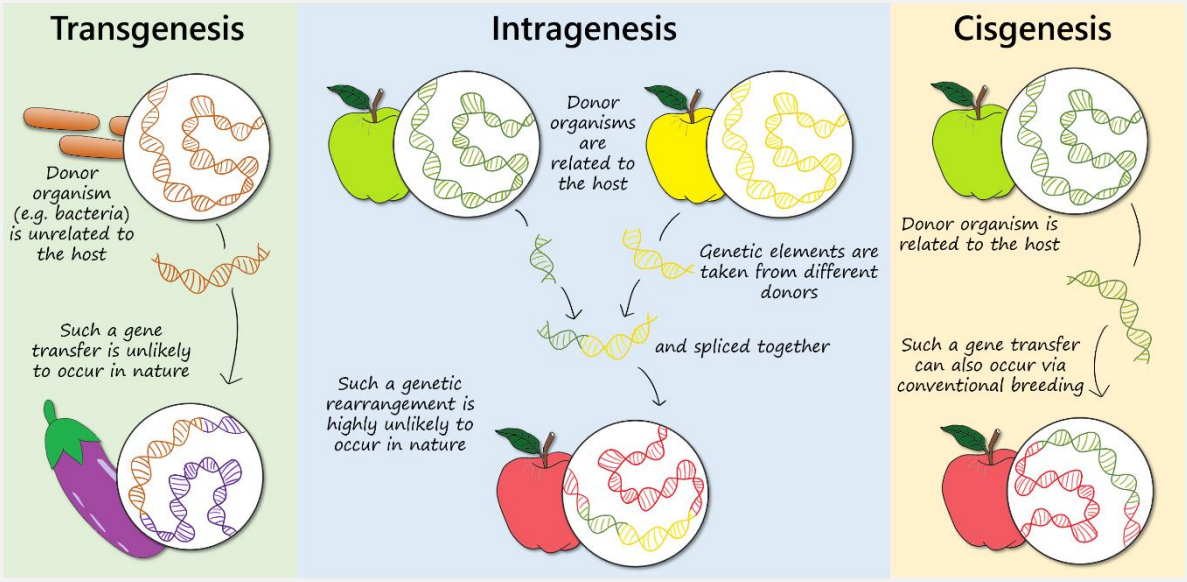
Appendix 2: Equivalence assessment

Appendix 2 outlines some of the NBTs used to produce food and the potential for these products to be equivalent to food derived using conventional breeding methods.

Genome contains new DNA

This category includes transgenesis, intragenesis and cisgenesis (Box 2).

Box 2 | Genome contains new DNA

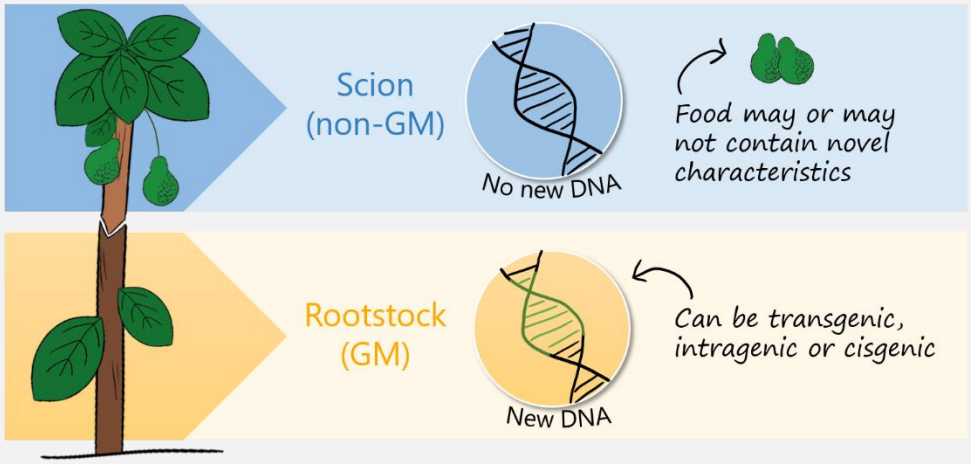


While all three techniques involve introducing new DNA into the genome, cisgenesis may be distinguished from intragenesis and transgenesis because it typically involves transferring traits between related varieties or breeds and may therefore reproduce outcomes that could be achieved using cross-breeding. Food derived from cisgenic organisms may therefore be similar in terms of its characteristics to food derived through cross-breeding.

Similarly, GM rootstock grafting may, in some circumstances, result in foods that are similar to conventional foods (Box 3). Some genetic modifications to the rootstock may influence the characteristics of the upper part of the plant (scion) and potentially also the food, while others may not. In the latter case, the final food, such as a fruit, will be identical in its characteristics to conventionally bred fruit already in the food supply.

Box 3 | GM rootstock grafting

Involves joining the vegetative (upper) part of a compatible plant variety to the rootstock of a GM plant.



Genome unchanged by gene technology

The techniques in this category are those producing null segregants. Such techniques are highly diverse but the end result is that the final food producing line will not contain any new DNA as a result of the use of gene technology because it will be segregated away (see example in Box 4).

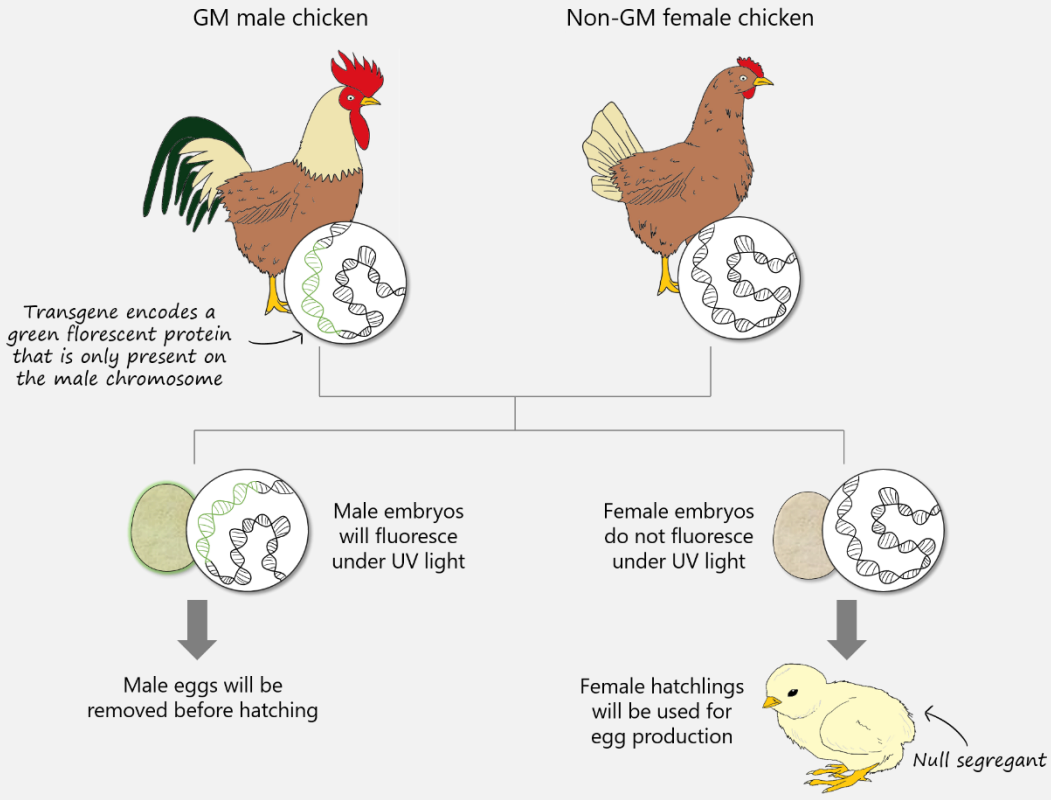
Once any introduced DNA has been segregated away, any changes associated with that DNA should no longer be present in the final food producing lines or derived foods. The food will therefore be equivalent to food derived using conventional methods approaches.

There is a clear case for excluding food derived from null segregants from pre-market assessment and approval as it would be indistinguishable from conventional food and be equivalent in terms of risk. FSANZ also notes that under the 2019 amendments to the *Gene Technology Regulations 2001*, the OGTR has clarified that null segregant organisms are not GMOs and do not pose risks as a result of gene technology because they do not possess traits introduced using gene technology. For a number of years it has also been common practice for FSANZ to allow the use of null segregants as non-GM comparators for the purpose of GM food safety assessment[19].

[19] FSANZ *Application Handbook (1 July 2019)*, page 35.

Box 4 | Sex selection in layer chickens

Male hatchlings of layer chickens are normally culled after hatching. A NBT could allow the detection and removal of male eggs before hatching. This technique will result in null segregant female hatchlings.



Genome changed but no new DNA

This category refers specifically to the genome editing techniques. The edits to the genome typically include point mutations, small insertions/deletions (indels) and larger deletions. These types of genome changes are not particular to genome editing. They also occur spontaneously in nature and are the basis of natural variation used in conventional breeding[20]. Similar changes can also be randomly induced using classical mutagenesis methods. Some of the foods produced using genome editing techniques may therefore be equivalent, if not identical, in their characteristics to foods that have been produced using classical mutagenesis methods, or that exist in nature.

One of the most frequently raised concerns in relation to genome editing is the potential for off-target changes to be introduced as a result of a double-stranded break being introduced at other than the intended site, or other changes that may occur during repair of the double-stranded DNA break.

[20] For more information see Custers et al (2018) Genetic Alterations That Do or Do Not Occur Naturally; Consequences for Genome Edited Organisms in the Context of Regulatory Oversight. In *Frontiers in Bioengineering and Biotechnology* 6:213.

FSANZ notes that both genome editing and classical mutagenesis can produce double-stranded breaks as well as errors during the repair process. In the case of genome editing, off-target changes may also occur. The frequency of such off-target changes is typically much lower than the frequency of non-targeted random changes that occur with classical mutagenesis methods[21]. Irrespective of whether the double-stranded DNA break is a result of genome editing or classical mutagenesis, the process of double-stranded DNA break repair is the same[22]. Errors during repair is a normal part of this process and occur irrespective of whether the double-stranded break has occurred as a result of classical mutagenesis methods or through genome editing.

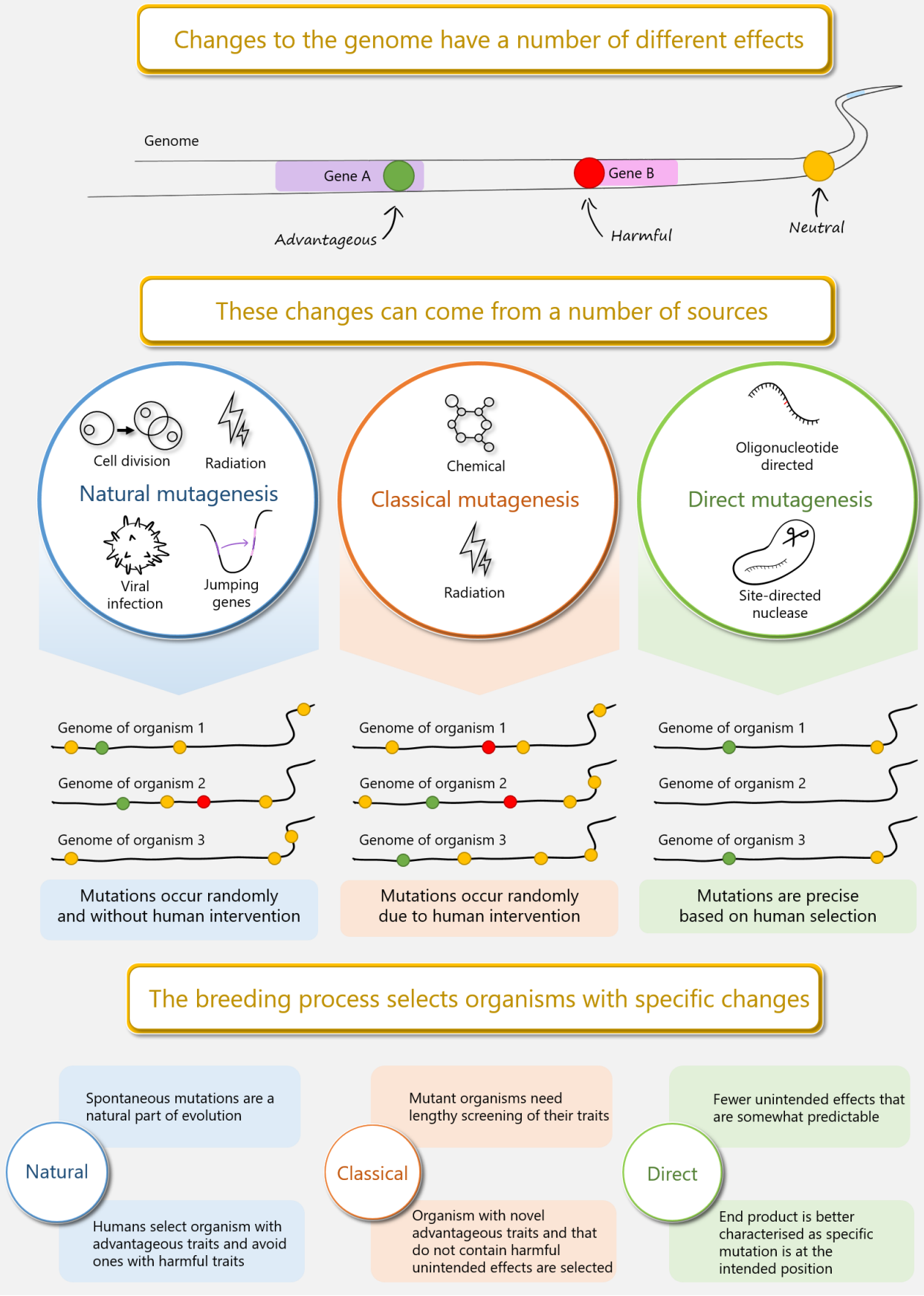
The most significant difference between genome editing and classical mutagenesis is that the site of DNA breakage is pre-determined in the design of the genome editing tool, while the DNA breakage is random in classical mutagenesis. Since the genetic change is much more predictable and directed than classical mutagenesis, genome editing tools are much less prone to off-target changes[20] (Box 5).

The sequence specificity of genome editing tools means that any off-target sites are generally similar in sequence to the intended target site therefore the potential for an off-target event can be predicted to some extent. Importantly, an off-target change does not necessarily equate to a harmful consequence in the final food produced.

[21] For more information see Zhao, H. & , Wolt, J. D. (2017) Risk associated with off-target plant genome editing and methods for its limitation. *Emerging Topics in Life Sciences* 1:231–240

[22] More information is available from Current Biology

Box 5 | Mutagenesis – off-target and unintended changes



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?

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

Consultation paper

Food derived using new breeding techniques

February 2018

How to make a submission

Submissions must be in writing and should be sent electronically where possible.

All submissions must be received by **12 April 2018**. If there is an extension to the due date this will be advised on the Food derived using new breeding techniques[1] web page.

If you have any difficulties lodging your submission online please contact NBTConsultInfoRequest@foodstandards.gov.au

What should my submission include?

Your submission should include:

- the title of the Consultation paper you are commenting on
- your name and contact details including: position, address, telephone number, fax and email address
- for organisations, the level at which the submission was authorised.

Your submission may have greater impact if it:

- comments on the specific issues raised and responds to the questions in the paper
- provides as much supporting evidence as possible.

Your submission should:

- be simple, clear and concise
- be supported by relevant, reputable and current data where possible
- use appropriate and specific case examples
- include a brief summary, especially if the submission is lengthy.

Lodging a submission

FSANZ prefers that you lodge your submission by email to NBTConsultSubmissions@foodstandards.gov.au

Many submissions are received that raise issues and concerns which FSANZ does not have responsibility for and cannot address. In this case, these issues should be raised with the relevant Commonwealth agency, State, Territory or New Zealand Governments. If in doubt, email NBTConsultInfoRequest@foodstandards.gov.au.

What happens to my submission?

FSANZ will endeavour to acknowledge all submissions within three working days.

Under the Information Publication Scheme, your submission will be published on our website unless you provide appropriate reasons for FSANZ to treat it as confidential. Submissions will be published as soon as possible after the end of the consultation period. Details such as

[1] http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx

direct phone numbers, personal email addresses or addresses of private individuals are redacted from documents before publication.

Under our legislation, FSANZ is required to treat information as confidential if it identifies trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be destroyed or diminished by disclosure. Confidential commercial information should be clearly identified and separated from your submission. If FSANZ does not agree that the information meets the criteria for confidential information, you will be given an opportunity to withdraw the submission before it is made public.

You may want to keep only parts of your submission confidential. If this is the case, this should also be indicated in your submission.

All relevant issues raised in submissions will be considered by FSANZ. Subsequent reports will address these issues.

Any enquiries about making submissions or the consultation process should be emailed to NBTConsultInfoRequest@foodstandards.gov.au.

Contents

1. Introduction

Food Standards Australia New Zealand (FSANZ) is undertaking a review of the *Australia New Zealand Food Standards Code* (the Code) to consider its application to the food products of new breeding techniques (NBTs).

Specifically, the review is to consider the definitions for '*food produced using gene technology*' and '*gene technology*'. The review is being undertaken in accordance with section 113 (s.113) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)[2].

The s113 review will not consider issues related to labelling, nor will it directly result in changes to the Code. As soon as practicable after completing the review, FSANZ will decide whether to prepare a proposal to amend the Code. Any subsequent proposal to amend the Code will be done separately and involve additional public consultation.

FSANZ has established an Expert Advisory Group on New Breeding Techniques (EAG NBT) to assist with the review. This group will provide advice on relevant issues, such as the current science, potential food safety issues and stakeholder concerns associated with NBTs.

The purpose of this Consultation Paper is to seek views from a broad range of stakeholders on some of the specific issues and questions raised by the review.

1.1 The issue

Section 1.1.1—10 of the Code provides that a food produced using gene technology cannot be sold or used as an ingredient unless it has been assessed and listed in Schedule 26. Section 1.1.2—2 includes interacting definitions for '*food produced using gene technology*' and '*gene technology*'. The definitions refer to gene technology techniques that result in inserting new pieces of DNA into a genome (see also Appendix 1), producing what is commonly referred to as a genetically modified (GM) organism. The technique most commonly used to introduce new DNA into an organism is called transgenesis[3]. All the approved foods listed in *Schedule 26 – Food produced using gene technology* of the Code have been derived from plants modified by inserting new DNA.

New DNA means a piece of DNA that is new to the host organism in terms of its nucleotide sequence, genome location or orientation of insertion

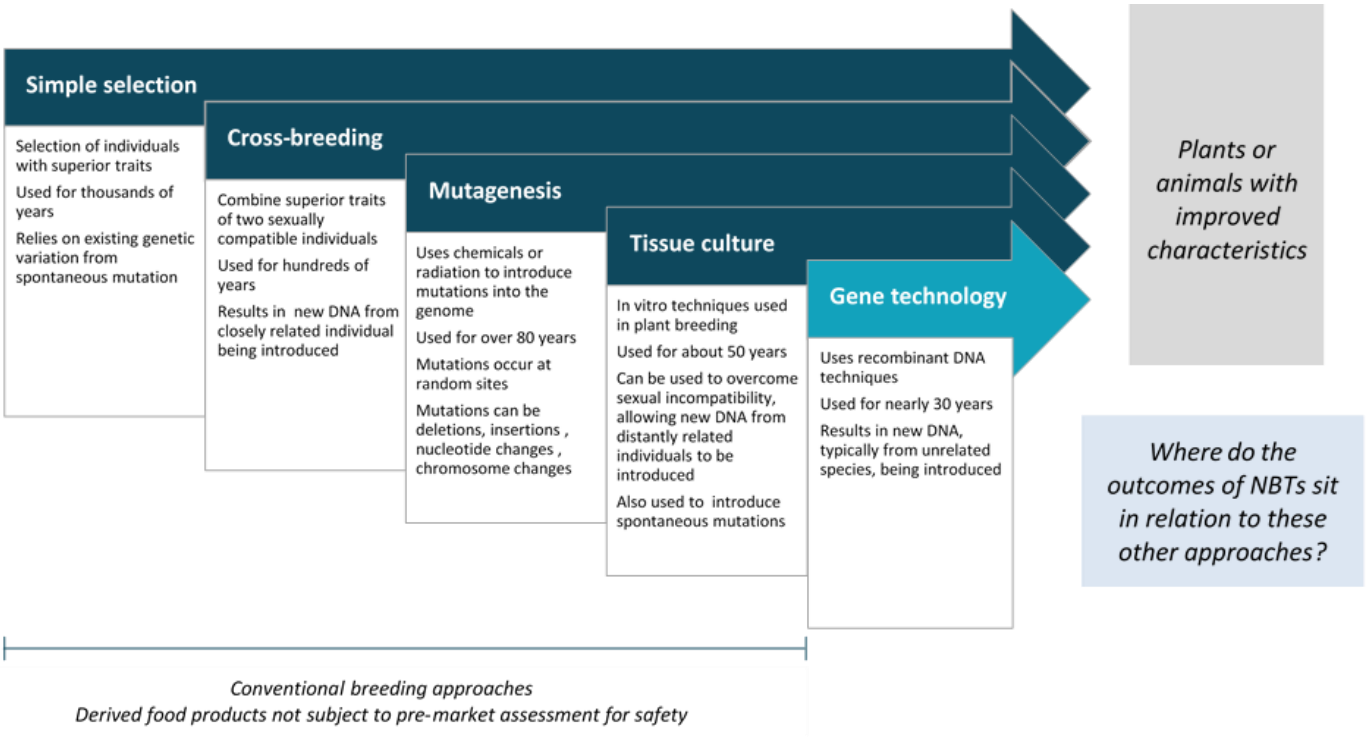
NBTs are a highly diverse set of new technologies being developed and applied in plant and animal breeding, with similar techniques being applied to medical therapies. Some of the products of NBTs are foods. A degree of uncertainty exists about whether foods produced using NBTs are '*food produced using 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. The organism from which the food for sale is obtained may therefore contain genome changes but these will not include new DNA.

[2] Available from the Federal Register of Legislation (https://www.legislation.gov.au/Details/C2016C01118)

[3] Transgenesis involves transferring DNA between unrelated organisms, e.g. transferring a gene from a bacterium to a plant.

As a result, some foods produced using NBTs can be similar to foods that have been produced using conventional methods of plant and animal breeding that do not involve gene technology (Figure 1).

Figure 1: Different approaches used in plant and animal breeding



Foods derived using conventional breeding, referred to as 'conventional foods', are generally considered to have a long history of safe use and are not typically subject to pre-market safety assessment before entering the food supply. The Code makes a clear distinction between conventional breeding techniques and techniques involving gene technology described by the current definitions[4].

There has been ongoing scientific and public debate about the nature of the risks associated with foods produced using NBTs and whether pre-market assessment and approval is appropriate for those foods.

The issue being considered for this review is whether (and the extent to which) the food products of NBTs require pre-assessment for safety, before they can be sold as, or used as ingredients in, food.

1.2 Background

FSANZ has been considering the issue of NBTs for some years. The techniques were considered at workshops in 2012 and 2013[5]. These workshops were held to gain more understanding of how the techniques were being used and the types of foods that may result

[4] Under Schedule 26 of the Code, conventional breeding means all methods used to produce plants, excluding techniques that use gene technology.

[5] Reports from both workshops are available from the FSANZ website (http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx)

from their use.

The NBTs considered most likely to be used in food production, and which were the subject of discussion at the workshops are:

- **genome editing** – techniques that can be used in both plants and animals to make changes at specific targeted locations in the genome (see Appendix 1 for detailed description)
- **GM rootstock grafting** – involves joining the vegetative (upper) part of a conventional plant to the rootstock of a GM plant
- **cisgenesis and intragenesis** – involves introducing DNA obtained from the same or a cross-compatible species into the genome of an organism
- **techniques producing null segregants** – null segregants are the progeny of GM plants or animals that have not inherited the new DNA (see Appendix 1).

Of these, genome editing, GM rootstock grafting and techniques producing null segregants are the NBTs generating the most uncertainty with respect to the definition for '*food produced using gene technology*'.

1.3 Relationships to other reviews

FSANZ's review is separate to two other reviews currently being undertaken by the Office of the Gene Technology Regulator (OGTR)[6] and for the Legislative and Governance Forum on Gene Technology[7]. Any decisions or actions taken as a result of these reviews, including changes to the Gene Technology Act and its Regulations, will not change the parts of the Code that relate to food produced using gene technology.

2. Gene technology and FSANZ

2.1 Role of FSANZ and the food regulatory system

FSANZ is a statutory authority in the Australian Government Health portfolio, established under the FSANZ Act. FSANZ is responsible for developing food standards for Australia and New Zealand.

Food standards developed and gazetted by FSANZ are compiled as the Code. These standards apply to food produced for sale in, or imported into, Australia and New Zealand.

FSANZ is one part of the food regulatory system. Policy is set by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum). Australian state and territory and New Zealand government agencies are responsible for implementing, monitoring and

[6] Information about the OGTR's Technical Review of the Gene Technology Regulations is available from the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1).

[7] Information about the Third Review of the National Gene Technology Scheme is available from the Australian Government Department of Health website (https://consultations.health.gov.au/health-systems-policy-division/genetechreview2017/).

enforcing food regulation through their own Food Acts and other food-related legislation. The Australian Government Department of Agriculture and Water Resources is responsible for enforcing food regulation at the border.

2.2 Food produced using gene technology

Food produced using gene technology cannot be sold unless expressly permitted by, and listed in, Schedule 26 of the Code. It is an offence under Australian Commonwealth, state and territory and New Zealand food laws to not comply with the Code.

The key definitions in the Code are:

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

Foods are captured according to the process used to develop them.

These definitions were drafted with the intent of capturing only those foods derived from organisms modified using gene technology, while at the same time excluding foods derived from organisms modified using conventional breeding. Gene technology is limited to recombinant DNA techniques, which are not defined[8] although the practical effect has been the capture of foods derived from organisms which contain new pieces of DNA in their genome derived from any source, including the same species.

Since the adoption in 1999 of pre-market assessment and approval arrangements for food produced using gene technology (under Standard 1.5.2 – Food produced using gene technology), more than seventy foods have been approved and listed in Schedule 26 of the Code. For a variety of reasons, not all of these foods end up in the food supply.

2.3 Pre-market safety assessment and labelling

Food that meets the definition of '*food produced using gene technology'* is assessed by FSANZ under Standard 1.5.2. The safety assessment is done according to procedures outlined in the FSANZ *Application Handbook*[9]. These procedures are consistent with internationally agreed guidelines and principles developed by the Codex Alimentarius Commission for conducting GM food safety assessments[10]. The Commission is the international food standards setting body established by the United Nation's Food and

[8] There is no single definition for recombinant DNA techniques but generally it is taken to mean the recombining or joining of DNA from two or more sources and inserting it into an organism.

[9] Part 2.3 (page 30) and Guideline 3.5.1(page 97) of the March 2016 edition of the Handbook, available from the FSANZ website (http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx).

[10] Codex (2009) Foods derived from modern biotechnology, second edition. Available from the Food and Agriculture Organization website (http://www.fao.org/3/a-a1554e.pdf)

Agriculture Organization[11] and World Health Organization[12].

Approved foods are also subject to labelling provisions under section 1.5.2—4 of Standard 1.5.2. Subject to certain exceptions[13], GM foods and ingredients (including substances used as food additives and processing aids) must be identified on labels with the words 'genetically modified', if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food. Some foods may also be required to be labelled with the words 'genetically modified', as well as other additional labelling, regardless of the presence of novel DNA or novel protein in the foods[14]. 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.

If the food for sale is not required to bear a label (for example, the food is displayed in an assisted service display cabinet or is made and packaged on the premises from which it is sold), Standard 1.2.1 requires the labelling information to accompany the food or be displayed in connection with the display of the food.

Foods that do not meet the definition for '*food produced using gene technology*' are not required to undergo pre-market safety assessment and approval or comply with the mandatory labelling requirements in Standard 1.5.2. Such food must still however comply with the general provisions of Australian, state and territory, and New Zealand food laws relating to safe food as well as general labelling provisions. It is the legal responsibility of those who trade in food to ensure it is safe and suitable and complies with relevant labelling requirements.

3. Issues to consider and questions

3.1 NBT outcomes

NBTs are a diverse range of techniques for modifying genomes. To help consider the issues further, FSANZ has grouped the various techniques according to the types of outcomes they produce in the genome of the organism from which the food for sale is obtained (Figure 2). These different outcomes are discussed separately below.

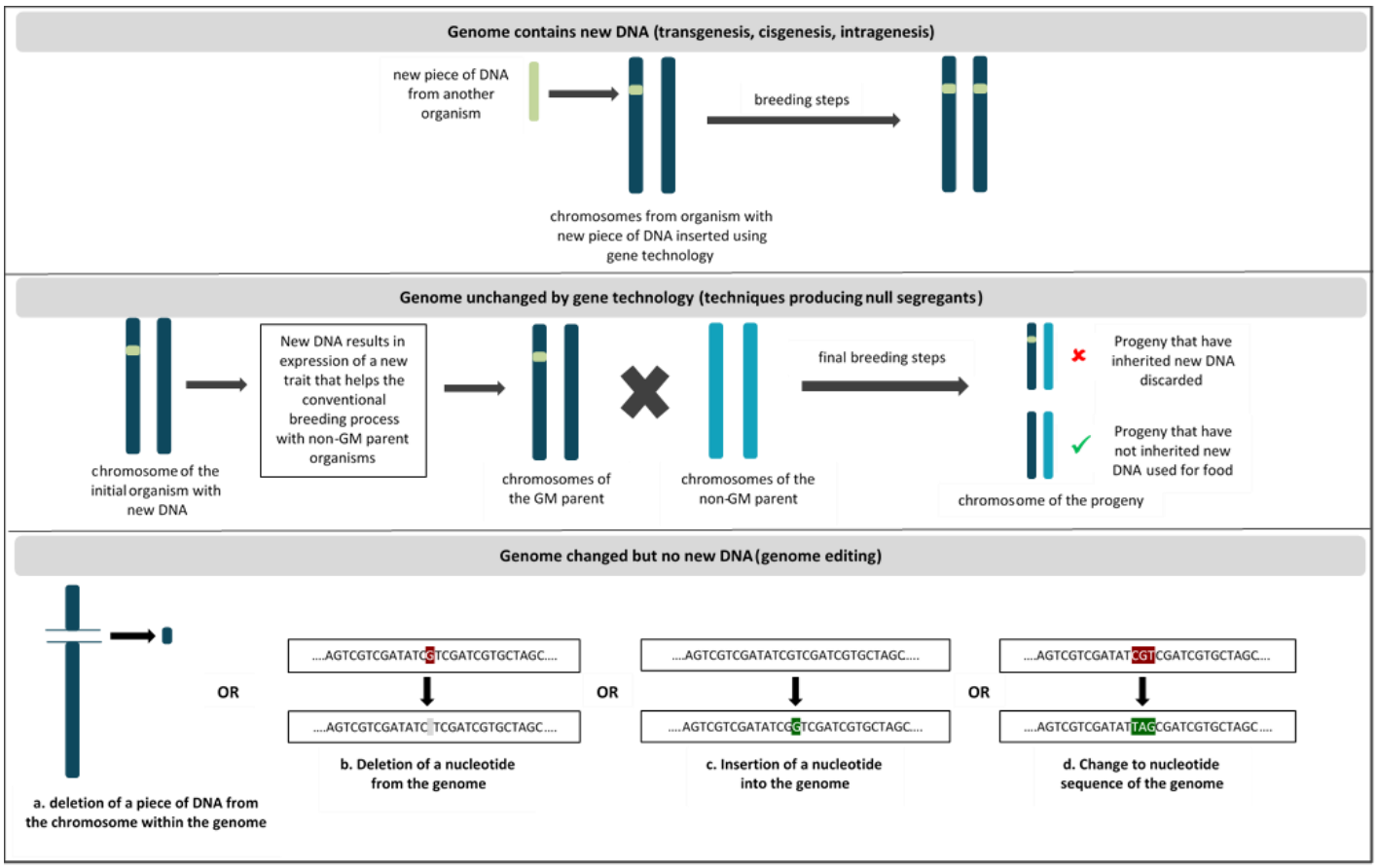
[11] http://www.fao.org/home/en/

[12] http://www.who.int/en/

[13] A number of exemptions from the requirement to label food as 'genetically modified' apply. These exemptions are listed in Standard 1.5.2, which can be accessed from the FSANZ website (http://www.foodstandards.gov.au/code/Pages/default.aspx).

[14] Schedule 26 lists the foods that require labelling as 'genetically modified' or other additional labelling regardless of the presence of novel DNA or novel protein. The Schedule can be accessed from the FSANZ website (http://www.foodstandards.gov.au/code/Pages/default.aspx.

Figure 2: Outcomes of techniques on the genome of the organism from which food is obtained



3.1.1 Genome contains new DNA

NBTs producing this outcome include intragenesis and cisgenesis. Although not a NBT, transgenesis would also belong in this group. The new DNA that is inserted typically gives rise to the expression of a new or modified form of a protein. However, this will not always be the case, for example where an RNA interference approach is being used to silence the expression of a specific gene.

New pieces of DNA are inserted into the genome and remain in the organism from which food for sale is obtained

Capturing food derived from organisms with new DNA inserted would be consistent with the types of approved foods already listed in Schedule 26. While FSANZ has yet to receive an application for a food derived using cisgenesis, applications for foods derived using intragenesis have been received and subsequently approved[15]. From a technical perspective there is no distinction between cisgenesis, intragenesis and transgenesis as all three techniques involve introducing new pieces of DNA into the genome using gene technology[16].

3.1.1 Questions

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?

One technique that involves inserting new DNA but does not fit neatly into this category is GM rootstock grafting. Grafting is a very old plant propagation technique that involves joining the rootstock of one plant variety to the upper part (scion) of a compatible plant variety, creating a composite plant. Grafting enables plants with superior characteristics to be combined into one plant without the need to undertake complex and often time consuming breeding.

GM rootstock grafting is somewhat unusual compared to the other techniques in this category because the new DNA that is inserted is confined to the rootstock[17]. The scion, from which food, such as fruit would be obtained, will not contain any new DNA. In some cases, the expression of new DNA in the rootstock may be used to alter the characteristics of the scion, including derived food. Changes to the food, should they occur, would not however be heritable/transmitted through the seed as the DNA of the scion would remain unchanged.

The issue to be considered for this technique is whether the absence of new DNA in the upper part of the plant, from which food is obtained, changes the risk, given the potential for the characteristics of the food to be influenced by the expression of new DNA in the rootstock.

[15] Application A1128 Food derived from potato line E12 and Application A1139 Food derived from potato lines F10, J3, W8, X17 & Y9.

[16] This was the conclusion of the technical workshop hosted by FSANZ in 2012. The report of that workshop is available from the FSANZ website (http://www.foodstandards.gov.au/publications/Pages/New-plant-breeding-techniques-workshop-report.aspx)

[17] Typically the rootstock is transgenic, but cisgenic or intragenic rootstocks could also be used.

3.1.2 Genome unchanged by gene technology

The NBTs in this group are those producing null segregants. The techniques are highly diverse but they all have in common the use of an initial organism into which new DNA has been inserted. The new trait that results is used to facilitate the breeding process or breeding objective but serves no purpose in the final organism from which food will be obtained. Towards the end of the breeding process progeny are selected that have not inherited the new DNA. These progeny are referred to as "null segregants".

New DNA is inserted into an initial organism but is not present in the final organism from which food for sale is obtained

The question for this category is whether there is sufficient justification (based on risk) to require pre-market assessment and approval for food obtained from null segregants. By definition, null segregant organisms would not contain any new DNA from the initial GM organism and also no longer exhibit the GM trait. It has been common practice for a number of years for FSANZ to allow the use of null segregants as non-GM comparators for compositional analysis as part of a GM food safety assessment (FSANZ 2016)[18]. FSANZ also notes the OGTR has stated that, under the Gene Technology Regulations, null segregants are not GMOs[19].

3.1.2 Questions

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?

[18] Page 32 of FSANZ *Application Handbook*.

[19] Page 18 of the *Discussion Paper: Options for regulating new technologies*, released by the OGTR in October 2016 as part of the Technical Review of the Gene Technology Regulations 2001. The discussion paper is available from the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm) .

3.1.3 Genome changed but no new DNA

The NBTs producing this outcome are the genome editing techniques. In some cases, introducing the edit can involve the insertion of new DNA coding for a protein that facilitates the editing process. If this is the case, progeny will be selected that do not contain the new DNA once the edit has been made. Some genome edited organisms may therefore also be null segregants.

Changes are made to the existing genome but no new DNA is present in the organism from which food for sale is obtained

The issue to be considered for this category is the nature of the genome changes that may be introduced (both targeted and off-target) and the extent to which they may be similar to changes introduced using conventional techniques such as chemical or radiation mutagenesis (which introduce similar changes to genome editing except at random sites in the genome), or that occur spontaneously in nature (and are representative of natural variation).

This is a relatively complex category because the techniques can be used to introduce a variety of genome changes of different complexity and scale. The changes introduced include deletions of pieces of DNA, insertion and/or deletion of one or a few nucleotides (indels) or re-writing the existing DNA sequence (typically involving only a small number of nucleotides although could be more extensive). DNA deletions as well as indels are typically associated with the loss of function or "knock-out" of a gene or genes, whereas a change to the DNA sequence would typically be done to modify the function or characteristics of an existing protein.

Genome editing may be used to produce organisms with novel traits (e.g. herbicide tolerant plants, hornless dairy cows) but this may not necessarily result in food with novel or altered characteristics. Also, the size of the genome change (e.g. a large deletion versus a single nucleotide change) is not a predictor of whether there is likely to be any impact on the food.

In addition to targeted changes, some degree of off-targeting may be associated with genome editing which means genome changes may also be introduced at other than the intended site. The likelihood of an off-target change occurring at a given site in the genome can be predicted to some extent because generally off-target sites are similar in sequence to the intended target site. A number of strategies have been developed to reduce or, in some cases, prevent the occurrence of off-target changes, and several approaches are also available for the detection of off-target changes[20].

3.1.3 Questions

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?

[20] For a review, see 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)

3.2 Other techniques

In undertaking this review the focus has been on those techniques considered most likely to be used in food production and which were the subject of technical workshops hosted by FSANZ in 2012 and 2013 (see Section 1.2).

It will be important however to also have regard to other types of techniques which may not currently have food applications but could do so in the future as the technology develops.

An example would be DNA methylation techniques which may be used to alter the methylation status of the genome without changing the DNA sequence itself. Changes to the methylation pattern of a genome can change the characteristics of an organism (and potentially derived food products) by altering how genes are expressed. In some cases these methylation changes can be inherited by the next generation.

3.2 Questions

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?

3.3 Regulatory trigger

The current process-based definitions for '*food produced using gene technology*' and '*gene technology*' were developed nearly 20 years ago. They were a simple way of making a clear distinction between foods from organisms with new pieces of DNA inserted and conventionally derived foods. At the time, DNA insertions were generally expected to be a complete gene or genes sourced from an unrelated organism. Derived food was therefore thought to be a potentially greater source of risk in contrast to conventional foods.

As a mechanism for capturing foods with new DNA inserted, the process-based approach has generally worked well, in that it achieved its intended purpose. However, the issue to be considered in relation to NBTs is whether the use of a process-based trigger for pre-market approval is an approach that remains fit for purpose given the rapid pace of technological change and also whether such an approach is likely to deliver appropriate risk-based outcomes in terms of what foods are captured for pre-market safety assessment.

3.3 Questions

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?

3.4 Other relevant issues

This paper is focussed on the Code and whether foods produced using NBTs should be the subject of a pre-market safety assessment before being permitted for sale.

Should FSANZ proceed with a proposal to change the Code, there are a number of other issues that FSANZ would need to consider including maintaining confidence in the food supply, ensuring regulation is proportionate to the risk and provides a net benefit, and the enforceability of the proposed changes. The FSANZ Act also includes specific criteria that FSANZ **must** have regard to when assessing proposed amendments to the Code (see Appendix 2).

3.4 Question

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?

Appendix 1

New DNA

For the purposes of this paper, 'new DNA' means a fragment of DNA that is introduced to a host organism, irrespective of its source. That is, the DNA may be derived from an unrelated organism, the same species, or the host organism itself.

Examples where DNA may be considered new include:

- the DNA sequence was not previously present in the host organism;
- the DNA sequence is present in the host organism but has been reintroduced at a different location in the genome;
- the DNA sequence is present in the host organism but has been rearranged or introduced into the host organism in a different orientation.

Genome editing[21,22]

Genome editing refers to a set of techniques which can be used to introduce targeted changes into the genome. Currently the predominant approach involves the use of site-directed nuclease techniques. Other methods such as oligo-directed mutagenesis and the more recently developed base-editing are also being used. These approaches can be used in both animal and plant cells.

Site-directed nuclease (SDN) techniques

Engineered SDNs are used to cut both strands of the DNA at a precise location in the genome, introducing what is called a double-stranded DNA break. The cell's own enzyme machinery can repair the break in the DNA using one of two mechanisms – non-homologous end joining (NHEJ) or homology directed repair (HDR). It's during the repair process that changes to the DNA sequence at the break site can occur.

In the case of NHEJ-based repair, the cell's enzymes repair the DNA break by directly joining the two ends back together. Usually the repair is faithful to the original DNA sequence but occasionally errors may be introduced, typically small deletions or small insertions (called indels). When these small errors occur the DNA sequence change is entirely random. Deletions of pieces of DNA are made by introducing two DNA breaks, rather than one. The piece of DNA between the two breaks is lost.

HDR involves the use of a DNA template which has a DNA sequence that complements the DNA sequence at the break site. The template can be one that already exists within the cell (a homologous chromosome or a sister chromatid) or it can be supplied externally. Externally

---

[21] Songstad, D.D., Petolino, J.F., Voytas, D.F., Reichert, N.A. (2017) Genome editing of plants. *Critical Reviews in Plant Sciences* **36**: 1-23 https://doi.org/10.1080/07352689.2017.1281663

[22] http://www.sciencemag.org/news/2017/10/novel-crispr-derived-base-editors-surgically-alter-dna-or-rna-offering-new-ways-fix

supplied templates can be designed to introduce precise modifications to the DNA sequence during the repair process. These modifications can range from single nucleotide changes, indels up to the insertion of new pieces of DNA such as whole genes. The use of SDNs to introduce new genes is a form of transgenesis, the only difference is that the DNA is inserted at a precise location, rather than randomly.

Oligo-directed mutagenesis (ODM)

ODM does not require a DNA break at the target site but is DNA template based. Short pieces of DNA (called oligonucleotides) are made that complement the DNA sequence of the target site, except for one or a few differences. Once the oligonucleotide binds to the target site the small mismatch in DNA sequence will trigger the cell's repair mechanism. The cell uses the oligonucleotide as a template to guide the repair, resulting in the DNA sequence at the target site being changed to match that of the oligonucleotide. The oligonucleotides are synthesised to contain chemically modified nucleotides to prevent them being incorporated into the host genome. The oligonucleotide is eventually degraded by the cell.

Base editing

Base editing is a relatively new form of genome editing that involves the chemical modification of nucleotides at a specific target site in the genome. This chemical modification results in their conversion to a different nucleotide, thus changing the DNA sequence. This can be achieved without introducing a DNA break or relying on an externally provided DNA template. These types of nucleotide changes are called transitions. It's possible to chemically convert all four nucleotides (A, C, T, G) that make up the genetic code – A to G, C to T, T to C and G to A.

Examples of techniques producing null segregants

Accelerated breeding following induction of early flowering[23]

This aim of this technique is to shorten the time it takes for a plant to flower. Some tree species can have long flowering times (10 years or more) which means the breeding process can be both time consuming and costly. Shortening flowering time is therefore a very important breeding objective for some species.

While early flowering can be induced using conventional approaches, more significant reductions in flowering time have been achieved using transgenic approaches. The transgenic approach involves over-expressing genes involved in the flowering pathway. These transgenic lines (with a shortened flowering time) can then be used to accelerate subsequent conventional breeding steps, e.g. to introduce a disease resistance gene from a related variety using traditional cross-breeding. In the final stages of breeding, null segregant lines are selected that have not inherited the early flowering transgene. These lines (now having a normal flowering time) would then be used to obtain the final commercial lines.

[23] Flachowsky, H., Hanke, M.-V., Piel, A., Strauss, S.H., Fladung, M. (2009) A review of transgenic approaches to accelerate breeding of woody plants. *Plant Breeding* **128**: 217-226
http://onlinelibrary.wiley.com/doi/10.1111/j.1439-0523.2008.01591.x/pdf

Sex selection in layer chickens[24]

Male hatchlings of layer chickens have no economic value – they can't lay eggs, and are not considered suitable for meat production – and are culled after hatching.

Current research is looking for a way to detect and remove eggs with male embryos prior to hatching. Recent advancements could allow marking of the male chromosome by inserting a gene coding for green fluorescent protein. Developing male embryos will fluoresce when the egg is exposed to UV light enabling them to be identified and removed well before hatching. Female embryos do not inherit the marked chromosome and are thus considered null segregants – their genome does not contain any new DNA. Null segregant female chicks would be used for egg production.

[24] Doran T. (2016) Sex selection in layer chickens. Animal Production Conference, Adelaide. http://www.asap.asn.au/wp-content/uploads/abstract-2015/332/attach_brief.pdf

Appendix 2

Statutory criteria for assessment of proposed amendments to the Code

Is each amendment required in order to:

(a) protect public health and safety;

(b) enable consumers to make informed choices by providing them with adequate information relating to food; and/or

(c) prevent misleading or deceptive conduct?

Would the costs that arise from the amendments outweigh the direct and indirect benefits to the community, Government or industry?

Are there other measures (available to FSANZ or not) that would be more cost-effective than the amendments? If so, what are they and how and why are they more cost effective?

Are there any relevant New Zealand standards? How are they affected by the amendments? How would they relate to the amendments?

Is each amendments based on or justified by a risk analysis that used the best available scientific evidence?

Will the amendments promote consistency between domestic and international food standards? If so, how?

Will the amendments contribute to an efficient and internationally competitive food industry? If so, how?

Will the amendments promote fair trading in food (i.e. in the consumer protection sense)? If so, how?

Is each amendment consistent with any relevant policy guidelines formulated by the Forum on Food Regulation?

Are there any other relevant matters that need to be considered?