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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 3

Decision Regulation Impact Statement

Proposal P1055 – Definitions for gene technology and new breeding techniques

Office of Impact Analysis ID 22-03666

Executive summary

FSANZ has prepared and assessed a proposal to amend the definitions for 'food produced using gene technology' and 'gene technology' in the *Australia New Zealand Food Standards Code* (the Code).

This Decision Regulation Impact Statement (DRIS) has been developed and provided to decision makers to inform their decision to approve the proposed changes.

The DRIS contains the impact analysis (including the consideration of costs and benefits) of the proposed changes.

FSANZ expects the proposed changes to the Code will lead to an overall net benefit to the community, Government and industry. The proposed changes are largely deregulatory where food developers and government authorities will benefit from an unambiguous and updated definition for genetically modified (GM) food in light of new breeding techniques (NBTs) being used in the production of food. There may be some cost to consumers who perceive a decrease in informed choice as a result of the new definition for GM food.

The proposal achieves objectives related to providing regulatory clarity as to what foods are GM food for Code purposes, future-proofing the Code for future technology developments, and ensuring such foods are being regulated in a way that is commensurate to their risk.

What is the problem?

The definitions for 'food produced using gene technology' and 'gene technology' are over 25 years old and were developed to capture the type of genetic modification in use at the time.

New technologies have emerged since the definitions were introduced, referred to as NBTs. NBTs can make the same genetic changes as older GM techniques and can also be used to make the same genetic changes as conventional breeding or that occur naturally. There is currently uncertainty about the regulatory status of NBT foods, specifically whether such

foods would be considered GM foods and therefore require applications to FSANZ for pre-market assessment and approval.

In an earlier review (2017-2019), FSANZ considered how the definitions for 'food produced using gene technology' and 'gene technology' apply to NBT food. The review found the definitions are no longer fit for purpose and there may be a case, based on risk, to exclude some NBT foods from the requirement of pre-market assessment and approval as GM foods. The review also noted the divergent views that exist about how best to regulate NBT foods.

Why is government action needed?

In 2020, FSANZ commenced proposal P1055 with the following regulatory objectives:

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

FSANZ considers the best way to address the problem and achieve these objectives is to amend the definitions for 'food produced using gene technology' and 'gene technology'.

Using non-regulatory measures alone to address the problem was not considered as a viable option as the definitions would continue to be outdated and not reflective of the techniques now in use.

Government action is required to continue capturing GM foods and some NBT foods for pre-market approval to confirm the safety of these foods, however, regulating all NBTs as GM foods would be disproportionate to the risk they pose and would encounter enforcement challenges.

What options are to be considered?

The DRIS analyses two options to address the identified problems:

1. Maintaining status quo (rejecting the draft variations)
2. Amending the definitions in the Code (approving the draft variations)

What is the likely net benefit of each option?

FSANZ does not have information to enable a quantitative analysis of the options. The regulatory analysis qualitatively discusses the impacts of the options and uses a criteria to assess the options.

The net benefit of the status quo option (option 1) by definition is zero as it involves no change. However, it is anticipated that status quo definitions will become increasingly problematic to apply and to get appropriate regulatory outcomes as technology continues to advance and develop.

The most significant impacts of option 2 are:

- clarifying what foods and ingredients are GM for Code purposes
  - Protecting public health and safety by closing regulatory gaps that make it unclear when an NBT food is required to undergo pre-market approval.
  - Benefitting food developers by being clear on when an NBT food is required to be submitted to FSANZ for pre-market approval.
  - Providing government agencies with an enforceable definition.

  - Perceived decrease in informed choice for some consumers as a result of some NBT foods not being subject to mandatory GM labelling and certain GM foods (e.g. food additives and processing aids) no longer being subject to mandatory GM labelling under the new definition for GM food (despite these foods being highly unlikely to be labelled GM under existing Code requirements).

- changing the types of food available in the Australian and New Zealand food supply
  - In the medium to long term, the proposed changes may mean different foods or ingredients become used in foods, incentivised investment and innovation into new food developments, and regulatory alignment with other countries where NBT food and ingredients are also available.
  - New food developments could offer direct benefits to consumers in terms of health and nutrition, convenience, and taste, and could have economic benefits in terms of productivity gains for food producers.

The assessment concludes that the direct and indirect benefits to the community, Government and industry that would arise from amending the Code as proposed in option 2 are expected to outweigh the costs and return a net benefit.

Who was consulted and how was their feedback incorporated?

Two call for submissions (CFS) reports on the proposal were released for public comment in October 2021 and in July 2024. The first report provided a detailed safety assessment, FSANZ's preferred approach to amending the definitions, suggested criteria for excluding certain foods from revised definitions, and a preliminary cost benefit analysis. Following consideration of submitter feedback at the 1st CFS and further assessment, FSANZ revised its approach, prepared a new definition for genetically modified food and presented draft variations to the Code at the 2nd CFS. A supporting document containing the consideration of costs and benefits was also presented for stakeholder feedback.

The submissions received from both rounds of consultation reflect diverse views and raise a wide range of issues.

FSANZ considered all comments and undertook additional consultation with targeted stakeholder groups following the 2nd CFS to gain a deeper understanding of issues raised. Minor changes have been made to the draft variations as a result of the 2nd CFS, but the approach remains the same.

What is the best option from those considered and how will it be implemented?

FSANZ considers option 2 to be the best available option.

Option 2 meets the proposal objectives by:

- Providing clarity around what foods and ingredients are GM in light of technological developments.
- Future-proofing the definitions by focussing on the outcome of the genetic modification rather than the technology.
- Achieving a risk-proportionate approach through outcomes more relevant to risk.

Implementation and enforcement of the draft variations to the Code would be the responsibility of the Australian states and territories, the Australian Government for foods imported into Australia, and New Zealand food regulatory agencies.

The draft variations are:

- unlikely to have any impact on products currently on the market; or
- are deregulatory in nature and provide exemptions to current requirements for products on the market.

Therefore, FSANZ is proposing there will be no transition period. The standard 12-month stock-in-trade provisions contained in Standard 1.1.1—9 will apply.

How will the chosen option be evaluated?

Agencies with responsibility for food policy or implementation or standards development could act individually or in concert to evaluate and/or monitor the standards. Such monitoring and evaluation can be coordinated either through the Food Regulation Standing Committee or the Implementation Sub-committee for Food Regulation.

The results of any concerns identified through monitoring and evaluation will ultimately be communicated through the food regulatory system to FSANZ for potential action.

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Glossary

Term	Description
Cell culture	The practice of growing plant, animal or microbial cells in an artificial environment.
Cell-cultured food	A food obtained by culturing cells isolated from any of the following sources: livestock; poultry; game; seafood (including fish); an egg or an embryo of any of the former.
Cell line	A collection of cells grown in cell culture originating from a single cell that was prepared under specific culture conditions. Cell lines have a uniform composition and are intended for use in the production of a cell mass.
Conventional breeding	Use of traditional methods for developing new traits in plants or animals e.g. cross breeding, classical mutagenesis.
DNA	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.
Food additives	A substance added to the food to perform a technological purpose (specified in section 1.1.2—11 of the Code).
Genetic modification (GM)	The process of altering the DNA of an organism.
Genetically modified organism (GMO)	Defined by the *Gene Technology* Act 2000 as 'an organism that has been modified by gene technology'.
Genome	The complete set of genetic material in a living cell or organism.
GM food	Food derived from organisms whose genome has novel DNA. This proposal contains a new Code definition for 'genetically modified food'.
New breeding techniques (NBTs)	A wide range of new techniques used to modify the genomes of plants, animals and microorganisms.
NBT food	Food from an organism modified using a new breeding technique.
Novel DNA	A term FSANZ has adopted to define DNA that is considered 'foreign' to an organism. That is, from a source that is unrelated to that organism or DNA that is unlikely to be produced using conventional breeding methods or that does not occur naturally. This proposal contains a new Code definition for 'novel DNA'.
Novel food	A non-traditional food that requires an assessment of public health and safety considerations (specified in section 1.1.2—8 of the Code).
Novel protein	Protein encoded by novel DNA. This proposal contains a new Code definition for 'novel protein'.
Nutritive substances	A substance added to food to achieve a nutritional purpose (specified in section 1.1.2—12 of the Code).
Precision fermentation	A technology that uses microorganisms to produce specific products such as proteins, human-identical milk oligosaccharides, vitamins or steviol glycoside sweeteners.
Processing aids	A substance that is used during the course of food processing to (1) perform a technological purpose in the course of processing and (2) not perform a technological purpose in a food for sale (specified in section 1.1.2—13 of the Code).
Recombinant DNA	*In vitro* laboratory techniques are used to recombine or join DNA from one or more sources.
Transgenesis	Transfer of DNA between two different species, unable to normally breed or exchange DNA.

1. Introduction

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.

FSANZ proposes to introduce a new definition for 'genetically modified food' to replace the existing definitions for 'food produced using gene technology' and 'gene technology' in the Code under proposal P1055 – Definitions for gene technology and new breeding techniques.

The objective of the proposal is to make the definitions clearer, fit for purpose and reflective of the diversity of techniques that are now in use or that may emerge in the future.

This Decision Regulation Impact Statement (DRIS) contains the impact analysis (including the consideration of costs and benefits) FSANZ has undertaken on the proposed changes, which will be provided to decision makers.

The DRIS has been prepared to meet the requirements of:

- *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies* of the Office of Impact Analysis (the Guide; 2023)
- Section 59 of the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act).

1.1. Assessment of the Office of Impact Analysis

This DRIS has been prepared in line with the Guide.

The Office of Impact Analysis (OIA) guidance requires FSANZ to answer the following impact analysis questions when developing a DRIS:

- What is the policy problem?
- Why is government action needed?
- What are the objectives of government action?
- What policy options are to be considered?
- What is the likely net benefit of each option?
- Who was consulted and how was their feedback incorporated?
- What is the best option from those considered?
- How will the chosen option be implemented and evaluated?

These questions have been answered in the sections that follow.

The OIA has assessed the DRIS as being compliant with the requirements.[1]

1.2. Consideration of costs and benefits

In assessing this proposal and in making its decision to prepare the proposed draft variations to the Code, FSANZ is also required by Section 59 of the FSANZ Act to have regard to, among other things, whether the costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, Government or industry.

[1] Refer to the OIA website - https://oia.pmc.gov.au/

As explained, FSANZ has decided to prepare a set of proposed amendments to the Code. This decision reflects in part FSANZ's assessment that the direct and indirect benefits to the community, Government and industry that would arise from amending the Code as proposed are expected to outweigh the costs of the proposed measures. The DRIS sets out the reasons for that assessment in section 5 below.

The assessment was based on the best available information at the time the decision was made to prepare the amendments. That included submissions received from stakeholders in response to the 1st and 2nd Call for Submissions (CFS).[2]

1.3. Scope

Proposal P1055 includes consideration of the following:

- the current definitions for 'food produced using gene technology' and 'gene technology' in section 1.1.2—2 of Standard 1.1.2 – Definitions used throughout the Code; and
- any consequential amendments to the Code that may be necessary to give effect to the revised definitions or to clarify other Code provisions that interact with the revised definitions. This includes, but is not limited to:
    - Standard 1.5.2 – Food produced using gene technology.
    - Schedule 26 – Food produced using gene technology.

Proposal P1055 does not change the overall policy or regulatory approach to genetically modified (GM) food. That is, foods that are GM foods under the amended definitions will continue to require an application to FSANZ for pre-market safety assessment and approval.

The GM labelling approach is also out of scope of this proposal. If approved and listed in the Code, GM foods will continue to be subject to mandatory GM labelling requirements.

1.4. GM food in the Australian and New Zealand food supply

To be sold, all GM foods and ingredients must undergo pre-market safety assessment and be listed in the Code. FSANZ typically receives 4-5 GM food applications each year. Permitted GM foods are listed in Schedule 26 of the Code, with the majority being derived from organisms modified using transgenesis. Most of these foods are from GM plants, including corn, canola, soybean and sugar beet. Approved GM food may be present in the Australian and New Zealand food supply in ingredients such as flour, oil, starches and syrups.

A small number of foods or food ingredients in Schedule 26 are derived from GM microorganisms. These permissions are primarily nutritive substances for use in infant formula.

Food available in Australia and New Zealand may also contain food additives and processing aids derived from GM microorganisms, which are permitted in Schedule 15 and Schedule 18, respectively.

Not every approved GM food enters the Australian and New Zealand marketplace. Many GM crops approved for use as food are grown overseas for other markets or for animal feed. Approval is often sought by companies to facilitate global trade, i.e., to allow manufacturers to have choice in products or in the event of inadvertent presence in the food supply due to

[2] Refer to Stakeholder Feedback Summary Reports – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

co-mingling through the supply chain. Some approved GM organisms (from which permitted GM foods are derived) do not make it to the market for a variety of reasons, e.g., they are not commercially viable.

2. What is the problem?

Standard 1.5.2 was adopted in 1998, making the definitions for 'food produced using gene technology' and 'gene technology' over 25 years old.

'Food produced using gene technology' is defined as:

> ***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' is defined as:

> ***gene technology*** means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

Current definitions were adopted with the intent of capturing the types of GM foods that existed at the time, that is food produced using a technique called transgenesis where DNA from an unrelated organism is transferred to the food producing organism. The introduction of Standard 1.5.2 established a dichotomy between GM foods and conventional foods (food produced using conventional breeding methods), with GM foods requiring pre-market safety assessment and explicit approval before they may be sold.

Despite the substantial changes to food organisms through conventional breeding techniques, conventional food has a long history of safe use and is not subject to pre-market assessment.

To be sold, a GM food must be:

- permitted as a GM food and listed in Schedule 26; or
- permitted as a food additive and listed in Schedule 15; or
- permitted as a processing aid and listed in Schedule 18.

Substances that are 'used as a nutritive substance', as defined in section 1.1.2—12 of the Code, and which are also 'food produced using gene technology', must be listed in Schedule 26.

For a GM food to be listed in Schedule 26 or permitted for use as either a food additive or a processing aid, an application must be made to FSANZ.

New technologies have emerged that are increasingly being applied to the production of food

Since the introduction of Standard 1.5.2, a variety of new breeding techniques (NBTs) have emerged that are increasingly being applied to the production of food. While NBTs can be used to make genetic modifications that are similar to those introduced using older GM techniques, they can also be used to make genetic modifications that are similar to those introduced using conventional breeding or that occur naturally. Box 1 provides examples of NBTs.

As NBTs can be used to make similar changes to conventional breeding, this means some food derived using NBTs (NBT foods) will be no different to conventional foods in terms of their characteristics and will therefore also be equivalent in terms of their risk.

As conventional foods are not required to undergo pre-market safety assessment before being sold, this raised the question about whether all NBT foods should be regulated as GM foods requiring pre-market safety assessment, or whether they should be regarded similarly to conventional foods.

Box 1. New breeding techniques

Examples of NBTs include:

- *Genome editing* – a group of techniques that make precise changes (edits) at targeted locations in the genome of an organism.
- *GM rootstock grafting* – where a GM plant is used as the rootstock onto which a non-GM plant is grafted. Grafting is a very old technology, but using GM rootstocks is a more recent development.
- *Cisgenesis* – DNA from the same or a closely related species is inserted into the genome of an organism without changing the inserted DNA sequence or arrangement.
- *Intragenesis* – similar to cisgenesis, except the DNA is changed from its original form, often to include additional pieces of DNA from the same or a closely related species, and/or rearranged in some way before being inserted in the genome.
- *Techniques producing null segregants* – typically involves using older GM techniques to introduce genetic changes that help with the breeding process or breeding objective (e.g. make it faster). At the end of the breeding process, progeny will be selected that have not inherited the genetic change, as it serves no purpose in the final organism from which food will be produced.

No NBT food has yet been commercialised in Australia or New Zealand. A 2020 European Commission dataset reports the application of NBTs and their commercialisation stage (Parisi & Rodriguez Cerezo 2020). For Australia and New Zealand, 23 uses of NBTs were registered across animals and plants (15 uses in Australia and 8 in New Zealand). Only 2 Australian uses of NBTs were categorised as being in pre-commercial stage: hornless cattle and heat-resistant cattle. All other uses were classed as being in the early to advanced research and development stage.

Globally, only two applications of NBTs to food were identified in the 2020 dataset as being commercialised: soybean with high oleic acid content in the United States and tomato supplemented with the dietary supplement gamma-aminobutyric acid or GABA in Japan. More recent NBT developments in Canada include the commercialisation of modified potato, mustard greens and strawberry.[3] Other NBT food developments known in other countries include high starch corn, non-browning lettuce, reduced browning banana and non-browning mushroom.[4]

The definitions for 'food produced using gene technology' and 'gene technology' do not reflect the diversity of techniques now in use, or that may emerge in the future

While Standard 1.5.2 has been effective at capturing foods produced using older GM techniques for pre-market safety assessment and approval, the emergence of NBTs has generated uncertainty about the regulatory status of NBT food. Specifically, this uncertainty has centred around: (i) whether current regulations for GM foods capture such foods, and (ii)

[3] https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative/list-non-novel-products-plant-breeding-food-use.html#wb-auto-4
[4] https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/

whether there is sufficient justification based on risk to subject NBT foods to pre-market regulatory oversight similar to GM foods.

This uncertainty has not been isolated to Australia and New Zealand but across the globe, with a number of countries either adopting new regulatory approaches or revising existing regulatory approaches to address NBTs (refer to Appendix B).

FSANZ's consideration of NBTs dates back to 2011 and was prompted by a number of enquiries about whether certain NBTs came within the scope of the current GM food definitions. These early enquiries triggered two technical workshops, and then a specific review.

Technical workshops were held in 2012 and 2013. In both technical workshops, the differences in the outcomes of various techniques were noted, particularly whether new genetic material is introduced and remains in the final organism used to produce the food. Where such genetic material does not remain, it was concluded that derived food products would be similar to food produced using conventional breeding methods and should not be regarded as GM food. Reports from both workshops are available on the FSANZ website.[5]

In June 2017, FSANZ commenced a review to consider how the Code should apply to NBT food. The review considered the lack of clarity in the current definitions in relation to specific NBTs such as genome editing and techniques producing null segregant organisms. [6]

The review identified scenarios where food developers could interpret the Code differently, producing outcomes potentially impacting the general public and government. These scenarios include:

- non-compliant NBT foods entering the marketplace – a food developer might incorrectly believe their product does not require pre-market assessment and approval and place it on the market without any pre-market assessment by FSANZ. This may pose risks to public health and safety.
- an increase in applications to FSANZ – a food developer might take a cautious approach and submit an application to FSANZ when one may not be required. This may have cost implications for both product developers and FSANZ.
- the abandonment of or delay in NBT product development – there may be negative impacts on innovation because developers are uncertain about the regulatory pathway for a particular NBT food.

Discussions with product developers indicate the last scenario may be the most likely as many developers would rather wait for regulatory change than bear the cost of engaging with the regulatory system.

The review concluded:

- the definitions for 'food produced using gene technology' and 'gene technology' are no longer fit for purpose. The definitions were found to lack clarity, were outdated, and not reflective of the diversity of techniques now in use.
- there may be a case, based on risk, for some NBT foods to be excluded from the requirement of pre-market safety assessment.

The review also noted the divergent views that exist among stakeholders about the acceptability and risk of NBT foods and how best to regulate them.

[5] https://www.foodstandards.gov.au/consumer/gmfood/New-plant-breeding-techniques-in-the-spotlight
[6] https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

3. Why is government action needed?

Government action is needed to update the definitions in the Code to address continual technology development and regulatory uncertainty.

In revising the definitions, the review proposed that the following objectives should be considered:

1) *Improve clarity about what foods are captured for pre-market approval as GM foods*

   Develop clear definitions to provide greater regulatory certainty about what foods are GM foods for Code purposes.

2) *Better accommodate new and emerging technologies*

   To avoid further periods of uncertainty as new technologies continue to emerge, adopt an approach, including new definitions, that is forward looking and agile while also remaining focussed on managing legitimate food risks.

3) *Regulate NBT foods in a manner that is commensurate with the risks they pose.*

   Facilitate innovation by adopting an approach that is grounded in science and proportionate to the level of risk posed by NBTs.

FSANZ considers the best way to address the problem and achieve these objectives is to amend the current definitions for 'food produced using gene technology' and 'gene technology'. Doing so will improve risk proportionality across the whole range of new and emerging genetic technologies and increase clarity whether new products require pre-market safety assessment.

This section covers the reasons why FSANZ considers explicit regulation to be appropriate for GM foods and some NBT foods, how FSANZ has considered whether non-regulatory options can solve the problem, and explains why regulating all NBT foods as GM foods in the Code is not appropriate government action.

3.1. Maintaining explicit regulation for GM food and some NBT food is still appropriate

The general regulatory approach to GM foods, including the approach to pre-market safety assessment, is out of scope for this proposal.

As mentioned in section 1.4, all GM foods intended for sale in Australia and New Zealand must undergo a pre-market safety assessment and be listed in Schedule 26. Standard 1.5.2 ensures that only assessed and approved GM foods enter the food supply.

Most of the organisms listed in Schedule 26 are transgenic organisms. A presumption of greater risk exists for these types of GM foods because the transferred novel DNA may encode a novel protein, or other substance, and may not have a safe history of use in food. A pre-market assessment is therefore required to confirm safety for these types of foods.

Some NBTs can be used to make genetic modifications that are similar to those introduced using older GM techniques. Capturing these NBT foods as GM foods for Code purposes is appropriate as these foods may not have a history of safe use and, like traditional GM foods, a pre-market safety assessment is required to confirm safety for these types of foods.

Standard 1.5.2 also prescribes mandatory labelling requirements for GM foods. It is consistent with the expectation of Food Ministers in Australia and New Zealand that a product-based approach to GM labelling is appropriate. That is, a food must be labelled as

'genetically modified' if the final food product contains novel DNA, novel protein, or has an altered characteristic.

Maintaining requirements for labelling of GM foods is not an issue of public health and safety, rather it acknowledges that GM foods can be an issue of consumer interest.

Where standards exist and are adequately enforced, consumers can trust that approved GM foods are safe and suitable. If there was no explicit standard regulating GM foods, this would impact consumer trust which would in turn impact food producers and manufacturers. The existence of such a standard is also important for trade and enabling products to be exported into markets that would otherwise not accept them.

3.2. Non-regulatory measures are not considered to be a viable option to resolve the identified problems

FSANZ has explored whether introducing non-regulatory measures to clarify the interpretation of the definitions could address the identified problem without amending the Code.

The NBT review investigated the development of guidance or a code of practice as possible non-regulatory options to clarify the interpretation of the current definitions in the Code.[7]

While providing interpretive guidance may help address regulatory uncertainty, it alone is not considered to be a viable option to address the problem because the definitions would continue to be outdated and not reflective of the diversity of techniques now in use. There is a risk some NBT foods would be deemed out of scope of the current definitions in the Code where pre-market safety assessment may be justified, or alternatively that some NBT foods would be deemed in scope of the current definitions and subject to onerous pre-market assessment when this is not warranted (see 3.3 below).

3.3. Regulating all NBT foods as GM foods would be disproportionate to the risk they pose and encounter enforcement challenges

FSANZ undertook a safety assessment as part of this proposal, separate to the preliminary analysis completed in the NBT review.[7,8] The assessment analysed whether pre-market assessment of all NBT food is justified based on risk.

The safety assessment had similar findings to the NBT review, including:

- The genetic changes introduced using certain NBTs are consistent with those from conventional breeding or that occur naturally. Conventional food is therefore a suitable benchmark for assessing the risks from NBT foods.
- When assessing the risks from NBT food, the most important consideration is whether the food has been changed in a way that may raise safety concerns.
- Because NBTs can introduce similar genetic changes to conventional breeding, some NBT foods will be similar, or in some cases identical, in their product characteristics to conventional food. Some NBT foods will also have different product characteristics to conventional food.

[7] Refer to the Final Report – https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

[8] Refer to 1st CFS Supporting document 1 - https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

The safety assessment concluded that when the characteristics of a NBT food are equivalent to those in conventional food with a history of safe use, the NBT food is also equivalent in risk to conventional food.

The current definitions do not specifically exclude any foods products. It is well understood, however, that conventional food is not captured by these definitions because conventional breeding does not use gene technology. Conventional food is not subject to pre-market safety assessment because it has a long history of safe use. Under food law, conventional food is still required to be safe and suitable and to comply with existing food standards, including those relating to content and labelling.

FSANZ notes concerns expressed in the previous NBT review about the possibility that some NBT foods could enter the food supply without a safety assessment by FSANZ. While these concerns would be addressed by capturing all NBT foods for pre-market assessment, this would not be justified based on risk and would also raise significant enforcement challenges for jurisdictions because of the difficulty distinguishing NBT food analytically from conventional food.

The ability to determine whether a product in the food supply is non-compliant is critical to the enforceability of food regulations. Issues may arise if it is difficult to tell a non-compliant food apart from a compliant food. In terms of NBT food, the ability to identify them in the food supply and distinguish them from conventional food is an ongoing topic of discussion and research.[9]

A clear, unambiguous definition and approach as to what is a GM food for Code purposes will facilitate effective and consistent implementation, interpretation and enforcement of food regulation by the jurisdictions.

Furthermore, following the conclusions of the safety assessment, capturing all NBT foods for pre-market assessment would place excessive regulatory burden on NBT foods that are equivalent in risk to conventional food.

4. What options are to be considered?

As discussed in section 2 and 3, FSANZ considered a range of options in earlier work to address the identified problem.

At the 1st CFS FSANZ considered three options: maintaining status quo, status quo combined with the introduction of non-regulatory measures, and amending the definitions in the Code (indicated as FSANZ preferred option). FSANZ sought stakeholder feedback at the 1st CFS on its initial approach to amending the definitions in the Code.

FSANZ initial approach included an expanding process-based definition for ‘gene technology’ to capture all methods for genetic modification other than conventional breeding and revising the definition for ‘food produced using gene technology’ to include a specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as a GM food.

This approach was revised in light of the feedback received from the 1st CFS to make the approach simpler and clearer, and additional feedback was then sought on the proposed

[9] FSANZ is aware of a European Union funded project investigating analytical methods for detecting and ascertaining the origin of genome edits. This project is in the research and development phase. It is unclear whether such methodologies will be able to accurately discern between NBT and conventional products. See https://darwin-ngt.eu/about/

draft variations to the Code during the 2nd CFS. Further detail of the consultation FSANZ undertook during this proposal can be found in section 6.

At the 2nd CFS FSANZ considered two options: maintaining status quo and amending the definitions in the Code.

The approach at the 2nd CFS proposed an outcomes-based definition for 'genetically modified food', definitions for 'novel DNA' and 'novel protein' and explicit exemptions for food derived from null segregants and grafted plants, substances regulated by other standards of the Code and substances used in cell culture.

At both stages of consultation FSANZ considered regulatory approaches to NBTs in other countries or regions. Appendix B provides a summary of some of these approaches.

FSANZ has had regard to submitter feedback provided at the 2nd CFS in finalising the draft variations to the Code. Further detail as to how FSANZ incorporated stakeholder feedback into the proposal can be found in section 6.

At Approval stage, FSANZ is considering two options:

1. Maintaining the status quo (rejecting the draft variations)
2. Amend the definitions in the Code (approving the draft variations).

These are discussed in more detail below.

4.1. Option 1 – Maintaining the status quo (rejecting the draft variations)

In any consideration of changes to regulation, the status quo must be a part of FSANZ's assessment. The status quo is the option against which other options are considered.

Under this option, the current definitions for 'food produced using gene technology' and 'gene technology' would remain unchanged. Food would continue to be captured for pre-market assessment and approval on the basis of the use of gene technology, as currently defined.

Food developers would continue to experience regulatory uncertainty in relation to the regulatory status of food produced using NBTs. Faced with definitions that are outdated and lack clarity, enforcement agencies would have reduced legal certainty in making a determination on whether a NBT food is compliant or not with the Code. This option may also result in regulatory gaps, where certain NBT foods may not be captured as GM foods, even though pre-market assessment and approval may be justified.

The challenges under status quo may be exacerbated by future development of gene technologies that outdated definitions do not account for and by a changing international regulatory landscape where countries are shifting their approach to regulation of GM and NBT foods to have less regulatory oversight of NBT foods. The latter point may impact enforcement at the border as NBT foods are developed overseas. Appendix B details the changes to regulations overseas.

As discussed in section 3, FSANZ explored whether introducing non-regulatory measures to clarify the interpretation of the definitions could address the identified problem without amending the Code. However, this was not considered to be a viable option as the definitions would continue to be outdated and not reflective of the diversity of techniques now in use.

4.2. Option 2 – Amend the definitions in the Code (approving the draft variations)

Option 2 is FSANZ's preferred option.

Under this option FSANZ would approve the draft variations. Proposed amendments to the Code include the following:

- a single outcomes-based definition for 'genetically modified food' based on the presence of novel DNA
- new definitions for 'novel DNA' and 'novel protein'

The current definitions are process-based. That is, food is captured for pre-market assessment and approval if the process of gene technology (as currently defined in the Code) has been used in its development. In contrast, outcomes-based definitions are focussed on the outcome of a process, for example, the presence of novel DNA in the genome.

A definition based on novel DNA addresses the problem of regulatory uncertainty by providing a clear and objective measure to determine whether a food is a GM food for Code purposes. A definition based on the outcome of a process, rather than the process itself, is also less likely to become outdated as other genetic modification technologies emerge, addressing the problem of definitions in the Code becoming outdated due to technology developments. This is because whatever genetic modification process is used, the insertion of novel DNA will either be an outcome of that process or it will not.

The new GM food definition will continue to capture the types of GM foods currently listed in Schedule 26, consistent with the existing policy settings. A presumption of greater risk exists for these types of GM foods because the transferred novel DNA may encode a novel protein, or other substance, and may not have a safe history of use in food. A pre-market assessment is therefore required to confirm safety for these types of foods.

The new definition, however, addresses the problem of risk-proportionality because it does not capture genetic changes that are equivalent to those introduced through conventional breeding or that occur naturally. These types of genetic changes have a presumption of safety from their longstanding use in conventional breeding.

Amendments to the Code under option 2 also include:

- explicit exemptions from the new GM food definition for certain foods and substances added to food, including:
    - food derived from null segregant organisms and grafted plants;
    - substances regulated by other standards in the Code (food additives and processing aids);
    - substances used in cell culture to support the growth and viability of cells, and to process cells, for the production of cell-cultured food.

Exemptions are proposed for food derived from null segregants and grafted plants as they are considered to be equivalent in risk to conventional foods and therefore do not require pre-market assessment to confirm their safety.

Food additives and processing aids are proposed to be exempt as, irrespective of whether they are GM derived or not, they are regulated under other parts of the Code and subject to

pre-market safety assessment, which includes consideration of the production process. Section 5.4. discusses how this simplifies the Code.

Substances used in cell culture for the production of cell-cultured food are proposed to be exempted from the GM food definition as they do not require explicit regulation as GM foods in the form of individual permissions listed in the Code as they are not added to the cell culture medium for the express purpose of being a food ingredient. The safety of such substances, should residues remain present on a cell-cultured food, will in any case be determined as part of the pre-market assessment of a cell-cultured food under other parts of the Code.

Following the 2nd CFS, the proposed explicit exemption of nutritive substances from the new GM food definition has been removed. Following approval of the draft variations, nutritive substances will continue to be captured as GM foods under the new definition.

Option 2 would also make other consequential amendments, including:

- substituting references in the Code to 'food produced using gene technology' with 'genetically modified food'
- the removal of three labelling exemptions that are redundant as a result of the new definition for 'genetically modified food'.

The amendments to labelling exemptions do not change the existing regulatory approach for mandatory labelling of GM food.

A food that is not a GM food under the Code may still be subject to other Code provisions, including for novel food.[10] However, based on the types of NBT food products that have been produced to date using genome editing for example, FSANZ expects the majority would not be considered novel food under the Code. This is because they would either be considered traditional food by virtue of their similarity to conventional food already on the market (e.g. a new variety of corn), or if considered non-traditional, to have characteristics that would not require an assessment of public health and safety as such characteristics are already present in conventional foods and considered to have a history of safe use (e.g. increased levels of oleic acid in the oil).

Appendix A summarises the intended regulatory outcomes of different types of foods and substances under status quo and option 2.

5. What is the likely net benefit of each option?

At the 2nd CFS, FSANZ stated that it is difficult to place monetary value on many of the costs and benefits involved in moving away from status quo.

At consultation FSANZ asked stakeholders whether they had any information that may be able to quantify the impacts that may arise from the proposed amendments. Some submitters described what some costs or savings may look like, and submissions were also received highlighting how NBTs could be used in practice and the subsequent benefits that the technology could have on industry (see Box 5 below).

FSANZ does not have information to enable a quantitative analysis of the options. Rather, FSANZ has determined suitable criteria to assess the options logically and consistently. The criteria are aligned with the objectives of the proposal and FSANZ objectives under the FSANZ Act.

[10] https://www.foodstandards.gov.au/business/novel

The criteria are as follows:

- Regulatory certainty – Will the option deliver clarity to industry and government about what foods are captured for pre-market assessment as a GM food?
- Future-proof – Will the option accommodate new and emerging technologies by providing clarity in the long-term to industry and government?
- Risk-proportionality – Is the option risk-proportionate as to not impose unnecessary regulatory burden on NBT foods that are equivalent in risk to conventional foods?
- Adequate information – Will the option provide consumers with adequate information relating to food to enable consumers to make informed choices?
- Consumer confidence – Will the option provide consumers with a high degree of consumer confidence in the quality and safety of food produced, processed or exported from Australia and New Zealand?

The following section qualitatively analyses the impacts associated with maintaining status quo (option 1) and amending the Code (option 2). Section 5.8 applies the criteria above to compare whether option 2 leaves stakeholders better, worse, or no better or worse off than under status quo.

5.1. Option 1 – Maintaining status quo (rejecting the draft variations)

Option 1 would involve no change to the definitions for 'food produced using gene technology' and 'gene technology' in the Code and represents the status quo against which option 2 is compared. Under option 1 the definitions would continue to be unclear regarding which NBT foods are required to undergo pre-market assessment and approval as GM foods, with potential implications for safety, enforcement and innovation.

As discussed in previous sections, current Code definitions for 'food produced using gene technology' and 'gene technology' do not account for NBTs that have emerged since the definitions were introduced. As a result, the definitions may not capture all NBT foods as GM foods for pre-market assessment and approval. Maintaining status quo would not alleviate potential public health and safety risks to the wider Australian and New Zealand community in terms of NBT foods that may carry a level of risk that justifies pre-market assessment.

Under the current definitions, enforcement agencies will continue to face uncertainty in determining whether foods are GM foods under the Code. Outdated definitions may hamper the ability to effectively and consistently enforce the Code. This may become a wider challenge in the future for border enforcement given the changing international regulatory space to having less regulatory oversight of NBTs (see Appendix B for further detail).

Maintaining status quo is likely to lead to future costs for food developers. Regulatory uncertainty may discourage investment if it is unclear to a firm how their innovation can be brought to market and could lead to developers shifting their business overseas where relevant regulations are up to date with the latest technologies (Kollmann et al. 2020; Whelan et al. 2020).

This evidence is one of the main drivers for preparing proposal P1055. Many submitters agree that this lack of clarity with the current definitions needs to be addressed.[11, 12]

[11] Refer to the Final Report – https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

[12] Refer to Stakeholder Feedback Summary Reports – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

As discussed in section 2 and 3, requiring pre-market assessment for all NBT foods is not scientifically supported and represents an excessive regulatory burden for food developers, who would need to prepare and submit application packages. FSANZ would in turn face resource constraints in assessing these applications. In addition, defining all NBT foods as GM foods would be unenforceable. Given that some NBT foods are indistinguishable from conventional foods, enforcement agencies would have no way to identify which foods in the marketplace or at the border were non-compliant with the Code, in the same way a GM food can be identified through the presence of novel DNA.

5.2. Option 2 – Amend the definitions in the Code (approve the draft variations)

Option 2 involves replacing the definitions for 'food produced using gene technology' and 'gene technology' in the Code to include a single definition for 'genetically modified food' based on the presence of novel DNA. Amendments also include new definitions for novel DNA and novel protein, and explicit exemptions from the new GM food definition for certain foods and substances added to food, as discussed in section 4.

Discussion of the long-term impacts that may arise from amending the Code has not been explored in depth due to the challenges in predicting how the changes proposed in P1055 might incentivise innovation of NBT foods and how long it may take for the community to experience these wider food system impacts.

Table 1 summarises the potential impacts that may arise from the proposed measures for each stakeholder group. These are discussed in more detail in the following sections, which also provide a brief overview of potential long-term impacts and include feedback from submitters on how access to NBTs could impact their business.

Table 1. Impact on different stakeholder groups arising from option 2

Stakeholder group	Notes on impact	Criteria
Consumers	Consumers may perceive their ability to make informed choices is impacted due to certain NBT foods not being subject to mandatory GM labelling (despite these foods being highly unlikely to be labelled GM under existing Code requirements). The changes may also result in a perceived decrease in choice for foods. Consumers may rely on food products labelled with organic certification to avoid NBT ingredients. As organic certified foods are often sold at a price premium, consumers who change their purchasing behaviour due to the new definition for GM food may be impacted by a higher price for food. Consumers may gain access to an increased range of foods with enhanced attributes that better meet their needs (e.g. nutrition or taste), or lower prices as a result of production efficiencies.	Adequate information: No better or worse than status quo. Consumer confidence: Better than status quo.
Food Industry (food developers and manufacturers that use GM ingredients)	Businesses will benefit from improved regulatory certainty from simple and up-to-date definitions in the Code. A clear regulatory approach to GM and NBT food may incentivise businesses to innovate. Businesses may also benefit from reduced regulatory burden for certain GM and NBT foods and ingredients getting to market. Industry may benefit from harmonisation of regulatory requirements with international competitors such as Europe, the United Kingdom and the United States. Industry may encounter short term costs associated with familiarisation with the new framework and the self-determination of their product. These businesses may incur costs in terms of time submitting an enquiry to the Advisory Committee on Novel Foods.	Regulatory certainty: Better than status quo. Future proof: Better than status quo. Risk proportionality: Better than status quo. Consumer confidence: Better than status quo

Stakeholder group	Notes on impact	Criteria
Food Industry (organic food operators)	Where there may be increased prevalence of NBT ingredients in the future due to definitional changes, organic operators may encounter increased burden of maintaining their system integrity. Greater availability of NBT ingredients may also lead to difficulty sourcing certified organic or non-GM ingredients. It may also increase demand for their products from certain segments of the population.	Certified organic operators are not expected to be significantly impacted under option 2. Option 2 is therefore no better or worse for organic food operators than status quo.
Government	Government agencies may find more efficient implementation of the Code through definitions that are easily understood and that can be consistently implemented and enforced. Clearer definitions will potentially facilitate better compliance with the GM food standard which benefits the food regulatory system. More risk proportionate definitions allow food agencies to direct their resources to areas of greatest need in terms of managing food-related risks.	Regulatory certainty: Better than status quo. Future proof: Better than status quo. Risk proportionality: Better than status quo. Consumer confidence: Better than status quo
Long-term impacts	In the longer term, innovation and competition are likely to make food cheaper than it would have been under the status quo. This is due to food producers achieving production efficiencies, adapting to issues like climate change, and lowering their regulatory costs. This should be seen as a transfer of benefits between the food industry to consumers (Kollmann et al. 2020). Ultimately, innovation benefits consumers by providing higher-quality products at more affordable prices (Kollmann et al. 2020).	Comparison criteria do not directly relate to the analysis of the long-term impacts. Overall, option 2 is expected to be better than status quo in the long-term.

5.3. Impact to consumers from option 2

Consumers may be impacted by the changes proposed in option 2 by:

- Perceived lack of informed consumer choice due to NBT foods not being subject to mandatory GM labelling.
- Increased range of foods with enhanced attributes that better meet their needs, or lower prices as a result of production efficiencies.

Most NBT foods would not contain novel DNA or novel protein. Under the existing labelling provisions, NBT foods that do not contain novel DNA or novel protein would not be labelled as 'genetically modified' unless they have an altered characteristic.[13] The existing regulatory approach for GM labelling is based on the final food 'product' ('product-based labelling'). This approach relies on the GM food for sale being analytically different from a conventional counterpart food. Although this is the existing regulation, many consumers consider that all GM foods, including NBT foods, should be subject to labelling based on the use of GM processes ('process-based' labelling).

The proposed draft variation retains the existing regulatory approach for GM labelling. However, the proposed new definitions for 'genetically modified food' and 'novel DNA' would mean that NBT foods that do not contain novel DNA or novel protein would not be GM foods. While these foods would not be labelled under existing regulation, this change has led to a perceived loss of information through labelling and, consequently, a perceived decrease in choice for foods. Appendix C compares the labelling outcomes on GM and NBT foods under status quo and option 2.

The proposed new definitions would clarify which NBT foods are GM foods for Code purposes and would therefore be subject to GM labelling requirements. NBT food that contains novel DNA or novel protein, and may also have an altered characteristic, will be considered a GM food and accordingly will be required to be labelled as 'genetically modified' unless an exemption applies. NBT food that is not a GM food but has an altered characteristic will not be labelled 'genetically modified', however may be subject to assessment and labelling considerations via other regulatory pathways (e.g. as a novel food).

Other proposed changes to the definition of novel DNA have the effect of making certain labelling exemptions redundant (e.g. an exemption for a GM food that is a substance used as a food additive or substance used as a processing aid in food and no novel DNA or novel protein from the substance remains present in the food). Under the proposed draft variations, these labelling exemptions would be removed because food additives and processing aids would not be GM foods. FSANZ also notes that, currently, these substances are highly unlikely to require GM labelling under existing requirements.

Consumers wishing to avoid NBT foods and ingredients may rely upon food represented as 'organic', 'non-GM', 'non-GMO', 'GM free' or 'GMO free' to meet their needs. These types of voluntary representations are regulated by consumer protection legislation and are outside FSANZ remit.[14] Given that food products labelled as certified organic are often sold with a price premium, consumers who change their purchasing behaviour due to the new definitions may be impacted by higher prices for food.

[13] For the purposes of labelling an altered characteristic is limited to food characteristics (e.g. a different fatty acid profile). Not all genetic modifications, including those introduced using NBTs, result in altered food characteristics. Of the GM foods approved so far, only a small number have required GM labelling for an altered food characteristic.

[14] For example, the ACCC in Australia: https://www.accc.gov.au/consumers/advertising-and-promotions/organic-claims

Consumer acceptance of NBT foods may be influenced by factors like benefits and perceived risks, awareness and knowledge, the need for clear communication and information. Box 2 summarises the consumer research that FSANZ has completed for P1055.

Box 2. FSANZ consumer research has found consumer attitudes towards GM foods and NBT foods are nuanced and can vary depending on the intended purpose

During proposal P1055, FSANZ undertook three pieces of bespoke consumer research designed to assess general community attitudes towards NBT foods:

- a systematic literature review on consumer responses to the use of NBTs in the production of food (2021)
- focus groups on consumers' responses to the use of NBTs in food production (2021)
- a consumer survey on consumers' perceptions of and attitudes towards GM foods (2022)

FSANZ also incorporated a number of questions about GM foods and NBTs used in food production into FSANZ's annual *Consumer Insights Tracker*, a nationally representative survey of 2,000 Australian and New Zealand consumers.

The evidence from FSANZ consumer research indicates Australian and New Zealand consumer attitudes towards GM foods and NBT foods are nuanced and can vary depending on the intended purpose. Consumers tend to have higher levels of support for applications that have health and/or environmental benefits rather than cosmetic or economic benefits. Consumer acceptance of NBT foods may be in large part contingent upon scientists and producers ensuring they are understood by consumers to be operating in good faith and in ways that have an explicit and realised benefit for wider society.

FSANZ consumer research also found that the majority of consumers do not consider GM foods or food ingredients as a top food safety issue, however, when directly asked, a substantial proportion of consumers raised concerns about the long-term effects of using gene technology in food production.

In the long term, consumers may gain access to an increased range of foods with enhanced attributes which better meet their needs (e.g. nutrition or taste), or lower prices as a result of production efficiencies. This is further discussed in section 5.7 below.

5.4. Impact to the food industry (food developers and manufacturers that use GM ingredients) from option 2

Food developers and manufacturers that use GM ingredients may be impacted by the changes proposed in option 2 by:

- clarifying what food and ingredients are GM for Code purposes.
- changing the types of ingredients and food products that may be available in the Australian and New Zealand food supply.

Compared to status quo, the proposed new definitions may provide cost and time savings for businesses developing GM and NBT foods. By providing clarity on what foods and ingredients are GM for Code purposes, these businesses will benefit by not having to generate unnecessary application packages for NBT foods that are equivalent in risk to their conventional counterparts. Testing and applications to gain regulatory approval is estimated to add 2 to 3 years to the research and development processes for genome edited developments and around $15 to $30 million (AUD) in regulatory compliance costs, depending on the development (Kalaitzandonakes et al. 2022).

There may be a small benefit to food developers when seeking FSANZ approval of processing aids or food additives from a GM source. While these substances still require a pre-market assessment under other parts of the Code, amendments will exempt these substances as being a GM food, making it simpler for developers to: (i) determine the category of their product, and (ii) understand data requirements for their application.

Food developers may also benefit from other exemptions in the draft variations for food from null segregants, grafted plants and substances used for the production of cell-cultured food. The amendment will give clarity to developers that these foods and substances are not required to undergo pre-market assessment as GM foods. Some may still however be regulated under other Code provisions including for novel food.

Reducing the regulatory burden of bringing certain NBT products to market could be particularly beneficial to small and medium NBT food developers, where these costs act as a barrier to market entry, and particularly as development of NBT foods typically come at a lower cost than using traditional GM methods (Kalaitzandonakes et al. 2022). Box 3 discusses the impact on NBT developments when changes were made to the regulatory approach in Argentina.

Box 3. Impact of regulatory frameworks on NBT innovation in Argentina

Argentina was the first country to introduce NBT-specific regulations and are therefore recognised as a country with the greatest experience in NBT foods (Genetic Literacy Project n.d.).

Preliminary evidence finds that the deregulation of certain NBT products in Argentina may be playing a role in reducing the barriers to market entry for small and medium sized businesses and encouraging the development of innovative NBT products (Whelan et al. 2020).

- NBT products submitted for regulatory approval in Argentina have been found to be driven by small and medium businesses and public research institutes, with a small proportion of NBT products submitted by large businesses. This compared to traditional GM developments where large businesses dominate the market.
- Analysis of the traits introduced in the NBT developments in Argentina finds diverse modifications, compared to traditional GM, including traits not present in traditional GM products such as consumer preference and improved animal welfare traits. NBT products are also found among a higher number of crop categories and species than traditional GM products.

While businesses may face some initial costs associated with adapting to the proposed approach, these are expected to be minimal. For example, familiarisation with the new GM framework arising from the changes and potentially changes to individual business documentation and processes to be consistent with the changes. Businesses are anticipated to know their products and maintain data about the presence of novel DNA in their products, meaning it will not be overly burdensome to self-determine whether their product meets the new GM food definition.[15]

Food developers may incur costs in submitting enquiries to the Advisory Committee on Novel Foods for products that are potentially novel. Such enquiries are voluntary and may not be a new cost as for certain foods this is the process used under status quo.

[15] https://stewardshipfirst.com.au/best-practice-use-of-crops-on-the-gmo-register/

New developers of GM and NBT foods often rely heavily on funding from investors, attributed in part to high start-up costs and lengthy timeframes during technology development (Kalaitzandonakes et al. 2022). Greater legal certainty as to when an NBT food is a GM food in the Code and reducing regulatory burden for food and ingredients that have been found to carry low safety risk may encourage investment into GM and NBT food development, enabling higher levels of innovation to occur (Kollmann et al. 2020; Whelan et al. 2020). As described in Box 3, a change in regulatory approach in Argentina giving certainty as to how NBT foods are regulated saw an increase in NBT innovation.

Innovating, such as improving the quality of a product or creating a new product, is one of the key ways food developers compete with their rivals. Innovation can also lead to improvement in a developer's productivity. This could assist in producing goods at a lower cost and could help businesses afford the high cost of developing export markets. Innovating to develop cost-effective and differentiated products may assist developer's in obtaining market share in the short to medium term and will be necessary to maintain their competitiveness in the longer term.

Food manufacturers that currently choose to use GM ingredients may benefit from having access to NBT ingredients that become available in the future. Some manufacturers that do not currently use GM ingredients may choose to use these NBT ingredients. Benefits could include process efficiencies and food quality improvements. Use of these ingredients are voluntary and will only be used where a business sees there is a net benefit to using an ingredient.

Option 2 also clarifies the current labelling provisions for GM food to ensure the policy intent is retained in light of the new GM food definition. As this provides regulatory clarity, some businesses may benefit from these amendments. FSANZ did not receive concerns from stakeholders that this clarification would result in a significant negative impact when this specific change was proposed at the 2nd CFS.

As discussed in section 2, a number of countries are either adopting new regulatory approaches or revising existing regulatory approaches to address NBTs, and are opting to reduce or have no government oversight of NBT foods that have the same product characteristics as conventional foods. Appendix B summarises the recent updates or proposed updates to some of these regulatory approaches.

Option 2 is largely consistent with the direction of the updated international approaches. As a result, Australian and New Zealand food businesses may find more success, compared to status quo, when competing in international markets with regard to GM or NBT foods. This impact is also in part due to the clear regulatory pathways and support for innovation discussed above. In the short term, there may be increased competition from other countries where similar frameworks are already in place.

5.5. Impact to organic food operators from option 2

Organic food operators may be impacted by the changes proposed in option 2 by:

- changing the types of ingredients and food products that may be available in the Australian and New Zealand food supply.

Organic certification is outside FSANZ's remit. Organic standards used in Australia and New Zealand are generally owned and managed by private organisations. Some organic standards are based on National Organic Standards or programmes set by the Department of Agriculture, Fisheries and Forestry (DAFF) in Australia and the Ministry for Primary Industries (MPI) in New Zealand, respectively.

However, the organic sector, including certified organic operators / producers, have expressed concerns at the 2nd CFS that approving the draft variations will undermine the integrity of Australian and New Zealand certified organic systems. The reason provided was an increased difficulty in maintaining the absence of GM material in certified organic processes. Box 4 provides background information on organic systems and certifying processes.

Box 4. Organic production and foods

Organic is a values-based production system referring to the way agricultural products such as fruits, vegetables, grains and meat are produced and processed. Organic systems avoid or exclude the use of most synthetic pest control compounds and fertilisers, antibiotics, growth promotants, and food additives derived from non-organic sources, as well as GM and irradiation.

An organic food operator can verify that their systems are organic and become certified. Certification involves an organic operator demonstrating compliance with relevant private organic standards through documented management plans. Depending on the type of organic operator, such documented details include:

- record-keeping systems
- separation of organic and non-organic
- traceability.

Certified organic operators are regularly audited to ensure they are compliant with their relevant organic standard.

Currently, only those Australian and New Zealand organic operators who export their products are required to meet the National Organic Standards or programmes set by the DAFF and MPI, respectively.

All genetic modification techniques, including NBTs, are prohibited in organic food operations.

Following the 2nd CFS, FSANZ has undertaken targeted consultation with a number of stakeholders in the organic sector to gain a deeper understanding of organic operations, and how the proposed changes may impact these businesses and their ability to produce certified organic food products.

FSANZ understands certified organic operators adopt a variety of practices to ensure GM materials do not contaminate their operations, among other residue contaminations, including:

- operating in a controlled supply chain where only certified organic ingredients are used, enabling traceback from farm to fork of organic certified ingredients and processes.
    - Where certified organic ingredients are not available, an operator may use product specifications or Product Information Forms to confirm an ingredient is not GM. In the absence of information an operator may use affidavits with their suppliers.
- using paper trails to provide assurances of the integrity of their product, rather than relying on GM labelling to know whether an ingredient is GM or using analytical testing to confirm non-GM status.[16]

[16] GM labelling may not be present on all GM ingredients, such as those that are highly refined.

- FSANZ is aware of a European Union funded project investigating analytical methods for detecting and ascertaining the origin of genome edits.[17] This project is in the research and development phase. It is unclear whether such methodologies will be able to accurately discern between NBT and conventional products. Should such analytical methodologies become validated and reliable, it will be up to organic certifiers to decide whether to require organic operators to use them, taking into account the successful use of other practices that maintain the integrity of organic systems.

Certified organic operators have strong traceability capabilities. This provides a guarantee to consumers they can trust they are purchasing an organic product.

The proposed amendments are unlikely to significantly impact Australian and New Zealand certified organic producers. There may be potential for impact in the long term if moving away from status quo leads to the increased prevalence of NBT food and ingredients in the Australian and New Zealand food supply.

The challenge in differentiating between NBT and conventional ingredients may make it more difficult over time to source certified organic ingredients if suppliers are less confident and less able to verify their non-GM status. Consultation has highlighted that many certified organic ingredients are imported so this challenge may not be a direct result of the proposed changes to the Code and rather in part due to the global regulatory shift in use of NBTs.

This challenge may present an opportunity for suppliers to provide ingredients to organic operators to meet the organic specification.

Similarly, in the long term there is an economic incentive for organic producers to continue producing organic food products. For exported organic products, NZIER (2024) reports that consumers are on average willing to pay a 39% premium. Some consumers may choose to shift their food purchases to organic food products if they wish to avoid all NBT foods and ingredients.

Organic operators intending to export their products are required to meet the National Organic Standards and programmes set by DAFF and MPI. Pathways already exist for recognising organic status between countries, including those where GM and NBT foods already coexist with organic foods. Frameworks are also available to support the coexistence of conventional and GM crops in the supply chain.[18]

5.6. Impact to government of option 2

Government and enforcement agencies will be impacted by the changes proposed in option 2 by:

- clarifying what food and ingredients are GM for Code purposes.

Government agencies may find benefits from moving away from status quo by having definitions that clearly delineate how different gene technologies are treated under the Code. Clear definitions will also facilitate better compliance with the GM food standard and assist with effective enforcement.

Government and enforcement agencies may benefit from more efficient implementation of the Code through definitions that are easily understood and that can be consistently implemented and enforced.

[17] https://darwin-ngt.eu/about/
[18] For example, the *Market Choices Framework* developed by Grain Trade Australia – https://www.graintrade.org.au/plant-breeding-innovation

There may also be cost savings to government related to pre-market assessment under option 2. An application made to FSANZ typically takes 9-12 months of assessment. The updated definitions provide clarity to developers and risk proportionality where some foods derived from new technologies are not required to undergo pre-market assessment. FSANZ, along with other food agencies in the food regulation system will benefit by being able to direct regulatory resources to areas of greatest need in terms of managing food-related risks.

There may be a small initial cost to government and enforcement agencies across Australia and New Zealand in order to familiarise themselves with the proposed measures.

Enforcement agencies may incur an additional burden in auditing and reviewing how businesses have self-determined their food products. Agencies may also incur costs of providing advice on Code interpretation, as a result of updating the definitions. While agencies may find they receive more enquiries after the proposed changes to the Code are gazetted, this is assumed to be a business-as-usual cost.

Submitters suggested that government may incur costs arising from inconsistent implementation by jurisdictions due to lack of clear guidance from FSANZ as how to apply the new definitions in the Code. Submitters also raised concerns regarding the capacity of regulators to enforce the proposed approach in the absence of clear expectations for testing and traceability methods, in particular, the difficultly in making distinctions between the products of NBTs and conventional breeding.

To minimise this cost and support consistent implementation, FSANZ has undertaken targeted consultation with jurisdictions throughout the proposal. This includes consultation on the proposed approach, drafting, and highlighted the need for guidance material.

The proposed approach and new definitions increase clarity with respect to what is a ‘GM food’ for Code purposes. A food that is not a GM food, will either be a conventional food or equivalent to a conventional food. Making distinctions between products of conventional breeding or NBTs that are not GM foods, is not required from an enforcement perspective.

5.7. Long term impacts of option 2

In the long term, a broad adoption of NBT foods may lead to wider food system impacts.

As noted at the beginning of this section, discussion of long-term impacts have not been explored in depth due to the challenges in predicting how the changes proposed in P1055 might incentivise innovation of NBT foods and how long it may take for the community to experience these benefits.

Providing clarity as to how an NBT food can be brought to market may incentivise the uptake of NBT crops and livestock by food producers who supply fresh produce, ingredients and food products to Australia and New Zealand.

A clear and predictable pathway to market is important because new technologies, such as NBTs, although not widely available, could be useful tools that may contribute to more sustainable food production (Brookes & Barfoot 2020; Qaim 2020; Kovak et al. 2022).

Particular NBT developments include increasing the ability of major food crops and livestock to withstand climate adversity including traits such as drought and salinity tolerance in crops, and heat tolerance and disease resistance in livestock (Ahmad 2023). These traits could have economic benefits in terms of productivity gains for food producers.

Box 5 provides information from submitters on how using NBTs developments may benefit them.

Box 5. Potential use of NBTs to provide agricultural resilience

Submissions received at the 2nd CFS highlighted direct benefits that may impact the agricultural sector from use of NBTs.

Australian Grape and Wine provided a specific example from their industry and included financial figures. As the technology improves, the introduction of disease resistance traits could potentially allow grape growers to mitigate risks of having to replant entire vineyards in the event of an infection. The economic benefits are considered to be significant. Avoided crop losses vary considerably depending on the site but average ~ $7,000 per hectare, usually over several years, plus avoided replanting costs at ~ $60,000 per hectare.

Costs associated with vineyard machinery and pesticides are estimated to be approximately $1800 per hectare. If this could be reduced by 30% through the introduction of disease resistance, the savings across Australia's 146,000 hectares of vineyard would be significant (around $78m per annum).

NBTs also offer potential benefits for wine producers linked to improvements in the efficiency of the winemaking process and potentially wine quality. Introduction of desirable traits into winery yeast and bacteria can enhance efficiency of fermentation, reduce processing time, lower production of undesirable flavour compounds and control or prevent microbial spoilage, offering significant consumer benefits in terms of sensory quality. Associated health benefits are also possible such as through lowered alcohol production.

AUSVEG highlighted how NBTs provide an opportunity to tailor crops to suit localised Australian conditions and providing additional options for growers. There is also the opportunity to cater to specific consumer preferences including more nutritious and diverse options.

In the long term, consumers may receive benefits from innovations and efficiencies in the food industry in the form of cheaper, higher quality, and new food products (Kollmann et al. 2020). There may be more GM and NBT food and ingredients that meet unmet consumer needs. Such products could offer direct benefits to consumers in terms of health and nutrition, convenience, and taste. NBT food developments underway include tomatoes with increased nutrient content, removing undesirable tastes in potatoes, and seedless tomatoes, watermelons and cucumbers (Kalaitzandinakes et al. 2022).

The uptake of NBT foods may depend on consumer acceptance. Many studies have found that consumers may have a lower willingness to pay for NBT foods compared to their conventional counterparts (Lemarie & Marette 2022). FSANZ consumer research (see Box 2) suggests that consumers value the indirect benefits that NBTs may bring to wider society around issues such as environmental sustainability, human health, and animal welfare.

5.8. Comparison of options against the criteria

The net benefit of the status quo option (option 1) by definition is zero as it involves no change. The status quo is the option against which all other options are considered. If no other options are likely to achieve a net benefit, option 1 would be the preferred option of the analysis.

Option 2 involves amending the definitions for ‘food produced using gene technology’ and ‘gene technology’ in the Code. Changing the definitions will provide clarity around what foods are GM for Code purposes.

The various impacts of moving to option 2 are discussed against the criteria listed in section 5, below.

Regulatory certainty

Under status quo, unclear definitions may lead to applications being made to FSANZ where it may not be considered necessary or could discourage developers from innovating all together.

Food developers and government authorities may experience the most immediate benefit of amending the definitions from regulatory certainty provided in option 2 around what is required to undergo pre-market assessment and what is considered GM food for Code purposes.

While providing regulatory certainty is unlikely to have an immediate noticeable impact, in the long term it may eventually mean different ingredients or foods may be available in the Australian and New Zealand food supply than under status quo. This could provide a variety of benefits in the long term for consumers, in terms of food that may meet their specific needs or direct benefits such as nutrition or health, and to food manufacturers who may benefit from ingredients available to them to allow for efficiencies in their processes and improve the quality of their products.

Overall, regulatory certainty under option 2 is expected to be better than under status quo.

Future-proof

Food developers and government authorities will benefit from a definition focussing on the outcome of the genetic modification (whether novel DNA is present in the final food) and not basing the definitions on a specific technique or technology. An outcomes-based approach is less likely to become outdated than a process-based approach.

The ability to provide long-term clarity around what foods are required for pre-market assessment is better under option 2 than under status quo.

Risk-proportionality

Option 2 provides an approach with more risk-proportionality than under status quo in terms of what NBT foods are captured as GM food for Code purposes and required to undergo a pre-market safety assessment. Food that will not be captured for pre-market approval are expected to contain genetic changes consistent with changes that have been introduced through conventional breeding and that have a history of safe use. This provides a benefit to NBT food developers who will avoid regulatory burden that is incommensurate to the risk of the food they are developing.

Government authorities will also find option 2 better than under status quo by being able to direct regulatory resources to areas of greatest need in terms of managing food-related risks.

Adequate information

While option 2 clarifies what foods are GM, doing so also clarifies what foods are required to be labelled as GM. While the approach to labelling has not changed from status quo, it is the

perspective of some stakeholders that all NBT and GM foods should be labelled as 'genetically modified'. The changes in option 2 have also led to a perceived loss of information through labelling and, consequently, a perceived decrease in choice for foods. To align with their values, some consumers may choose to purchase certified organic or 'non-GM' products.

Overall, the information available to consumers to enable informed choice is no better or worse than status quo. Appendix C compares the labelling outcomes on GM and NBT foods under status quo and option 2.

Consumer confidence

Maintaining status quo may lead to NBT food entering the marketplace without undergoing pre-market assessment where it may be warranted. Such a scenario may have flow-on impacts to the wider community in terms of public health and safety and is a reputational risk for the Government.

Under option 2, consumers can be confident in a safe food supply. Where standards exist and are adequately enforced, consumers can trust that all products are safe and suitable. Bringing the definitions in the Code up-to-date with the latest technological developments and science is expected to improve consumer confidence.

In turn, food developers, manufacturers and government authorities may benefit from any increased consumer confidence that may flow onto increased demand.

5.9. Conclusion of analysis

Following the comparison criteria, it is expected that option 2 will leave stakeholders in a better position than under status quo.

FSANZ's assessment remains that the direct and indirect benefits to the community, Government and industry that would arise from amending the Code as proposed in option 2 are expected to outweigh the costs and return a net benefit.

6. Who was consulted and how was their feedback incorporated?

Consultation is a key part of FSANZ's standards development process and is underpinned by a statutory consultation process. FSANZ consults with stakeholders to ensure we understand their business, and to seek information and advice to inform the proposal assessment and standard development.

6.1. Who and how we consulted

Two CFS reports were released, one in October 2021 and the other in July 2024.

The 1st CFS included a detailed safety assessment, FSANZ's preferred approach to amending the definitions, suggested criteria for excluding certain foods from revised definitions, and a preliminary cost benefit analysis.[19]

Following consideration of submitter feedback, including the need for a more simple and clear approach (discussed in section 6.2), along with further assessment, FSANZ presented a revised approach, prepared a new definition for genetically modified food and prepared

[19] Refer to 1st Call for Submissions – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

draft variations to the Code at the 2nd CFS. A supporting document containing the consideration of costs and benefits was also presented for stakeholder feedback.[20]

1736 and 1485 responses were received from stakeholders at the 1st and 2nd CFS, respectively. The stakeholders FSANZ heard from include:

- Community groups
- Government
- Individual businesses
- Individuals
- Industry bodies
- Non-government organisations
- Research groups

As part of the assessment under P1055, FSANZ also undertook additional targeted consultation with the groups listed below:

- Expert Advisory Group – consisting of expert academics to provide ongoing technical and scientific advice to FSANZ regarding the proposed amendments to definitions of terms used in the Code relating to genetic technologies.

- Australian state and territory and New Zealand food authorities, and government departments such as the Australian Department of Agriculture, Fisheries and Forestry and the New Zealand Ministry of Business, Innovation and Employment – to ensure the proposed approach and draft variations was implementable and enforceable.

- Organic industry peak bodies and organic certifiers – to understand the impacts to certified organic and non-GM operators as expressed by the sector through the submissions process.

- Biotechnology industry and research sector – to ensure the proposed draft variation was clear and easy to comply with.

In addition to FSANZ's standard consultation process and targeted engagement, FSANZ also held two public webinars for this proposal and provided updates at the following FSANZ stakeholder committees:

- Binational Food Industry Dialogue
- Consumer and Public Health Dialogue
- Jurisdictional Technical Forum.

6.2. Stakeholder views

The submissions received from both rounds of consultation reflect diverse views and raise a wide range of issues, some of which have been previously considered by FSANZ as part of the earlier NBT work.[21]

The key outcomes from feedback received from FSANZ approach at the 1st CFS include:

- The majority of submitters supported revising the current definitions in the Code for 'gene technology' and 'food produced using gene technology'. However, views were divided on

[20] Refer to 2nd Call for Submissions and Supporting document 2 – Cost benefit considerations – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

[21] Refer to the Final Report – https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

how the definitions should be revised, including whether the ‘gene technology’ definition should be expanded.

- Views were divided on the risks or safety of NBT foods and the merits of excluding some NBT foods from pre-market safety assessment.
- Views were divided on the need for government oversight of all NBT foods and the potential economic and other benefits of excluding some NBT foods from pre-market safety assessment.
- A number of concerns were raised by submitters about the lack of clarity in the proposed definitional criteria for the ‘gene technology’ definition and product-based exclusion criteria.
- Labelling of GM foods continued to be an important issue for certain submitters who wish to exercise purchasing choice. These submitters also want GM labelling applied to food derived using NBTs.
- Views were divided about the benefits and risks of traceability in terms of compliance and enforcement.

The issues raised at the 2nd CFS were more varied and detailed that those raised at the 1st CFS. This most likely reflects that FSANZ consulted on the proposed draft variation to the Code.

The submissions received at the 2nd CFS can be divided into two broad categories; the biotechnology sector, research groups and government were generally supportive of the proposed approach and draft variations. While the organic sector, community groups, non-government organisations and most individuals were strongly opposed.

The key issues raised by those who were generally supportive include:

- Lack of clear and consistent regulatory outcomes for nutritive substances.
- Lack of clarity in the proposed new definition for ‘novel DNA’.
- Precision fermentation products and refined ingredients were not considered to be addressed.
- Support for guidance material

Those who were strongly opposed to FSANZ approach at 2nd CFS thought:

- All food derived from genetic technologies should be captured and labelled as GM food.
- Had general safety concerns regarding GM and NBT food.
- Consumer ability to make informed choices were affected in FSANZ approach, impacting ‘right to know’ and trust in the food supply.

Many submitters also highlighted the importance of guidance material being available for both consumers (e.g. plain English education material) and industry and jurisdictions (e.g. decision trees, case studies, clarification of the interaction with the novel food standard).

The integrity of certified organic and non-GM systems was a concern raised at the 2nd CFS. Specifically, there was a view that approving the draft variations could negatively impact organic and non-GM operators through increased risk of contamination with NBT ingredients, higher operational costs due to stricter sourcing requirements (and consequently, elevated

consumer prices), potential loss of consumer trust in organic certification, and possible export difficulties to countries with strict GM regulations.

The issue of consumer choice was also raised by some submitters. These submitters stated that consumers have a right to know, for various reasons, if food has been genetically modified and the proposed draft variation would affect their ability to make informed choices. Some of these submitters misunderstood existing GM labelling to be processed-based, while others requested that the labelling approach be changed from product-based to process-based.

6.3. How we incorporated feedback

Throughout the consultation process FSANZ revised its approach in light of the stakeholder feedback received.

Based on submitter feedback and further assessment, FSANZ revised its approach, particularly in regard to submitter suggestions to instead focus on the presence of novel DNA in the genome as an outcome.

Feedback provided by stakeholders at the 2nd CFS was considered in the final analysis and preparation of the approval report and DRIS.

In response to feedback received from the organic sector, FSANZ has conducted targeted consultation with peak organic industry bodies and organic certifying bodies to gain a deeper understanding of this industry and how they may be impacted by the proposed definitional changes. The final analysis and report incorporates the concerns raised by the organic and non-GM sector through both submissions and targeted consultation (see section 5.5), however, as the proposed amendments are unlikely to significantly impact the Australian and New Zealand organic sector the approach has not been changed.

FSANZ has acknowledged stakeholder feedback relating to GM labelling issues, however the existing regulatory approach for GM labelling has been retained and is out of scope of this proposal.

Following the 2nd CFS, FSANZ approach remains the same. Amendments were made to the draft variations to make definitions clearer. The proposed explicit exemption to nutritive substances was removed and status quo is maintained for these substances.

7. What is the best option from those considered and how will it be implemented?

Maintaining status quo does not achieve the proposal objectives as the definitions will remain ambiguous and outdated. The definitions will still be unclear as to whether some NBT foods are required to undergo pre-market approval.

Some NBT foods that may warrant pre-market safety assessment could slip through regulatory gaps as a result of a definition that does not capture new methods. Other NBT foods that are captured for pre-market safety assessment under status quo may be subject to regulation disproportionate to the risk posed by the food.

Option 2 involves amending the definitions for ‘food produced using gene technology’ and ‘gene technology’ in the Code. FSANZ considers option 2 to be the best available option.

Option 2 meets the proposal objectives by:

- providing clarity around what ingredients and foods are GM in light of technological developments.

Updating the over 25-year-old definitions in the Code will make it clear to food developers and government authorities what ingredients or foods are required to undergo pre-market approval.

- future-proofing the definitions by focussing on the outcome of the genetic modification rather than the technology.

The new definition for 'genetically modified food' contained in the draft variations is based on the presence of novel DNA. Novel DNA provides a clear and objective measure to determine if a food is a GM food for Code purposes. The approach aims to capture newer gene technologies, along with future technology developments, by focussing on the outcome of the genetic modification and not basing the definitions on a specific technique or technology.

- achieving a risk-proportionate approach through outcomes more relevant to risk.

The presence of novel DNA is consistent with GM foods currently listed in Schedule 26 and the types of genetic modifications that carry a greater presumption of risk, because the transferred DNA may encode a novel protein, or other substance, and may not have a safe history of use in food. These foods will continue to be captured for pre-market approval. A food that is not GM may be subject to other Code provisions, including for novel food. Food that will not be captured for pre-market approval are expected to contain genetic changes consistent with changes that have been introduced through conventional breeding and that have a history of safe use.

7.1. Decision-making process for the proposed changes

The FSANZ Board will make a decision to approve, amend or reject the draft variations to the Code.

All FSANZ decisions on proposals are notified to Food Ministers (from the Commonwealth, Australian States and Territories and New Zealand) who can, within 60 days of notification from FSANZ, decide to either:

- ask for a review, or
- agree that the standard should become law.

If ministers do not seek a review, the changes are:

- registered as legislative instruments in Australia on the Federal Register of Legislative Instruments and gazetted
- issued as a food standard in New Zealand by the New Zealand Minister for Food Safety.

If a review is requested, FSANZ will review the proposal. Review requests must be finalised within three months, unless an extension is granted by the Food Ministers. The proposal will come back to the Board who will decide to either:

- reaffirm its decision (with or without changes to the proposal), or
- withdraw its approval (resulting in no change to the Code).

Reviewed decisions are returned to Food Ministers for further consideration. Food Ministers can accept, amend or reject the draft standard.

7.2. How will the proposed changes be implemented

If the draft variation is approved, implementation and enforcement of the draft variation to the Code would be the responsibility of the Australian states and territory and New Zealand food regulation agencies.

There was support for the development of guidance material from the government, research, and industry sectors with suggestions being made about the types of information that would be useful to include. For example, the scientific rationale for each exclusion, requirements for compliance, examples of different scenarios, and decision trees. FSANZ intends to engage with the Implementation Sub-committee for Food Regulation (ISFR) to prepare guidance material, should the Food Ministers Meeting make a decision to endorse a draft food regulatory measure approved by FSANZ.

7.3. Transitional arrangements

The draft variations are:

- unlikely to have any impact on products currently on the market; or
- are deregulatory in nature and provide exemptions to current requirements for products on the market.

Therefore, there will be no transition period. This approach to transitional arrangements was proposed at the 2nd CFS and FSANZ did not receive any feedback from submitters that this presented any issues.

The standard 12-month stock-in-trade provisions contained in Standard 1.1.1—9 will apply. This will permit foods produced or packaged before the official announcement of the proposed changes to remain legally available on the market for an additional 12 months.

8. How will the chosen option be evaluated?

Across Australia and New Zealand's food regulatory system, multiple agencies have responsibility for actively monitoring and evaluating food standards including FSANZ and other Commonwealth agencies and the jurisdictions.

Under the food regulatory system, the Commonwealth and jurisdictions develop the policy principles against which FSANZ consider when developing food standards. This structure also provides for reviewing the outcomes of the standards against their policy principles. Agencies with responsibility for food policy or implementation or standards development could act individually or in concert to evaluate and/or monitor the standards. Such monitoring and evaluation can be coordinated either through Food Regulation Standing Committee or ISFR.

Objectives of an evaluation for P1055 could focus on whether:

- the amendments to Standard 1.5.2 have delivered regulatory clarity as to what foods are GM foods for Code purpose.
- the amendments to Standard 1.5.2 have remained up-to-date with the latest technological developments.

Specific questions that may be asked could include:

  - Have the amendments to Standard 1.5.2 captured appropriate future technologies that did not exist at the time of assessment?

- How have food developers responded to the deregulation of certain NBT foods? For example, has there been a decrease of GM food applications made to FSANZ?
- Have new technological developments required the introduction of guidance material on how to interpret the Code?
- What is the categorisation of Code enquiries since the introduction of the amended Standard? Do the amount or type of enquiries indicate the amended Standard 1.5.2 is unclear?

FSANZ plans to continue to monitor consumers' attitudes and awareness of NBT's; and perceptions of GM foods, in the annual *Consumer Insights Tracker* survey. The *Consumer Insights Tracker* survey is a nationally representative survey of approximately 2,000 Australian and New Zealand consumers. The 2023 and 2024 findings have informed FSANZ with information such as:

- Consumers generally have low levels of awareness of gene-edited (GE) fruit and vegetables, meat or dairy. 69% had either never heard of or knew little/nothing about GE fruit and vegetables, and 77% in respect of GE meat or dairy (2023).
- GM foods or food ingredients was one of the least selected out of nine food safety concerns when asked about top food safety concerns, with 20% of consumers selecting it as one of their top three concerns in 2023, and 23% in 2024.

Findings from the *Consumer Insights Tracker* survey can inform FSANZ of emerging issues of importance to consumers and could be used to target consumer education or guidance.

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Appendix A. Intended regulatory outcomes under option 2

Food or substance	Status quo	Intended regulatory outcome at approval
Food from an organism or cells that contains novel DNA in its genome	GM food	**GM food** unless subject to exemption
Processed food ingredients from an organism or cells that contain novel DNA in their genome	GM food	**GM food** unless subject to exemption
Food from a null segregant	Unclear	**Not a GM food** (exempt)
Substances used as a food additive (FA) or processing aid (PA) from an organism or cells that contain novel DNA in its genome	GM food FA and PA are also subject to pre-market regulation under other parts of the Code	**Not a GM food** (exempt) FA and PA are subject to pre-market regulation under other parts of the Code
Substances used as a nutritive substance (NS) from an organism or cells that contain novel DNA in its genome	GM food NS are also subject to pre-market regulation under other parts of the Code	**GM food** NS are also subject to pre-market regulation under other parts of the Code
Precision fermentation product from a microorganism that contains novel DNA in its genome	GM food May also be subject to pre-market regulation under other parts of the Code	**GM food** unless subject to exemption May be subject to pre-market regulation under other parts of the Code
Food from a genome edited organism that contains novel DNA in its genome	Unclear	**GM food** unless subject to exemption
Food from a genome edited organism that does not contain novel DNA in its genome	Unclear	**Not a GM food** May be subject to regulation under other parts of the Code
Food from conventionally bred organisms	Not a GM food May be subject to regulation under other parts of the Code	**Not a GM food** May be subject to regulation under other parts of the Code
Food derived from the part of a grafted plant that does not contain novel DNA or novel protein	Unclear	**Not a GM food** (exempt) May be subject to regulation under other parts of the Code
Cell-cultured food derived from a cell line that contains novel DNA in its genome	GM food	**GM food**
Substances used to support the growth and viability of cells or process cells in culture as part of the production of cell-cultured food	Not a GM food Whether the substances are a FA, PA or NS will need to be determined on a case by case basis. FA, PA and NS are subject to pre-market regulation under other parts of the Code	**Not a GM food** (exempt) Whether the substances are a FA, PA or NS will need to be determined on a case-by-case basis. FA, PA and NS are subject to pre-market regulation under other parts of the Code

Appendix B. International regulatory approaches

The table below summarises the proposed or changed regulatory processes in Argentina, the European Union, the United Kingdom and the United States. FSANZ has compiled further information on international regulatory approaches and relevant definitions in other legislative and regulatory instruments that can be found on the FSANZ website.[22]

International jurisdiction	Approach
Argentina	Argentina were the first country to introduce NBT-specific regulations. Resolution 173/2015 was introduced by Argentina in 2015. It establishes a process whereby a pre-market consultation is used to determine whether an organism modified using a NBT is a GMO. Decisions are made on a case-by-case basis. The approach is based on whether the NBT results in a "novel combination of genetic material" in the final organism. This approach is based on the Cartagena Protocol on Biosafety definition of a 'Living Modified Organism'.
European Union	In 2024 the European Parliament voted in favour of a European Commission proposal[23] to introduce simpler and less onerous regulatory requirements for plants modified using new genomic techniques (NGTs; targeted mutagenesis and cisgenesis) including derived food and feed products. In 2025, the member states of European Council agreed to advance negotiations with the European Parliament on NGT regulations. While supporting the main elements of the European Commission proposal, the Council has proposed a number of amendments, largely around patentability aspects of NGT plants.[24] Under the proposal, plants derived using NGTs that could also occur naturally or by conventional breeding will be exempted from the requirements of the EU GMO legislation (EU Directive 2001/18/EC). For all other NGT plants the requirements of the current GMO legislation apply. The proposal, if adopted, would represent a significant change in approach following the 2018 European Court of Justice ruling that all genome edited organisms are GMOs.
United Kingdom	The Genetic Technology (Precision Breeding) Act passed into law in England in 2023[25]. The Act defines a precision bred organism (PBO) as a plant or vertebrate animal produced by precision breeding techniques such as gene editing, that could have been produced by traditional

[22] Refer to 1st CFS Supporting document 3 – Regulatory approaches and definitions – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

[23] European Commission proposal for a new regulation on plants produced by certain new genomic techniques – https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

[24] Council of the EU – negotiating mandate on NGT regulations, 7 March 2025 https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf

[25] Genetic Technology (Precision Breeding) Act 2023 – https://www.legislation.gov.uk/ukpga/2023/6/contents/enacted

International jurisdiction	Approach
	breeding processes. The main outcome of the Act is that PBOs will be regulated more like their conventionally bred counterparts, rather than as GMOs. The Department for Environment, Food & Rural Affairs (Defra) and the Food Standards Agency (FSA) are proceeding with the implementation of secondary legislation[26] which sets out the requirements for food and feed produced from precision bred plants to be placed on the market. Under this framework, the PBO status of organisms will first need to be confirmed by Defra. Following Defra's decision, an application for food or feed authorisation can be submitted to the FSA. The FSA will implement a two-tiered approach to the authorisation of PBOs as food or feed: • A 'Tier 1' application is required where developers can demonstrate that the potential safety risks of their PBO are understood. Tier 1 applications will be granted marketing authorisation without the need for a full safety assessment. Instead, they will follow a lighter-touch registration process, including an applicant-led safety assessment.[27] • Where the Tier 1 assessment identifies potential concerns, or where there is uncertainty, a 'Tier 2' application will be required, which involves a fuller assessment by the FSA before marketing authorisation is granted. Unlike GMOs, for both assessments, developers of precision bred plants will not be required to provide scientific detection methods as part of the authorisation process. Both Tier 1 and Tier 2 PBOs for use in food and feed will also be required to be listed on a public register before they can be placed on the market.

[26] The Genetic Technology (Precision Breeding) Regulations 2025 (Draft) - https://www.legislation.gov.uk/ukdsi/2025/9780348269123

[27] FSA draft technical guidance to applicants for the authorisation of PBOs for food and feed - https://www.food.gov.uk/document/draft-technical-guidance-to-applicants-for-the-authorisation-of-precision-bred-organisms-for-food-and-feed

International jurisdiction	Approach
United States	In the United States, the Food and Drug Administration (FDA) does not require pre-market approval for new plant varieties (NPVs) as a class. Product developers of new GM plant varieties however routinely consult with the FDA under their voluntary pre-market consultation programme for foods from NPVs. In 2024, the FDA issued new guidance for developers of foods derived from genome edited plants[28], outlining two voluntary processes that developers may use to inform the FDA of steps they have taken to ensure the safety of their product: • A pre-market consultation is recommended when genome editing results in changes that may raise safety questions or regulatory considerations that put the legal status of the food in question. • Where the genome editing does not raise safety questions according to the FDA guidance, they strongly recommend that developers schedule a pre-market meeting to inform the FDA about the type of food that will be entering the market and the steps they have taken to ensure safety. In 2024, the FDA also issued guidance for developers on their regulatory approach for oversight of intentional genomic alterations (IGAs) in animals.[29] The guidance includes a description of situations in which applications for approval may not be required, including in food animals where the alteration is equivalent to what could be theoretically achieved through conventional breeding.

[28] FDA Guidance for industry: foods derived from plants produced using genome editing – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-foods-derived-plants-produced-using-genome-editing

[29] FDA Guidance for industry: heritable intentional genomic alterations in animals (approach) – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-187a-heritable-intentional-genomic-alterations-animals-risk-based-approach

Appendix C. Comparison of labelling outcomes based on existing Code requirements and under the P1055 variation

Food or substance	Labelling outcome under existing Code			Labelling outcome under P1055 variation		
	Novel DNA or novel protein in the food for sale	**Novel DNA and novel protein not in the food for sale**	**The food has an altered characteristic**	**Novel DNA or novel protein in the food for sale**	**Novel DNA and novel protein not in the food for sale**	**The food has an altered characteristic**
Food or ingredient from an organism or cells that contain novel DNA in its genome	Labelled GM	No GM labelling	Labelled GM	Labelled GM	No GM labelling	Labelled GM
Processed food ingredients from an organism or cells that contains novel DNA in its genome	Labelled GM	No GM labelling	Labelled GM	Labelled GM	No GM labelling	Labelled GM
Substances used as a nutritive substance or a precision fermentation product, from an organism or cells that contain novel DNA in its genome	Labelled GM [1]	No GM labelling	Labelled GM [1]	Labelled GM [1]	No GM labelling	Labelled GM [1]
Cell-cultured food derived from a cell line that contains novel DNA in its genome	Labelled GM	No GM labelling	Labelled GM	Labelled GM	No GM labelling	Labelled GM
Food from a genome edited organism that contains novel DNA in its genome	If captured [2] labelled GM	No GM labelling	If captured [2] labelled GM	Captured [3] labelled GM	No GM labelling	Captured [3] labelled GM
Substances used as a food additive or processing aid from an organism or cells that contain novel DNA in its genome	Labelled GM [4]	No GM labelling	N/A [5] no GM labelling	Not captured [3, 4] no GM labelling	Not captured [3] no GM labelling	Not captured [3] no GM labelling
Food from a null segregant	N/A [6] no GM labelling	N/A [6] no GM labelling	N/A [5] no GM labelling	Not captured [3] no GM labelling	Not captured [3] no GM labelling	Not captured [3] no GM labelling
Food from a genome edited organism that does not contain novel DNA in its genome	If captured [2] no GM labelling	If captured [2] no GM labelling	If captured [2] labelled GM	Not captured [3] no GM labelling	Not captured [3] no GM labelling	Not captured [3,7] no GM labelling
Food derived from the part of a grafted plant that does not contain novel DNA or novel protein	If captured [2] no GM labelling	If captured [2] no GM labelling	If captured [2] labelled GM	Not captured [3] no GM labelling	Not captured [3] no GM labelling	Not captured [3,7] no GM labelling
Substances used to support the growth and viability of cells or process cells in culture as part of the production of cell-cultured food	No GM labelling	No GM labelling	No GM labelling	Not captured [3] no GM labelling	Not captured [3] no GM labelling	Not captured [3] no GM labelling

1. Note the type of substance and their production method will affect whether labelling applies (e.g. permitted human identical milk oligosaccharides are unlikely to be labelled due to filtration / purification steps that remove novel DNA and novel protein).
2. 'Captured' means the food is captured as a 'food produced using gene technology' (in accordance with subsection 1.1.2—2(3) of the Code) for the purposes of a pre-market assessment. The uncertainty of whether food from genome edited organisms and food from grafted plants is captured is part of the reason why FSANZ has prepared Proposal P1055.
3. 'Captured' means the food is captured by the definition of genetically modified food' (under section 1.1.2—16 of the variation) for the purposes of a pre-market assessment.
4. Novel DNA and novel protein from these substances is typically absent in the food for sale.
5. Not applicable because these substances do not have altered characteristics.
6. Not applicable because these foods do not contain novel DNA or novel protein.
7. Other labelling measures may be considered if alternative assessment processes are triggered.