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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 assessed a proposal to amend the definitions for ‘food produced using gene technology' and ‘gene technology’ in the Australian 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 food (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 and why is government action needed?**

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.

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.

**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.

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 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 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.
* 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 we see different foods or ingredients being 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 ingredients and foods 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 Food Regulation Standing Committee (FRSC) or Implementation Subcommittee for Food Regulation (ISFR).

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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## Introduction

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 Australia New Zealand Food Standards Code (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)[[1]](#footnote-2)
* Section 59 of the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act).

### Assessment of the OIA

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.

### 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.

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 4 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).

### 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.

### 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. Permitted GM foods are listed in Schedule 26 of the Code, with the majority being derived from organisms modified using transgenesis[[2]](#footnote-3). 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 GM food additives and GM processing aids, 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 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.

## What is the problem and why is government action needed?

Standard 1.5.2 was adopted in 1998, making the definitions for ‘food produced using gene technology’ and ‘gene technology’ over 25 years old. Current definitions were adopted with the intent of capturing the types of GM foods that existed at the time.

‘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.

To be sold, a GM food must be:

* permitted as a GM food and listed in Schedule 26.
* 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. Assessment of the application includes a pre-market safety assessment.

Foods that do not meet the definition of ‘food produced using gene technology’ are not required to undergo pre-market safety assessment and approval as GM foods. However, such foods may require pre-market assessment and approval under other Code provisions (e.g. for novel foods).

***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.

NBTs are a diverse collection of new techniques for genetic modification that have emerged over the last decade or more. As genetic modification technology is still evolving, NBTs also include techniques that may emerge in the future.

A distinction is made between NBTs and older GM techniques because NBTs can be used to make a wider variety of genetic changes. 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.

***Box 1. Presence of NBT food in the global food supply***

No food derived using NBTs (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 applications of NBTs were registered across animals and plants (15 applications in Australia and 8 in New Zealand). Only 2 Australian applications were categorised as being in pre-commercial stage: hornless cattle and heat-resistant cattle. All other applications were classed as being in the early to advanced research and development stage.

Globally, only two applications were identified in 2020 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.

Other NBT foods that have been approved for sale by other countries include high starch corn, non-browning lettuce, reducing browning banana and non-browning mushroom (Genetic Literacy Project, n.d.).

***Gene technology as currently defined in the Code no longer reflects the type of technologies available to use in food production***

The emergence of NBTs has generated uncertainty about the regulatory status of NBT food, specifically whether such foods would be considered food produced using gene technology and therefore require an application to FSANZ for pre-market assessment and approval.

In June 2017, FSANZ commenced a review of the Code to consider how it should apply to NBT food.[[3]](#footnote-4) The review identified instances where a food developer could interpret the Code differently, resulting in the inconsistent regulation of NBT food. 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. This may have risks to public health and safety.
* an increase in applications to FSANZ – a food developer might incorrectly believe their product requires pre-market assessment and submit an application to FSANZ. This may have cost implications for both product developers and FSANZ.
* the abandonment of NBT product development – there may be negative impacts on innovation because developers are uncertain about the regulatory pathway for a particular NBT food.

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.

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
2. better accommodate new and emerging technologies
3. regulate NBT foods in a manner that is commensurate with the risks they pose.

## What options are to be considered?

FSANZ considered various options in the NBT review and assessment of Proposal P1055.

As part of the NBT review FSANZ 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. A non-regulatory option was also considered at the 1st CFS.

Introducing non-regulatory measures alone is not considered to be a viable option to address the problem. Developing guidance or a code of practice would rely on interpretation of the current definitions in the Code.

Non-regulatory measures would not provide regulatory certainty for food developers on the required regulatory pathway to market for their products. It would also not enable enforcement agencies to efficiently determine whether a food is compliant with the Code.

Definitions would continue to be outdated and not reflective of the diversity of techniques now in use. There is a risk some foods would be deemed out of scope of the definitions in the Code where pre-market safety assessment might be justified.

FSANZ considers it is not possible to achieve the proposal objectives using non-regulatory options. It is necessary to amend the current regulatory approach but not remove it entirely. Doing so will improve risk proportionality across the whole range of new and emerging genetic technologies and provide the capability to identify whether new products require pre-market safety assessment.

At the 1st CFS FSANZ sought stakeholder feedback on an approach to amending the definitions in the Code. This approach was revised in light of the feedback received, and additional feedback was then sought on the proposed draft variations to the Code during the 2nd CFS.

FSANZ has had regard to submitter feedback provided at the 2nd CFS in finalising the draft variations to the Code. A summary of the feedback received is included in section 5 below.

At Approval stage, FSANZ is considering two options:

1. Maintaining the status quo (rejecting the draft variation)

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

These are discussed in more detail below.

### Option 1 – Maintain the status quo (rejecting the draft variation)

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 as to how the definitions in the Code are to be interpreted with the emergence of NBTs. Enforcement agencies would continue to encounter inefficiencies in their ability to determine whether a food is compliant with the Code. This disregards regulatory gaps that could occur, such as food entering the food supply without pre-market assessment where it is 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. The latter point may impact enforcement at the border as NBT foods are developed overseas.

### Option 2 – Amending 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
* 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.
* 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’.

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 provides a single outcomes-based definition for GM food. A definition based on novel DNA provides a clear and objective measure to determine whether a food is a GM food for Code purposes. An outcomes-based definition rather than a definition based on a specific technology or process also enables the definition to be used into the future as other technologies emerge.

Basing the definition for GM food on the presence of novel DNA will continue to capture the types of GM foods currently listed in Schedule 26 while being risk-proportionate in not capturing genetic changes that are equivalent to those introduced through conventional breeding and therefore of low risk. A food that is not a GM food under the Code may still be subject to other Code provisions, including for novel food.

Option 2 also proposes explicit exemptions from the new GM food definition. Food additives and processing aids are proposed to be exempt as they are regulated under other parts of the Code and subject to pre-market safety assessment where any genetic modification would continue to be considered. Substances used in cell culture for the production of cell-cultured food are proposed to be exempt as they do not require explicit regulation, and are in any case subject to assessment during the pre-market assessment of cell-cultured foods. To provide more clarity, exemptions are proposed for food derived from null segregants and grafted plants as they are considered to be equivalent in risk to conventional foods.

Appendix A summarises the intended regulatory outcomes of different types of foods and substances.

Option 2 also includes consequential changes to other parts of the Code as a result of the proposed new definition for GM food. This includes consequential and clarifying changes to the labelling requirements including a minor change to remove certain labelling exemptions that would be redundant under the proposed new definition e.g. the GM food is a substance used as a processing aid, where no novel DNA or novel protein from the substance remains in the food. These amendments do not change the existing regulatory approach for mandatory labelling of GM food.

## What is the likely net benefit of each option?

At the 2ndCFS, 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. Submissions were also received highlighting how NBTs could be used in practice and the subsequent benefits that the technology could have on industry.

FSANZ does not have information to enable a quantitative analysis of the options. The following section qualitatively analyses the impacts associated with maintaining status quo (option 1) and amending the Code (option 2).

### Option 1 – Maintaining status quo (rejecting the draft variation)

Option 1 would involve no change to the definitions for ‘food produced using gene technology’ and ‘gene technology’ in the Code and represent the status quo against which option 2 is compared. Under this option the definitions would continue to be unclear regarding which NBT foods are required to undergo pre-market assessment 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. 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.

Maintaining status quo is likely to lead to future costs for food developers. Regulatory uncertainty may discourage investment and innovation and could lead to developers shifting their business overseas where relevant regulations are up-to-date with the latest technologies.

Some submitters expressed their preference for FSANZ to maintain status quo. These submitters considered the current definitions to be clear, functional and objective. It was also the view of many submitters that rather than maintaining status quo, FSANZ should take a more stringent approach and capture all NBT foods for pre-market assessment and GM labelling.

Evidence that the current definitions lack clarity is well documented and discussed as part of FSANZ’s review of NBTs. This evidence is one of the main drivers for preparing Proposal P1055. Many other submitters agree that this lack of clarity with the current definitions needs to be addressed.

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.

### Option 2 – Amend the definitions in the Code (approve the draft variation)

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.

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

| **Stakeholder group** | **Notes on impact** |
| --- | --- |
| Consumers | Consumers may perceive their ability to make informed choices is impacted due to certain NBT foods not being subject to mandatory GM labelling. 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 or lower prices as a result of production efficiencies. |
| Food Industry (technology developers and manufacturers, including users of GM and NBT foods or ingredients) | 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.  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.  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. |
| Food Industry (organic operators) | Where there may be increased prevalence of NBT ingredients in the future, 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. |
| Government | 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. |
| 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.  Ultimately, innovation benefits consumers by providing higher-quality products at more affordable prices (Kollmann et al. 2020). |

### 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 (e.g. a different fatty acid profile). 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.

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 anyway.

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

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 describes the consumer research that FSANZ has completed for P1055.

***Box 2. 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. 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 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.

It 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.

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.

In the long term, consumers may gain access to an increased range of foods with enhanced attributes which better meet their needs or lower prices as a result of production efficiencies. This is further discussed in section 4.7 below.

### 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. This could be particularly beneficial to small and medium NBT food developers, where these costs act as a barrier to market entry.

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 (1) determine the category of their product and (2) 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, such as novel food.

While businesses may face some initial costs associated with adapting to the proposed approach, these are expected to be minimal. 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.

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.

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. 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). 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 does not expect this to be a significant negative impact as use of GM ingredients in domestic products appears to be minimal.

A number of countries 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 the regulatory approaches of the European Union, United Kingdom and United States.

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.

### Impact to organic food operators from option 2

Organic food producers 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. However, the organic sector, including certified organic operators, 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 3 provides background information on organic systems and certifying processes.

***Box 3. 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 producer can verify that their systems are organic and become certified. Certification involves an organic producer 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 producers are regularly audited to ensure a producer is compliant with their relevant standard.

Currently, only those Australian and New Zealand organic producers who export their products are required to meet the National Organic Standards or programmes set by the Department of Agriculture, Fisheries and Forestry (DAFF) and the Ministry for Primary Industries (MPI), respectively.

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

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 producers adopt a variety of practices to ensure GM materials do not contaminate their operations, among other residue contaminations, including:

* operating in a closed loop system where only certified organic ingredients are used, enabling traceback from farm to fork of organic certified ingredients and processes.
* Where certified organic ingredients aren’t available, a producer 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[[4]](#footnote-5) to know whether an ingredient is GM or using analytical testing to confirm non-GM status.
* FSANZ is aware of a European Union funded project investigating analytical methods for detecting and ascertaining the origin of genome edits.[[5]](#footnote-6) 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 producers 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.

### 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.

There may also be cost savings to government related to pre-market assessment under option 2. The updated definitions provide clarity to developers that some foods derived from new technologies are not required to undergo pre-market assessment.

As the proposed approach in option 2 incorporates risk proportionality, food agencies 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 the need for guidance material.

The proposed approach and new definitions increases 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.

### 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 4 provides information from submitters on how using NBTs developments may benefit them.

***Box 4. 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.

Another submitter 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 have a lower willingness to pay for NBT foods compared to their conventional counterparts (Lemarie & Marette 2022). FSANZ consumer research 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.

### Comparison of options

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.

Maintaining status quo may lead to 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.

Maintaining an outdated definition in the Code may also negatively impact food developers and the Government. The definition of GM food in the Code may lead to applications being made to FSANZ where it may not be considered necessary, or could discourage developers from innovating all together.

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.

Food developers and government authorities may experience the most immediate benefit of amending the definitions from regulatory certainty around what is required to undergo pre-market approval and what is consider 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.

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.

Regulatory certainty may encourage investment into NBT food innovations which could, depending on the innovation, flow-on as wider food system benefits in light of future challenges such as climate resilience and food security.

### Conclusion of analysis

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.

## Who was consulted and how was their feedback incorporated?

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

### 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.

Following consideration of submitter feedback and further assessment, FSANZ presented a revised approach, prepared a new definition for genetically modified food and prepared 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.

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

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

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:

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

### 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.[[6]](#footnote-7)

The submissions received can be divided into two broad categories; the biotech 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.

Key issues raised on the draft variations prepared at the 2nd CFS include:

* Inconsistencies with the proposed approach for nutritive substances and foods produced using precision fermentation.
* Lack of clarity in the proposed new definition for ‘novel DNA’.
* Support for guidance material to facilitate compliance and enforcement for industry and jurisdictions, respectively.
* The need for consumer education materials to explain technical concepts to consumers and help consumer understanding of the proposed changes.
* General safety concerns regarding GM and NBT foods.
* GM labelling of NBT foods for informed consumer choice

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.

### How we incorporated feedback

Throughout the consultation process FSANZ revised its approach in light of the stakeholder feedback received. Feedback provided by stakeholders at the 2nd CFS was considered in the final analysis and preparation of the approval report

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.

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.

Amendments to the draft variations have also been made following feedback provided by stakeholders at the 2nd CFS.

## 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 is captured for pre-market 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 safety assessment are expected to contain genetic changes consistent with changes that have been introduced through conventional breeding and that have a history of safe use.

### 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 ministers (from the Commonwealth, Australian States and Territories and New Zealand) responsible for food regulation who can 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. 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 ministers for further consideration. Ministers can accept, amend or reject the draft standard.

### 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.

The draft variations to the five Standards and three Schedules 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?

Across Australia’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 FRSC or ISFR.

FSANZ plans to continue to monitor consumers’: attitudes and awareness of NBT’s; and perceptions of GM foods, in the annual *Consumer Insights Tracker* (CIT) survey. The CIT is a nationally representative survey of approximately 2,000 Australian and New Zealand consumers.

FSANZ will monitor enquiries to Advisory Committee for Novel Foods[[7]](#footnote-8). This can be used to evaluate the types of NBT products that are excluded from the GM food definition but may require an assessment of public health and safety as a novel food. 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 equivalent to a traditional food, or if considered non-traditional, to have characteristics that would not require an assessment of public health and safety.

## References

Ahmad M (2023) [*Plant breeding advancements with ‘CRSPR-Cas” genome editing technologies will assist future food security*](https://www.frontiersin.org/journals/plant-science/articles/10.3389/fpls.2023.1133036/full) *Frontiers in Plant Science*, *14:*1133036

Australia and New Zealand Food Regulation Ministerial Council (2011)[*Labelling Logic: Review of Food Labelling Law and Policy*.](https://webarchive.nla.gov.au/awa/20170215181007/http:/foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic)

Brookes G & Barfoot P (2020) [*GM crop technology use 1996-2018: farm income and production impacts*.](https://www.tandfonline.com/doi/full/10.1080/21645698.2020.1779574) *GM Crops & Food*, *11*(4).

Commonwealth of Australia, Department of the Prime Minister and Cabinet (2023) [*Regulatory Impact Analysis Guide for Ministers’ Meetings and National Standard Setting Bodies.*](https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national)

Food Standards Australia New Zealand (2019) [*Final report: Review of food derived using new breeding techniques*](https://www.foodstandards.govt.nz/consumer/gmfood/Review-of-new-breeding-technologies)

Kalaitzandonakes N, Willig C, Zahringer K (2022) [*The economics and policy of genome editing in crop improvement*](https://acsess.onlinelibrary.wiley.com/doi/10.1002/tpg2.20248)*, The Plant Genome, 16:*e20248

Kollmann T, Palangkaraya A, Webster E (2020) [*Innovation in Manufactured Food and Infant Formula Sectors*. The Centre for Transformative Innovation](https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1155%20Review%20SD5%20Innovation%20in%20manufactured%20food%20and%20infant%20formula%20sectors.pdf), Swinburne University of Technology.

Kovak E, Blaustein-Rejto D, Qaim M (2022) [*Genetically modified crops support climate change mitigation.*](https://www.sciencedirect.com/science/article/pii/S1360138522000048?via%3Dihub) *Trends in Plant Science*, *27*(7).

Lemarie S, Marette S (2022) [*The socio-economic factors affecting the emergence and impacts of new genomic techniques in agriculture: A scoping review*](https://www.sciencedirect.com/science/article/pii/S0924224422003089?via%3Dihub) *Trends in Food Science & Technology 129*:38-48

NZIER (2024) [*Potential costs of regulatory changes for gene technology: economic assessments of an MBIE proposal. A report to Organics Aotearoa New Zealand*](https://www.oanz.org/new-blog/NZ%20exports%20risk%20multi-billion%20dollar%20hit%20if%20GMO%20rules%20deregulated)*.*

Parisi C, Rodríguez Cerezo E (2020) [*New genomic techniques*](http://data.europa.eu/89h/382e03fc-aac3-482a-9e81-9997789083b1). European Commission Joint Research Centre [Dataset]

Qaim M (2020). [*Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development*](https://onlinelibrary.wiley.com/doi/10.1002/aepp.13044). Applied Economics Perspectives & Policy, 42(2).

## Appendix A. Intended regulatory outcomes under option 2

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

## Appendix B. International regulatory approaches

| **International jurisdiction** | **Approach** |
| --- | --- |
| European Union | In 2024 the European Parliament voted in favour of a European Commission proposal[[8]](#footnote-9) 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.  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), though seeds produced using NGTs would still require labelling. 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[[9]](#footnote-10). 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 breeding processes. The main outcome of the Act is that PBOs are no longer subject to regulation as GMOs.  Late in 2023, the Food Standards Agency (FSA) consulted on a policy proposal for a new framework for the regulation of PBOs used for food and feed under the new Act.  Following the consultation, the FSA is proceeding with the implementation of secondary legislation[[10]](#footnote-11) that will include a two-tiered approach to the regulation of PBOs:     * For Tier 1 PBOs, where potential safety risks are understood, no application will be required although they will still need to be notified to the FSA. * Tier 2 PBOs, which require more regulatory scrutiny, will require an application to the FSA.   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. |
| 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 released new non-binding guidance for developers of foods derived from genome edited plants[[11]](#footnote-12), 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.[[12]](#footnote-13) 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. |

1. [Office of Impact Analysis' Guide for Ministers’ Meetings and National Standard Setting Bodies June 2023 (OIA Guide)](https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national) [↑](#footnote-ref-2)
2. Transgenesis is the process where DNA from an unrelated organism is inserted into the genome, in any configuration. [↑](#footnote-ref-3)
3. https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies [↑](#footnote-ref-4)
4. which may not be present on all GM ingredients such as those that are highly refined. [↑](#footnote-ref-5)
5. <https://darwin-ngt.eu/about/> [↑](#footnote-ref-6)
6. https://www.foodstandards.govt.nz/consumer/gmfood/Review-of-new-breeding-technologies [↑](#footnote-ref-7)
7. Advisory Committee for Novel Foods – <https://www.foodstandards.gov.au/business/novel/novelcommittee> [↑](#footnote-ref-8)
8. 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> 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> [↑](#footnote-ref-9)
9. Genetic Technology (Precision Breeding) Act 2023 – <https://www.legislation.gov.uk/ukpga/2023/6/contents/enacted> [↑](#footnote-ref-10)
10. Genetic Technology (Precision Breeding) Regulations 2025 (Draft) -

    <https://www.legislation.gov.uk/ukdsi/2025/9780348269123> [↑](#footnote-ref-11)
11. 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> [↑](#footnote-ref-12)
12. 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> [↑](#footnote-ref-13)