**7 October 2021**
**173-21**

# 1st Call for submissions – Proposal P1055

## Definitions for gene technology and new breeding techniques

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FSANZ has assessed a proposal prepared to revise and update the definitions in the Australia New Zealand Food Standards Code for '*food produced using gene technology*' and '*gene technology*' to make them clearer and to better reflect existing and emerging genetic technologies, including new breeding techniques. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

For information about making a submission, visit the FSANZ website at information for submitters. All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available through alternative means, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing, be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

**DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 3 December 2021**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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## Supporting documents (SD)

The following documents which informed the assessment of this Proposal are available on the FSANZ website: https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx

SD1 Safety assessment: full technical report
SD2 Safety assessment: plain English summary
SD3 Compilation of regulatory approaches and definitions for GMOs and NBTs

# Executive summary

P1055 is 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). These definitions determine what foods are classed as genetically modified (GM) food under the Code. Currently, all GM food available for sale in Australia and New Zealand must have been assessed for safety by FSANZ and be expressly permitted and listed in relevant Code schedules.

FSANZ commenced this proposal in early 2020 following completion of the *Review of food derived using new breeding techniques*. The review examined how the Code applies to food produced using new breeding techniques (NBTs), diverse genetic modification methods that have been developed over the last decade or so. It recommended amending the Code definitions for 'food produced using gene technology' and 'gene technology' after finding they lack clarity, and are not fit for purpose, resulting in uncertainty about assessment and approval requirements for NBT foods. The review also identified the need to regulate NBT foods in a manner that matches the risk they pose.

Outdated and unclear definitions may result in gaps in regulatory coverage of new technologies and also discourage innovation and investment. In addition, some NBT foods and refined ingredients have the same characteristics and risk as conventional foods that have a history of safe use, meaning a pre-market safety assessment as a GM food is not required in all cases. Updating the two definitions and adopting a risk-based regulatory approach to certain NBT foods and refined ingredients can help ensure public health and safety continues to be protected, meaningful information and labelling is provided to consumers, and new products have clear and predictable pathways to market.

FSANZ has considered what amendments to the definitions are necessary to:

- make them clearer and better able to accommodate food produced by existing, emerging and future genetic technologies, and
- ensure NBT foods are regulated in a manner that matches the risk they pose.

FSANZ's preferred approach to amending the definitions, and the reasons for this approach, are outlined in this report at Section 4.2.2.

The preferred approach is based on the conclusions of a detailed safety assessment of NBTs compared to other methods of genetic modification (see Supporting Document 1 and a plain English summary at Supporting Document 2). The safety assessment was informed by advice from FSANZ's Expert Advisory Group on New Breeding Techniques (EAG NBT). As part of its assessment, FSANZ also considered a range of other matters including: technology development, enforcement, alignment of gene technology definitions, international developments and how the preferred approach relates to current GM labelling requirements.

Revising the definitions as proposed will extend the reach of the Code to new and emerging genetic technologies and provide the capability to identify whether new products require pre-market safety assessment or not. Exclusions for certain foods would be based on specific product-based criteria. Food not meeting all exclusion criteria would require an application to FSANZ.

In addition to revised definitions, FSANZ has proposed non-regulatory measures including the establishment of an advisory committee on NBT foods and the development of specific guidance material. These measures will help facilitate implementation of revised definitions by jurisdictions and assist product developers to interpret and comply with the new provisions.

**Proposal P1055 at a glance**

FSANZ's assessment is that the current definitions for 'gene technology' and 'food produced using gene technology' in the Australia New Zealand Food Standards Code should be amended as follows:

- revise and expand the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding; and
- revise the definition for 'food produced using gene technology' to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM food. Foods not meeting all relevant exclusion criteria would require an application to FSANZ.

FSANZ's assessment is that NBT food and refined ingredients should not be GM food for Code purposes if they are equivalent in characteristics and risk to conventional food with a history of safe use. GM food will continue to require pre-market safety assessment and approval under revised definitions, with approved GM food subject to mandatory labelling.

It is proposed these regulatory changes be supported by non-regulatory measures, including the establishment of an advisory committee and development of new guidance materials to support implementation by enforcement agencies and industry.

Overall, this approach:

- will provide certainty that GM foods produced by new and emerging technologies are safe
- will limit the potential for gaps in regulatory coverage as technology develops
- is risk-proportionate, excluding foods that have the same characteristics as, and pose no greater risk than, conventional foods
- sets exclusion criteria based on food product characteristics which:
    - avoids some of the enforcement challenges that would occur if such products were captured by revised definitions, and
    - aligns with the current product-based GM labelling requirements.

# 1. Introduction

## 1.1 The proposal

Proposal P1055 – Definitions for gene technology and new breeding techniques commenced in February 2020. The purpose of the proposal is to revise and update the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to make them clearer and to better reflect existing and emerging genetic technologies, including new breeding techniques (NBTs).[1]

***Box 1: What are New Breeding Techniques?***

New breeding techniques or 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.

We make a distinction 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. Supporting Document 1 has detailed technical information about NBTs and how they compare to conventional breeding.

**Examples of NBTs:**

*Genome editing* – a group of techniques that make precise changes (edits) at targeted locations in the genome of an organism. CRISPR[2] technology is a form of genome editing.

*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.

[1] The regulatory arrangements for GM foods under the Code are separate and independent from those for genetically modified organisms (GMOs) under the *Hazardous Substances and New Organisms Act 1996* (HSNO Act) in New Zealand and the *Gene Technology Act 2000* (GT Act) in Australia. Any actions or decisions taken as a result of Proposal P1055, including amendments to the definitions for 'food produced using gene technology' and 'gene technology' in the Code, will not alter the regulatory arrangements for GMOs in either New Zealand or Australia. These can only be altered by a specific action to amend the HSNO Act in New Zealand and the GT Act in Australia. A genome edited organism that is a GMO under either the HSNO Act or the GT Act will continue to be a GMO for the purposes of that legislation, irrespective of whether food from that organism is considered a GM food or not.

[2] CRISPR stands for *Clustered Regularly Interspaced Short Palindromic Repeats* which are part of a microbial defense system that forms the basis for CRISPR-Cas9 genome editing technology.

## 1.2 Terminology used throughout this report

Many technical terms are used throughout this report. To aid understanding, and in particular to avoid confusion, the meaning of the most common terms used in the report (and supporting documents) are described below.

*GM food* is an abbreviated term that is distinct from 'genetically modified food', where the latter has a specific meaning in the Code for labelling purposes. The abbreviated term is used throughout this report as a substitute for the term 'food produced using gene technology', which is defined under the Code (see Section 2.2). The term 'food produced using gene technology' is only used in this report when specific reference is being made to the legal definition in the Code.

*Gene technology* refers to the process used to make GM food and is specifically defined under the Code (see Section 2.2). The use of the gene technology process typically results in the insertion of DNA from a different species, also referred to as foreign DNA. The term 'gene technology' is only used in this report when specific reference is being made to the legal definition in the Code.

*New breeding techniques* (NBTs) is a term used throughout this report to refer to a range of new techniques for genetic modification. This term is also used to distinguish the newer techniques from older methods of genetic modification used for GM food. It has no legal meaning under the Code.

*Conventional breeding* is a term used throughout this report to refer to longstanding methods for genetic modification that do not include either gene technology or NBTs. 'Conventional breeding' also has specific legal meaning under the Code (see Section 2.2). Food derived using conventional breeding methods is referred to as 'conventional food', another term commonly used throughout this report. 'Conventional food' has no legal meaning under the Code.

*NBT foods* is a term adopted by FSANZ to specifically refer to food developed using NBTs and to distinguish them from GM foods. It has no legal meaning under the Code.

*Genetic technologies* is a general term used occasionally throughout this report to refer to the collection of technologies other than conventional breeding methods that are used for the genetic modification of organisms. It has no legal meaning under the Code.

## 1.3 Reasons for preparing the proposal

The proposal was prepared following the December 2019 release of the final report for the FSANZ *Review of Food derived using New Breeding Techniques* (NBT review)[3] (see also Section 2.3.2). The review found the definitions for 'food produced using gene technology' and 'gene technology' were no longer fit for purpose and recommended a proposal be prepared to revise and update them.

FSANZ's assessment under this proposal indicates the review's conclusions remain valid, including that the current definitions are:

- unclear/ambiguous, resulting in uncertainty about whether NBT food requires pre-market assessment and approval under the Code; and
- outdated and so do not reflect the diversity of techniques now in use, or that may emerge in the future.

[3] https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Final%20report.pdf

Outdated definitions may result in regulatory gaps with products intended to be subject to pre-market safety assessment not being captured. Updated definitions for GM food will ensure public health and safety continues to be protected as new technologies are developed.

Regulatory uncertainty can deter investment in new technologies, potentially delaying or stifling innovation. Revised definitions for GM food will provide a clear and predictable pathway to market for investors and developers. This matters because new technologies, such as NBTs, are useful tools that may contribute to more sustainable food production, cheaper food and innovative food products which benefit the food and agriculture sectors as well as consumers.

## 1.4 Proposal objectives

The following objectives for revising definitions were proposed in the final report for the NBT review. In undertaking its assessment for this proposal, FSANZ had regard to these objectives, in addition to the statutory objectives and other obligations set out in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

***Box 2: Proposal objectives***

- *Improve clarity about what foods are captured for pre-market approval*

  Clear definitions for GM food will provide greater regulatory certainty which benefits all parties.

- *Better accommodate new and emerging genetic technologies*

  To avoid further periods of uncertainty as new technologies continue to emerge, the Code needs to be forward looking and agile while also remaining focussed on managing legitimate food-related risks.

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

  Regulation that is science-based and in proportion to the risk posed benefits all parties by protecting public health and safety while also facilitating innovation.

## 1.5 Procedure for assessment

The proposal is being assessed under the Major Procedure as set out in the FSANZ Act. The Major Procedure includes the release of two call for submission (CFS) documents.

The first CFS seeks comment from interested parties on FSANZ's assessment and preliminary conclusion about whether or not to prepare a variation to the Code, and if so FSANZ's preferred regulatory model.

The second CFS will set out FSANZ's proposed regulatory approach, including the draft variation to the Code. FSANZ's proposed approach will consider all submissions received in response to the first CFS.

## 1.6 Scope of the proposal

### 1.6.1 In scope

The scope of the proposal includes 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, including to Standard 1.5.2 – Food produced using gene technology and Schedule 26 – Food produced using gene technology, that may be necessary to give effect to any revised definitions or to clarify other Code provisions that interact with revised definitions.

### 1.6.2 Out of scope

In undertaking this work, FSANZ has not considered the overall policy or regulatory approach to GM food. GM food will continue to require pre-market safety assessment and approval under revised definitions. A broader policy discussion would be required before changes to the overall approach to GM food could be considered.

Approved GM food is subject to the mandatory requirement under the Code to label with the words 'genetically modified'. This labelling requirement is based on the presence of novel DNA/novel protein and/or altered characteristics. FSANZ has not changed the GM labelling approach under this proposal.

# 2. Background

## 2.1 Standard 1.5.2 and Schedule 26

Standard 1.5.2[4] has a long history dating back to 1993 and the subsequent preparation of Proposal P97 – Foods derived from gene technology. At the time, there were no specific food laws, including food standards, in either Australia or New Zealand, that prohibited the sale of GM food. The standard, when it was finally adopted in 1998, prohibited GM food unless expressly permitted under the Code[5].

To be sold, a GM food must be:

- permitted as a GM food and listed in Schedule 26[6];
- permitted as a processing aid and listed in Schedule 18; or
- permitted as a food additive and listed in Schedule 15.

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

[4] Originally gazetted in the Code as Standard A18

[5] Under paragraphs 1.1.1—10(5)(c) and (6)(g) of the Code, a food for sale must not consist of, or have as an ingredient or a component, a GM food, unless expressly permitted by the Code. Standard 1.5.2 sets out the relevant conditions for when a GM food is permitted for sale.

[6] Schedule 26 also provides definitions for 'conventional breeding', 'line' and 'transformation event'.

includes a pre-market safety assessment. The foods are assessed according to procedures in the FSANZ Application Handbook. These procedures are consistent with internationally agreed guidelines and principles[7] developed by the Codex Alimentarius Commission[8] for conducting such assessments.

Approved GM foods are subject to mandatory labelling under section 1.5.2—4 of Standard 1.5.2. The approach in these provisions reflects the policy position originally taken by Ministers over 20 years ago, which was re-affirmed by the Legislative and Governance Forum on Food Regulation in its response to the *Labelling Logic: Review of Food Labelling Law and Policy (2011)*[9]. The purpose of these provisions is to provide labelling information to assist consumers to make informed choices about the food they buy. Labelling is not required for safety reasons because only those GM foods assessed as safe are approved for sale. The approach to GM labelling is product-based. That is, labelling is based on the presence of novel DNA or novel protein in the final food, or an altered characteristic in the food. A number of exemptions to labelling may apply (e.g. the exemption for highly refined foods or ingredients). Further information about GM food labelling is available from the FSANZ website[10].

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 a GM food. Such food may still however require pre-market assessment and approval under other Code provisions (e.g. for novel foods). It is the legal responsibility of those who trade in food to ensure it is both safe and suitable and complies with relevant provisions in the Code.

## 2.2 Current definitions

'Food produced using gene technology' and 'gene technology' are defined[11] 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*** means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

These definitions were drafted with the intent of capturing the types of GM foods that existed at the time the standard was developed, and excluding foods developed using existing long-standing genetic modification methods, such as cross-breeding and selection, classical mutagenesis methods, and various cell and tissue culture techniques (see also Supporting Document 1). Such methods are collectively referred to as conventional breeding.

Under the definition, gene technology is limited to the use of recombinant DNA techniques, which is not itself defined in the Code. Recombinant DNA techniques are *in vitro* laboratory techniques used to join pieces of DNA together from two or more sources. This recombinant DNA is often referred to as 'foreign DNA', to indicate it has been sourced from a different species, however 'recombinant DNA' and 'foreign DNA' are not necessarily the same because recombinant DNA can be formed using DNA from the same species. The 'recombinant' or 'foreign' DNA is then inserted into the genome of a plant, animal or microorganism to make a GM organism. The insertion of foreign DNA into an organism is often referred to as transgenesis.

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

[8] The Commission is the international food standards setting body established by the United Nation's Food and Agriculture Organization and the World Health Organization

[9] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/review-food-labelling

[10] https://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx

[11] Under subsection 1.1.2—2 of the Code

All GM food currently listed in Schedule 26 of the Code has been derived from organisms modified in this way. The vast majority of these foods are from GM plants, with a small number of foods or food ingredients derived from GM microorganisms.

The Code (Schedule 26) also includes a definition for 'conventional breeding' which is defined in the following way:

> ***conventional breeding*** means all methods used to produce plants, excluding techniques that use gene technology.

Any food not explicitly captured as a GM food may therefore be considered a conventional food. In this way, the Code establishes a clear separation between GM food and conventional food. This distinction was made because the gene technology process generally results in outcomes that could not be achieved through conventional methods (e.g. the transfer of a bacterial gene to a plant) and was perceived at the time to pose a greater risk compared to conventional breeding.

The main concerns were the potential transfer of harmful characteristics between foods (e.g. allergens) and the possibility of unintended consequences arising from the random insertion of recombinant DNA into an organism's genome. It was therefore considered appropriate to single out GM food for additional regulatory oversight in the form of pre-market assessment and approval. Since the adoption of the standard, FSANZ has assessed and approved more than 80 separate GM foods. This approach is not applied to conventional food, which is considered to have a history of safe use (see Section 3 below and Supporting Document 1).

## 2.3 Previous FSANZ consideration

FSANZ's consideration of NBTs dates back to 2011, when these newer techniques first started to come to the attention of regulatory agencies around the world. FSANZ received a number of enquiries about whether certain NBTs came within the scope of the current definitions. These early enquiries triggered further consideration by FSANZ, resulting initially in two technical workshops, and then more recently a specific review.

### 2.3.1 FSANZ technical workshops on new plant breeding techniques

FSANZ held two technical workshops on new plant breeding techniques to further investigate NBTs; one in 2012 and a second in 2013. The purpose of these workshops was to enhance FSANZ's understanding of the various techniques and to discuss scientific and technical issues related to derived food products, including how such products might compare to GM foods. Reports from both workshops are available from the FSANZ website[12].

In both 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.

### 2.3.2 Review of food derived using new breeding techniques

The NBT review[13], which commenced in June 2017, considered how the Code should apply to NBT foods. The two key questions examined as part of the review were:

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

- are the definitions for ‘food produced using gene technology’ and ‘gene technology’ fit for purpose given the emergence of NBTs?
- is pre-market safety assessment of NBT foods justified based on risk?

The review was conducted over 2.5 years and included one round of public consultation. A preliminary report summarising the consultation outcomes was published in August 2018[14], with the final report, including FSANZ’s recommendations, published in December 2019.

The main finding of the review was that the current definitions in the Code are no longer fit for purpose. That is, they lack clarity, are outdated and do not reflect the diversity of techniques now in use.

The review considered whether other options were available, other than amending the Code, that could address the problem. Some of these options included the development of guidance, or alternatively a code of practice, to clarify the interpretation of the current definitions in the Code. The review found it was unlikely such approaches would be effective at addressing the problem because they would not provide legal certainty. The other disadvantage identified with such approaches is that they would only apply to the current definitions, which the review concluded are no longer fit for purpose (see Section 4.2). It was therefore recommended FSANZ prepare a proposal to amend the definitions in the Code.

There were two additional findings:

- there may be a case, based on risk, for some NBT foods to be excluded from the requirement for pre-market safety assessment; and
- divergent views exist among submitters about the acceptability and risk of NBT foods and how best to regulate them.

To address these findings, it was recommended that, as part of the proposal, FSANZ give consideration to process and non-process-based definitions and the need to ensure that NBT foods are regulated in a manner commensurate with the risk they pose. The final report for the NBT review noted that more scientific assessment would be required by FSANZ before any conclusions could be made about the exclusion of certain NBT foods from pre-market assessment.

The third and final recommendation was that in undertaking the proposal, FSANZ ensure there is open communication and active engagement with all interested parties and that FSANZ also explore ways to raise awareness about GM and NBT foods. This final recommendation is being addressed through various activities tied to the proposal (see Section 5.1).

# 3. Assessment

## 3.1 Background and assessment approach

Currently, each GM food is subject to pre-market safety assessment and approval by FSANZ before it may be sold. In considering revisions to the definitions for ‘food produced using gene technology’ and ‘gene technology’, the key question for FSANZ is whether this approach should be extended to NBT food, noting the third objective for this proposal which is to regulate NBT foods in a manner commensurate with the risks they pose.

In other words, is there a risk justification for subjecting all NBT food to pre-market safety

[14] https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Preliminary%20report.pdf

assessment under revised definitions?

Typically, pre-market safety assessment is reserved for those foods and substances which, on evidence-based consideration, require an additional layer of public health and safety protection over and above what is provided through the general provisions of food law and the Code.

In the case of GM food, the regulatory approach was adopted relatively early in technology development when few examples of commercialised products existed[15] and there was limited regulatory experience in their assessment or empirical evidence of either safety or harm. A number of submitters to the previous NBT review have argued this approach should be adopted for NBT food, particularly given NBTs are also at a relatively early stage of their development[16]. The primary food safety concerns raised by these submitters were the potential risks from unintended changes, with many questioning how public health and safety can be protected in the absence of a pre-market safety assessment.

While it is true that NBTs are at a relatively early stage of their development, there have been considerable advances since Standard 1.5.2 was adopted and our knowledge of genomes and biological processes has increased significantly. FSANZ has also gained extensive experience in GM food safety assessment and, with it, a greater understanding of the nature of potential food risks posed by genetic modification.

In the previous NBT review, FSANZ made a preliminary analysis of whether pre-market approval of all NBT food is justified based on risk. In considering this question, it was noted that NBTs may be used to produce a variety of different outcomes in food and that in some cases the outcomes may be similar if not identical to outcomes achieved using conventional breeding methods. FSANZ concluded there may be a case for excluding some NBT foods from pre-market safety assessment if they are equivalent in characteristics to conventional food. The rationale is that if a NBT food has equivalent product characteristics to conventional food, it must also be equivalent in risk. At the same time, FSANZ acknowledged views were divided on whether certain NBT foods should be allowed into the food supply without first being subject to oversight in the form of a pre-market assessment by FSANZ.

For the purposes of this proposal, and in accordance with section 59 of the FSANZ Act, FSANZ undertook a separate and new safety assessment having regard to all available evidence to date, including new evidence since 2019 when the final report for the NBT review was published. The safety assessment was also informed by advice from FSANZ's Expert Advisory Group on New Breeding Techniques (EAG NBT)[17].

For the assessment under this proposal, FSANZ applied the same comparative assessment approach that is used to assess the safety of GM food. This approach relies on comparisons to conventional food with a history of safe use. In this comparison, conventional food serves as the benchmark for safety. Such a comparison is valid because GM foods are developed through the genetic modification of conventionally bred organisms. If the comparison identifies any differences, these are further assessed to determine if they raise any food safety concerns. If no differences are identified, or the identified differences are assessed as safe, it can be concluded the GM food is as safe as conventional food.

FSANZ applied the same type of approach to determine how NBT food, as a broad class of products, compares to conventional food. The safety assessment examined the genome changes introduced using different types of NBTs, and compared these to the genome

[15] FLAVR SAVR (slow ripening) tomato, and chymosin from a GM microorganism.
[16] Preliminary report: Review of food derived using new breeding techniques – consultation outcomes. https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Preliminary%20report.pdf
[17] A list of EAG NBT members is available from https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx

changes introduced using conventional breeding, as well as those that occur naturally. FSANZ also explicitly considered unintended changes that may arise through the use of NBTs, and compared these to unintended changes from conventional breeding and GM techniques.

In applying this comparative approach to NBT food, FSANZ considered whether:

- conventional food is a suitable benchmark against which to compare NBT food, and
- similarity in product characteristics between an NBT food and a conventional food indicate they are also equivalent in terms of risk.

The outcome of the safety assessment is summarised in Section 3.2 below with further discussion about the implications of the safety assessment outcomes in Section 3.3. The full safety assessment is in Supporting Document 1 and a plain English summary of the assessment in Supporting Document 2.

## 3.2 Safety assessment outcomes and conclusions

The safety assessment outcomes are as follows:

- Significant genetic changes to food have occurred as a result of conventional breeding or from natural processes. This has resulted in wide genetic variation, which has served as a basis for food improvement throughout human history.
- Despite significant genetic changes to food organisms, conventional food has a long history of safe use.
- No evidence for novel or unique types of genetic changes from NBTs, either intended or unintended, have been found. The genetic changes introduced using NBTs are consistent with those from conventional breeding, older GM techniques 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. The method used to induce a genetic change; the size of the genetic change; or whether the change was intended or unintended, is irrelevant to food safety.
- 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.
- Similarly, some refined ingredients derived from GM food, where novel DNA and novel protein from the foreign DNA insertion have been removed through refining or purification, may also have the same or identical product characteristics as equivalent ingredients from conventional sources.

**Conclusion**

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. This is also true for refined ingredients from GM food that are identical to an equivalent ingredient from a conventional source.

## 3.3 Implications for risk management

The safety assessment findings above directly relate to risk management considerations around excluding certain products from a pre-market GM food safety assessment under revised definitions.

For determining risk, the assessment shows the focus should be on the food itself and its characteristics, not the types of genetic change occurring in a food organism or whether the changes were intended or unintended. This means a decision about risk equivalence of NBT food with conventional food can be made based on product characteristics alone, without the need to conduct a pre-market GM food safety assessment.

To further address this point, FSANZ has concluded that clear and objective criteria should be established on which to base equivalence. It is important these criteria are sufficiently certain and precise and not based on subjective or discretionary assessments. This will enable a developer to assess with certainty whether their product requires an application to FSANZ for pre-market assessment and approval as a GM food.

# 4. Risk management

## 4.1 Issues

Under the current approach, GM food is prohibited from sale unless expressly permitted in the Code[18]. The definitions for 'food produced using gene technology' and 'gene technology' are central to this approach as they determine what food is subject to the prohibition, and therefore require pre-market assessment and approval. By revising the definitions, FSANZ is seeking to clarify what foods, including NBT foods, are subject to the prohibition.

In considering options for revising the definitions (Section 4.2 below), FSANZ had regard to the following issues.

### 4.1.1 Technology development

When Standard 1.5.2 was adopted in 1998, a single technique (transgenesis) was being used to produce GM food. The gene technology definition was based on the transgenesis technique.

Since that time there has been a steady emergence of new techniques, now referred to as NBTs (see Box 1). Together, these techniques represent an expanded toolkit for genetic modification, which also includes conventional breeding methods. Genome editing is the dominant NBT at present and is itself continually being improved. In the future we can expect further improvements to existing NBTs as well the development of entirely new techniques.

Existing techniques can be used to introduce a variety of changes to the genomes of food-producing organisms as well as food. In some cases, a single technique (e.g. genome editing) can be used to introduce different types of changes (e.g. single nucleotide changes, whole gene deletions, or foreign DNA insertion). In other cases, different techniques can be used to produce the same change (e.g. a single nucleotide change using either genome editing or conventional mutagenesis). Instead of the simple dichotomy that previously existed between conventional breeding and GM techniques there is now a continuum of various overlapping tools for genetic modification. In the future, new techniques may expand the range of genetic modification beyond what is currently possible, and with it potentially

[18] Under paragraph 1.1.1—10(5)(c) of the Code, a food produced using gene technology is prohibited from being a food for sale or an ingredient of a food for sale unless expressly permitted by the Code.

generate new risks.

In revising definitions, it is important there is the capability to capture NBT food that may pose a greater risk compared to conventional food so that a pre-market safety assessment can be done.

***Key points*: Technology development**

- Technology developments are inevitable. It is impossible to predict with certainty how the technology may develop in the future, or the types of food products that may be produced. Some future products may pose new food risks.
- Revised definitions should provide the capability to capture those foods for which a pre-market safety assessment is justified, including potential future products.

### 4.1.2 Excluding foods from pre-market assessment and approval

The current definitions for 'food produced using gene technology' and 'gene technology' do not specifically exclude any food products. It is well understood however that conventional food is not captured by these definitions because conventional breeding does not use the gene technology process. Conventional food is not subject to pre-market safety assessment and approval because it has a long history of safe use (Supporting Document 1). Under food law, conventional food is still required to be safe and suitable and to comply with existing food standards relating to content and labelling.

The safety assessment has concluded that some NBT food, as well as certain refined ingredients derived from GM food, will be equivalent to conventional food in terms of risk. FSANZ examined this finding further as it relates to specific food categories, and also considered some of the practical issues associated with implementation and enforcement.

**Applying the safety assessment conclusions**

- *GM food* – the safety assessment did not explicitly consider GM food and its similarity or otherwise to conventional food as the general regulatory approach to GM food is not being reviewed as part of this proposal. GM food was however included in the analysis as a point of comparison for NBT food. Through this analysis it was noted that some refined ingredients, which do not contain novel DNA or novel protein arising from the foreign DNA insertion, will be indistinguishable in their characteristics from conventional food. The safety assessment supports the exclusion of certain refined ingredients from a revised definition. Refined ingredients are further discussed below.
- *Food from null segregant organisms* – null segregants are progeny that have not inherited a specific genetic modification introduced to an initial or parent organism using gene technology. They arise through the natural process of chromosome segregation that occurs during sexual reproduction. The safety assessment found that because null segregants have not inherited the genetic modification introduced using gene technology, they are the same as conventionally bred organisms. The safety assessment supports the exclusion of food from null segregants from a revised definition.
- *NBT food* - the safety assessment found that whether an NBT food is equivalent to a conventional food will depend on the type of genetic change introduced and its impact on the food. Some NBT food will therefore have the same characteristics as conventional food, while other NBT food may have new or altered characteristics compared to conventional food. The safety assessment supports excluding NBT food from a revised definition if it has the same product characteristics as conventional food. The safety assessment does not support excluding NBT food on the basis of the

specific technique used. This is because a single technique may be used to produce a variety of different genome changes, which may or may not change food characteristics in comparison to conventional food.

- *Refined ingredients* – the safety assessment noted that certain ingredients from GM food may also have equivalent characteristics to conventional food, but only when the food is refined or purified in such a way that novel DNA or novel protein resulting from the foreign DNA insertion is removed. The safety assessment supports excluding certain refined ingredients from a revised definition. In this context, 'refined ingredients' refers to two different categories of product:
    - processed food ingredients such as sugar, starches, protein concentrates, amino acids, gelatine products, fats, oils; and
    - substances added to food for a specific purpose, including food additives (e.g. steviol glycosides), processing aids (e.g. enzymes), and nutritive substances (e.g. vitamins, oligosaccharides). Substances added to food are often produced by microbial fermentation, and can be sourced from a GM microorganism.

The outcome of the above analysis is summarised in Table 1 below.

**Table 1:** Possible exclusions according to safety assessment conclusions

| **Food category** | **Captured for pre-market assessment & approval (Application to FSANZ required)** |
|---|---|
| Food produced using gene technology where foreign DNA inserted (GM food) | Yes apart from certain refined ingredients (see below) |
| Food from null segregants | No |
| NBT food that has the same characteristics as conventional food | No |
| NBT food that has new or altered characteristics compared to conventional food | Yes |
| Refined ingredients where no novel DNA and novel protein is present in the food for sale | No |
| Refined ingredients where novel DNA and novel protein is present in the food for sale | Yes |
| Conventional food | No |

**Implementation and enforcement**

A number of practical issues relating to implementation and enforcement must also be taken into account when considering whether to exclude certain foods from revised definitions. Fundamental to this, and consistent with the proposal objectives (see Box 2 in Section 1.4), is the need for a clear definition that is not open to multiple interpretations.

A clear unambiguous definition is important because it reduces uncertainty for product developers about whether pre-market approval is required and therefore assists them to comply with food regulations. A clear definition also facilitates effective and consistent implementation, interpretation and enforcement of food regulations by the jurisdictions. In particular, 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 has been a subject of ongoing discussion and research. Most of the focus has centred around food derived using genome editing because the types of changes introduced can be indistinguishable from those introduced using conventional mutagenesis methods, or that occur spontaneously in nature (Supporting Document 1).

In applying specific exclusions, a key consideration is the ability to distinguish between captured and excluded NBT foods and refined ingredients. In adopting such an approach, exclusions need to be based on unambiguous criteria that enable excluded products to be clearly and unequivocally distinguished from captured products.

While the safety assessment supports the exclusion of certain NBT foods and refined ingredients derived from GM foods on the basis of their risk equivalence to conventional foods, 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 and approval, this would raise significant enforcement challenges for jurisdictions because of the difficulty distinguishing NBT food from conventional food.

These enforcement challenges, particularly in relation to genome editing, were highlighted recently in a working document published by the European Commission (EC)[19]. The EC reported that while detection methodology exists to reliably detect small edits to a genome, that methodology cannot determine how the edit was introduced, i.e. whether it was from genome editing, conventional mutagenesis or natural mutation. Traceability systems[20] were also investigated as an alternative to analytical methods but these are considered too challenging, onerous and costly to implement effectively, particularly in relation to complex matrices such as processed food products, many of which may be imported. It was also noted that to be effectively implemented, a traceability system needs to include analytical capabilities, which in this case are inadequate.

***Key points*: Excluding foods from pre-market assessment and approval**

- The scientific assessment supports the exclusion of certain NBT products and refined ingredients from a revised definition based on their risk equivalence to conventional food.
- Concerns exist about NBT food entering the food supply without first being assessed for safety by FSANZ. However, capturing all NBT foods would be challenging to enforce because of the inability to tell some NBT foods and refined ingredients apart from conventional food.
- Exclusions should be based on clear unambiguous criteria to reduce uncertainty and facilitate effective implementation and enforcement.

### 4.1.3 Process versus product-based definitions

In revising the current definitions for ‘food produced using gene technology’ and ‘gene technology’, FSANZ has considered what type of definitional trigger will be most effective for meeting the proposal objectives.

The current definitions are process-based. That is, food is captured for pre-market assessment and approval if the process of gene technology has been used in its development. In contrast, product-based definitions are focussed on the outcome of a

[19] https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en This work was initiated following a court ruling that genome edited organisms are GMOs under EU legislation.

[20] For example, document traceability, digital tools (e.g. blockchain), NBT-free certificates, segregated supply chains.

process, meaning either the genome change that has been introduced, or any resulting change to derived food. At the present time, process-based definitions for GM food are the norm around the world (see Supporting Document 3).

The use of process and product-based definitions was also considered as part of the NBT review. Each were found to have both advantages and disadvantages, which are summarised in Table 2 below.

**Table 2:** Process versus product-based definitions

| Type of definition | Advantages | Disadvantages |
|---|---|---|
| Process-based | Clear way to indicate the regulatory status of food products | May not be fully risk-based or proportionate if foods are only captured according to process |
| | May be effective at reducing gaps in regulatory coverage because all foods from a specific technology will be captured | May result in identical products being regulated differently where one process is captured but not another |
| | | May quickly become outdated, and require regular review and updating |
| Product-based | May provide greater flexibility for addressing technology developments because they are independent of specific technology used | May be more open to interpretation than process-based criteria |
| | Less likely to become outdated because not based on specific technologies or techniques | May be more onerous to implement if additional supporting measures such as interpretive guidance and/or pre-market advice are required. |
| | More risk-based because the focus can be on characteristics more directly related to risk | |

A decision about the types of definitional triggers to use is complicated by the need to continue to exclude conventional food, while at the same time providing the capability to capture current and future food products that may have increased risk compared to existing conventional food. In addition, the assessment supports the exclusion of certain NBT foods and refined ingredients that are no different in terms of risk and also indistinguishable from conventional food.

To achieve these outcomes, and in particular to make clear distinctions between products for regulatory purposes, FSANZ has concluded it will be necessary to rely on a combination of both process and product-based definitional criteria.

***Key points: Process versus product-based definitions***

- Process and product-based definitions each have advantages and disadvantages.
- A hybrid approach, using both process and product-based definitional criteria, is necessary to achieve appropriate regulatory outcomes that can be justified in terms of risk, as well as effectively enforced.

### 4.1.4 Alignment between food and gene technology regulations

An issue that is often raised in relation to FSANZ's work on NBTs is the need to avoid inconsistencies between what is regulated as a 'genetically modified organism'[21] (GMO) and what is regulated as a GM food. A number of submitters to the previous NBT review supported greater alignment between relevant definitions in the Code and the *Gene Technology Act 2000* (GT Act) and its regulations. The same was not suggested for the *Hazardous Substances and New Organisms Act 1996* (HSNO Act) and its regulations.

In response to these submissions, FSANZ noted the objectives of the GT Act and the risks to be managed are significantly broader than those under Standard 1.5.2, which was put in place to manage the risks associated with the consumption of GM food. Also, given Standard 1.5.2 is a joint Australia New Zealand standard, FSANZ noted it would be difficult to align with definitions in both the GT Act and the HSNO Act and their respective regulations. This is particularly the case since the GT Regulations were amended to exclude organisms modified using a specific form of genome editing (SDN-1)[22].

FSANZ has given further consideration to this issue under this proposal, particularly in the context of the recent exclusion under the GT Regulations for organisms modified using SDN-1 editing, and has concluded that in revising definitions the focus should be on managing food-related risks. The safety assessment undertaken for this proposal makes it clear that any potential risks to the consumer will be determined by what change (if any) is made to the food, not the specific NBT process used to make that change. FSANZ also notes that two different forms of genome editing[23] could be used to make the same change to a genome, resulting in two food products that are identical in both their characteristics and risk to the consumer. It would be difficult to justify capturing one of those products for pre-market assessment and approval, but not the other.

In terms of more practical considerations, FSANZ also notes the potential enforcement challenges in trying to distinguish between identical foods on the basis of a specific genome editing process used. This is particularly the case when dealing with finished and sometimes highly processed products in the food supply, many of which will be imported.

***Key points: Alignment between food and gene technology regulations***

(i) Standard 1.5.2 applies to food sold in Australia and New Zealand.

(ii) The definitions for a GMO in Australia and New Zealand are not aligned. It would not be possible for FSANZ to align the Code definitions to both sets of GMO definitions.

(iii) FSANZ will revise the Code definitions according to what is most appropriate for managing potential risks arising from the food.

(iv) The safety assessment indicates it is not justified from a risk perspective to subject all food from organisms regulated as GMOs to pre-market assessment and approval as GM food.

### 4.1.5 Regulatory approaches to NBTs in other countries

The current situation internationally is highly dynamic with a number of countries either adopting new or revised regulatory approaches (e.g. Argentina, Brazil, Japan), or in various stages of reviewing their regulatory approach (e.g. Canada, European Union, United

[21] Genetically modified organism or GMO has a specific legal meaning under the *Gene Technology Act 2000* in Australia and the *Hazardous Substances and New Organisms Act 1996* in New Zealand.

[22] Sited-directed nuclease type 1. Defined in the GT Regulations as an organism modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was not added to guide homology-directed repair.

[23] SDN-1 and SDN-2 genome editing. Unlike SDN-1, SDN-2 relies on a nucleic acid template to guide homology directed repair.

Kingdom, United States). Some countries have developed or proposed approaches that apply to NBTs generally (e.g. Argentina), while others are specific to genome editing (e.g. United Kingdom). See Supporting Document 3 for more detailed information for specific countries.

These recent developments indicate an emerging trend towards regulatory approaches that are more flexible in terms of how they are applied, and also that can accommodate a variety of different technologies as well as derived food products. Most of these new or proposed approaches include provision for certain products to be excluded from pre-market regulatory requirements. While differences exist between countries in how this is done, a common feature is reliance on either similarity to the outcomes of conventional breeding, or the absence of foreign or recombinant DNA, as a basis for justifying exclusions. Such exclusions would be considered product-based.

For example, in Argentina the approach is based on whether the use of an NBT results in a "novel combination of genetic material" in the final organism[24]. If a novel combination results, the organism is considered to be a GMO. If not, the organism is considered to be a new conventional variety.

In a slightly different approach, Japan excludes NBT food if it is derived from organisms with genome modifications that are equivalent to those occurring naturally or through conventional breeding, with the resulting food products being indistinguishable from conventional food. More recently, Health Canada proposed exclusions based on the characteristics of the food product, particularly those characteristics that, if changed beyond the documented range for conventional food, would make the food novel under their novel food regulations.

To implement these approaches, a number of countries have established case-by-case pre-market or early consultation/determination processes, as well as developed guidance material for product developers to enable them to self-determine if their product is subject to the regulations.

***Key points: Regulatory approaches to NBTs in other countries***

1. A number of countries have adopted new or revised regulatory approaches to NBTs and their products, or are in various stages of reviewing their regulatory approach.
2. While international harmonisation is far from being realised, a trend is emerging for the adoption of approaches that exclude certain NBT products from pre-market regulatory requirements.
3. Most of the adopted or proposed approaches to exclusions are based on either the absence of foreign/recombinant DNA in the organism or the similarity of products to those from conventional breeding methods, or a combination of both.

[24] Based on the definitions for *Living Modified Organism* in the Cartagena Protocol – '*any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology*'.

## 4.2 Options

To decide the most effective risk management approach to address the problem, FSANZ must consider various options. FSANZ undertook a preliminary analysis of various options as part of the NBT review. These options are further assessed below.

### 4.2.1 Possible regulatory and non-regulatory options

**Option 1 – *Status quo***

The *status quo* must be considered by FSANZ in any proposal to change the Code. 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 approval on the basis of the use of gene technology, as currently defined.

Based on our assessment to date, this is not a viable option. The current ambiguous and outdated definitions would remain, further exacerbating the current regulatory uncertainty. There is also the possibility that some foods will fall outside the scope of current definitions, even though a pre-market safety assessment may be warranted.

**Option 2 – *Status quo* combined with non-regulatory approaches**

Under this option, FSANZ could develop guidance, or alternatively a statutory code of practice, to clarify the interpretation of the current definitions in the Code. This approach would not involve amending the Code.

Based on our assessment to date, this is not a viable option. These types of non-regulatory approaches would rely on interpretation of the current definitions and may not necessarily provide greater certainty nor would they address the fundamental problem of outdated definitions.

**Option 3 – Amend the definitions in the Code**

This option would involve amending the definitions in the Code for 'food produced using gene technology' and 'gene technology' to make them clearer and better able to accommodate both existing and emerging genetic technologies. This is FSANZ's preferred option because it is the only available option that directly addresses the problem.

The amended definitions may be supported by non-regulatory measures such as industry guidance, consumer education and the establishment of an advisory committee to oversee implementation of the revised definitions.

Information received in submissions and further assessment will inform our decision about whether to proceed with amending the definitions and, if so, the form those amendments will take.

### 4.2.2 Preferred approach under Option 3

FSANZ's assessment is that the current definitions should be amended as follows:

- revise and expand the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding; and
- revise the definition for 'food produced using gene technology' to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM food. Foods not meeting all relevant exclusion criteria would require an application to FSANZ.

This approach is preferred for the following reasons:

- it continues to protect public health and safety by taking into account the potential unknowns in relation to future technology development and future products;
- by capturing all food that does not meet specific exclusion criteria it will limit the potential for gaps in regulatory coverage as technology develops;
- it is more proportionate and risk-based because it excludes foods that pose no greater risk than conventional food. There will also be capacity to add or remove exclusion criteria in the future through a Code amendment should that be appropriate;
- because the foods to be excluded are ones that would be difficult to tell apart from conventional food, it avoids some of the enforcement challenges that would occur if such products were captured by revised definitions;
- because exclusion of certain foods is based on food product characteristics, it is compatible with the current product-based GM labelling requirements.

The rationale for the preferred approach is discussed below.

**A revised and expanded process-based definition for 'gene technology'**

FSANZ's assessment is that the process-based definition for 'gene technology' should be expanded for the following reasons:

- it will provide FSANZ with the capability to capture future products for pre-market safety assessment as GM foods, should that be warranted. Technologies and methods that fall outside the scope of a revised definition for gene technology will continue to be considered conventional, and therefore not subject to the GM food prohibition in the Code;
- continuing to rely on a process-based definition as the primary basis for capturing products for pre-market assessment and approval is the most effective way to maintain the exclusion for conventional food. While product-based definitions offer certain advantages (Table 2), it may be more difficult to clearly exclude conventional food using product-based criteria, while at the same time providing the capability to capture future products.

**Product-based pre-market safety assessment exclusions for certain foods**

FSANZ's assessment is that product-based exclusions for certain foods (as set out in Table 1 in section 4.1.2) should be applied for the following reasons:

- it will enable criteria to be consistently applied across a range of products, irrespective of the specific technology used to develop that product. This will also reduce the potential for revised definitions to become outdated as technology continues to develop;
- exclusion criteria will be focussed on food characteristics, resulting in more risk-based regulatory outcomes (in terms of what foods are captured versus excluded from pre-market assessment) than an approach based entirely on process.

FSANZ's assessment is that exclusions should apply to NBT foods that have the same product characteristics as conventional food with a history of safe use. The reasons for this are:

- the safety assessment indicates there is no risk justification for subjecting such foods to pre-market assessment as GM as the foods will be equivalent in risk to conventional

food;

- capturing NBT food for pre-market safety assessment that has the same product characteristics as conventional food would pose significant enforcement challenges because of the difficulty telling such foods apart.

It is also FSANZ's assessment that exclusions should be applied to processed food ingredients from GM food and GM-derived food additives, processing aids and nutritive substances, where no novel DNA and novel protein is present in the food for sale. The reasons for this are:

- it ensures consistency with the exclusions proposed to apply to NBT foods. Many processed food ingredients and substances from GM sources that are added to or used in food will be chemically identical to the same ingredient or substance derived from a non-GM source. Novel DNA and novel protein resulting from the foreign DNA insertion is also unlikely to be present.
- there are no safety concerns with excluding processed food ingredients from pre-market assessment as a GM food as they will be no different in risk to equivalent processed ingredients from non-GM sources.
- there are no safety concerns with excluding GM-derived food additives, processing aids and nutritive substances from pre-market assessment as a GM food. Such substances will be chemically identical to equivalent non-GM derived substances already assessed and permitted in the Code, or if not, will require pre-market assessment and approval as a new food additive, processing aid or nutritive substance.
- their exclusion will simplify compliance and enforcement as it will be difficult to tell many GM-derived ingredients and substances apart from equivalent non-GM derived ingredients and substances.

Specific product-based criteria for excluding certain NBT foods and GM derived refined ingredients and substances are further discussed under Section 4.3 Definitional criteria.

**Non-regulatory measures**

It is FSANZ's assessment that an advisory committee should be established to facilitate implementation of revised definitions by jurisdictions, as well as assist product developers to interpret and comply with the new provisions. The committee would be modelled on the Advisory Committee for Novel Foods[25]. The purpose of such a committee would be to serve as a point of enquiry in situations where a developer remains uncertain about whether an application to FSANZ may be required. Consultation with the advisory committee would be voluntary.

It is also FSANZ's assessment that guidance material, especially in relation to excluded products, should be developed to provide further assistance to product developers. This material would outline the steps a developer should take to determine if their product either does or does not meet specific exclusion criteria, including what evidence should be retained in order to demonstrate compliance.

[25] https://www.foodstandards.gov.au/industry/novel/novelcommittee/pages/default.aspx

## 4.3 Definitional criteria

### 4.3.1 Revised definition for 'gene technology'

The purpose of revising the definition for 'gene technology'[26] is to expand its scope so it captures the range of technologies now in use, as well as potential future products. In revising the definition, it will be important to ensure that conventional breeding methods are not inadvertently captured.

FSANZ has considered current definitions in the GT and HSNO Acts and their regulations, Codex guidelines for foods derived from modern biotechnology[27], the EU GMO Directive[28], as well as recently developed or revised definitions in other countries that may be applicable (e.g. United States) (Table 2, Supporting Document 3). A common strategy is to define methods of genetic modification (or gene technology or modern biotechnology) as well as methods that are not considered genetic modification or that give rise to a GMO. FSANZ notes many of these approaches result in definitions that are technically complex and contain multiple interacting elements.

FSANZ's preference would be to keep the definition for 'gene technology' as simple and clear as possible to avoid potential confusion about what products are captured for pre-market assessment and approval. In revising the gene technology definition, the main focus is on expanding it beyond the use of recombinant DNA techniques to ensure appropriate regulatory coverage of NBTs as well as potential future technologies, which could involve the development of synthetic organisms and/or novel types of nucleic acid.

FSANZ notes the United States Department of Agriculture recently adopted the following revised definition for 'genetic engineering'[29]:

> "techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome"

This language has appeal because it is simple yet has broad coverage in terms of how genomes may be modified and also recognises it is now possible to create genomes. The ability to create genomes was also highlighted recently in considering possible revisions to the definition for 'gene technology' in the GT Act[30]. FSANZ therefore proposes adapting the language in the United States definition for incorporation into a revised Code definition for 'gene technology'.

If FSANZ decides, after considering submissions, to proceed with such a measure, consideration would have to be given to whether a definition for conventional breeding is required. Currently, the Code defines conventional breeding as any method used to produce plants that does not involve gene technology. In revising the definition for 'gene technology', FSANZ will consider whether to retain this approach.

In relation to other aspects of the current gene technology definition, in particular the reference to altering the 'heritable genetic material of living cells or organisms', FSANZ considers this language would be redundant if the definition is revised to refer to modifying or creating a genome.

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[26] 'gene technology' means recombinant DNA techniques used to alter the heritable genetic material of living cells or organisms.

[27] http://www.fao.org/3/a1554e/a1554e00.pdf; the Codex definition for *modern biotechnology* is the same as that used in the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*

[28] Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms

[29] https://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf

[30] https://consultations.health.gov.au/best-practice-regulation/gene-technology-scheme-cris/supporting_documents/20201214%20GeneTech_CRIS%20Explanatory%20Paper_Approved%20Version.pdf

### 4.3.2 Exclusion criteria for certain foods

It is proposed the definition for 'food produced using gene technology' be revised to incorporate specific exclusions for certain products that FSANZ has determined are equivalent in risk to conventional food and therefore do not require pre-market safety assessment as GM food before being sold. Some products proposed for exclusion from pre-market assessment as a GM food, e.g. certain substances added to food, may still require pre-market assessment and approval under other parts of the Code (e.g. as a food additive).

While FSANZ has concluded that equivalence to conventional food is a legitimate basis for excluding certain foods from pre-market assessment as a GM food, specific criteria will be required so that a developer can determine if their particular product qualifies for exclusion or requires an application to FSANZ as a GM food. As noted above, it is important such criteria provide a clear basis to distinguish between food that is subject to the GM food prohibition in the Code, and food that is not.

Considerations around exclusion criteria for each of the food categories identified in Table 1, Section 4.1.2 are discussed below.

*Food from null segregants*

FSANZ noted in the final report for the NBT review that the definition for 'food produced using gene technology' is ambiguous with respect to null segregants. This is because the current definition refers to food that is "derived or developed from an organism which has been modified by gene technology". This could be interpreted as capturing food from null segregants, even though the final organism used to produce the food has not itself inherited the genetic modification introduced using gene technology.

It is FSANZ's assessment that food from null segregants not be a GM food for Code purposes. The reasons for this assessment are:

- it had not been intended that food from null segregants be captured as GM food;
- it has been longstanding practice by FSANZ to accept null segregants as non-GM comparators for the purpose of GM food safety assessment;
- the safety assessment indicates there is no risk justification for subjecting such foods to pre-market assessment as GM food as the foods will be equivalent in risk to conventional food.

To clarify the intent of the original definition, and remove any doubt, it is proposed to explicitly exclude food from null segregants from the definition of 'food produced using gene technology'.

If FSANZ decides, after considering submissions, to proceed with such a measure, consideration will be given to whether the Code should define 'null segregant' for the purposes of excluding food from null segregants from the definition of GM food. FSANZ notes null segregants are defined under Schedule 1 (Organisms that are not genetically modified organisms), Part 7 of the *Gene Technology Regulations 2001* as "An organism that is descended from a genetically modified organism (the **initial organism**), but which has not inherited any traits that occurred in the initial organism because of gene technology." Similar language could be adopted for a null segregant definition in the Code.

*NBT food that is the same as conventional food*

FSANZ's assessment is that NBT food should not be GM food for Code purposes if the NBT food is equivalent in its characteristics and risk to conventional food. To that end, the Code

should exclude a NBT food from pre-market assessment as a GM food if each of the following criteria[31] are met:

(i) no foreign DNA introduced using gene technology is present in the tissue or cells from which the food is derived; and

(ii) the trait introduced using gene technology does not modify the levels of key nutrients[32], endogenous toxicants[33] or anti-nutrients[34] so they are outside the documented range for an equivalent conventional food; and

(iii) the trait introduced using gene technology does not result in the synthesis of a substance that is not present in existing conventional food; and

(iv) the food does not contain endogenous proteins modified using gene technology that are now significantly similar[35] to known toxins or allergens; and

(v) the endogenous allergen content of the food has not been modified as a result of gene technology.

In relation to the above criteria, the following should be noted:

- food that does not meet one of more of the criteria may still be safe, however, a safety assessment by FSANZ would be required to confirm this.
- the intent of criterion (i) is to ensure that GM food continues to be captured, consistent with current policy. FSANZ notes however this will depend on how this criterion is worded and in particular how 'foreign DNA' is interpreted. Currently, there is no definition for 'foreign DNA' in the Code, but typically it is taken to mean DNA derived from a different species.
- the use of the term 'foreign DNA' as a means to capture GM food will need to be carefully considered, including whether the outcome in terms of what is captured as a GM food is consistent with current policy. All GM foods approved to date and listed in Schedule 26 of the Code are derived from either transgenic or intragenic organisms. If 'foreign DNA' is used, it would ensure that food from transgenic organisms is subject to a safety assessment by FSANZ before it is sold, but it may not capture food from intragenic organisms. If 'recombinant DNA' is used instead of 'foreign DNA' it would result in food from both transgenic and intragenic organisms being captured. FSANZ notes continuing to capture food from transgenic as well as intragenic organisms will also ensure such foods are subject to GM labelling, as is currently the case.
- if either 'foreign DNA' or 'recombinant DNA' is used, food from cisgenic organisms, would not be captured for safety assessment by FSANZ, providing the food also meets all the other exclusion criteria listed. The exclusion of such food is supported by the safety assessment, which found the genetic changes introduced using cisgenesis would be equivalent to those introduced using cross-breeding (see Supporting Document 1).
- because criterion (i) refers to no foreign DNA being present in the tissue or cells from which the food was derived, this would result in food from GM rootstock grafting being excluded from pre-market assessment as GM food, but only if that food was also able to meet exclusion criteria (ii) through (v).

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[31] Exclusion of foods using criteria based on specific food product characteristics is an approach recently proposed by Health Canada (see Table 1, Supporting Document 3).

[32] A key nutrient is a nutrient with an Estimated Average Requirement (EAR) and/or an Upper Level of Intake (UL) as described in the *Nutrient Reference Values for Australia and New Zealand.* Available from https://www.nrv.gov.au/

[33] Toxicologically significant compounds known to be inherently present whose toxic potency and level may be significant to human health.

[34] Compounds that interfere with the absorption of nutrients.

[35] >35% identity over a window of 80 or more amino acids.

- food derived from an organism which does not contain foreign or recombinant DNA as a result of gene technology, would still be captured if it was unable to meet all of the other criteria. For example, if genome editing had been used to alter the endogenous allergen content of a food. While no novel DNA or novel protein would be present in the food for sale (because foreign or recombinant DNA would be absent from the organism from which the food is derived), such food would not meet criterion (v) and therefore would require an application to FSANZ.
- guidance material will be developed to assist product developers to determine if their product meets relevant exclusion criteria. The guidance material would explain each of the criteria, the types of analyses that would need to be done to determine if a food meets each criterion, and provide relevant examples for different types of organisms and food products. Such guidance material would be revised and updated as the technology develops.

*Refined ingredients*

For the purposes of developing exclusion criteria, the refined ingredients category of products has been divided into the following sub-categories: (i) processed food ingredients and nutritive substances; and (ii) food additives and processing aids. This distinction was made to align with labelling considerations around altered characteristics, which only apply to processed food ingredients and nutritive substances.

For processed food ingredients (such as oils or sugars) and nutritive substances, exclusion would need to be based not only on whether novel DNA or novel protein is present in the food for sale, but also whether the ingredient or substance has a new or altered characteristic as a result of gene technology compared to an equivalent ingredient or substance derived from a conventional source[36]. Such products may warrant pre-market safety assessment by FSANZ as GM food.

For the exclusion of certain processed food ingredients to be of any practical consequence, all intended food products from the GM organism would need to meet the exclusion criteria. For example, this might apply in the case of sucrose from GM sugarcane or refined oil and linters from GM cotton. However, if a number of different food products are derived from the GM organism, some of which contain novel DNA or novel protein or a new or altered characteristic, then an application to FSANZ would still be required. This exclusion would therefore only be of use in a limited number of cases.

For nutritive substances, FSANZ is not currently aware of any examples with a new or altered characteristic as a result of gene technology. However, this approach would ensure any nutritive substances developed in the future, which have a new or altered characteristic, would be subject to pre-market assessment as GM food and also be subject to GM labelling.

For the exclusion of GM-derived food additives and processing aids, the only relevant consideration is whether novel DNA or novel protein is absent from the food for sale[37].

The outcome of FSANZ's assessment is that a refined ingredient should not be a GM food for Code purposes if it is:

(i) a processed food ingredient that is identical in composition to an equivalent ingredient derived from a conventional source and where no novel DNA or novel protein is present in the food for sale; or

[36] If a nutritive substance is excluded from pre-market assessment as a GM food, it may still require assessment and approval as a new nutritive substance.

[37] If a food additive or processing aid is excluded from pre-market assessment as a GM food, assessment and approval as a new food additive or processing aid may still be required.

(ii) a substance used as a nutritive substance that is identical in chemical structure to an equivalent substance from a conventional source and where no novel DNA or novel protein is present in the food for sale; or

(iii) a substance used as a food additive or a processing aid where no novel DNA or novel protein is present in the food for sale.

These proposed exclusion criteria for refined ingredients align with current product-based labelling requirements and exemptions (refer to Section 2.1).

# 5. Risk communication

## 5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. All submissions received are considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

Consultation with interested parties will include the statutory consultation processes specified in the FSANZ Act, including a 2nd call for submissions. We will also target consultation to jurisdictions and the research and industry sector to better understand their practices and constraints. These consultations will better inform any measures that may be considered.

The release of this 1st call for submissions will be supported by a media release, updated website information and notification via Food Standards News and social media channels. Fact sheets and short videos on GM food and NBT food have been made available on our website[38] to further the involvement of the general public.

Following the release of the 1st call for submissions, we will also hold webinars to further engage interested parties.

## 5.2 Consumer research

To supplement the information gained through the public consultation process, FSANZ has commissioned two pieces of work on consumer attitudes towards NBTs:

- A literature review on consumers' awareness, knowledge, risk perceptions and behaviours in relation to the use of NBTs, including genome editing, for food production. The review will also incorporate insights from the literatures on consumer attitudes towards genetic modification and on the public understanding of science.
- New research using focus groups to investigate consumer attitudes to NBTs in Australia and New Zealand. This will add to existing publicly available information identified through the literature review. This research will also explore public understanding of communication materials. It will also explore the relationship between regulatory oversight and consumer trust in the food supply.

The outcomes of the literature review and research, and public submissions to the process, will be used to inform our work and to better target communication messages.

[38] https://www.foodstandards.gov.au/consumer/gmfood/Pages/Education-materials-on-GM-foods-and-NBTs.aspx

## 5.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards for GM foods or NBTs. Amending the Code to revise the definitions for '*food produced using gene technology*' and '*gene technology*' may however have a significant effect on international trade because it will change the scope of the regulation for GM food in Australia and New Zealand.

This issue will be fully considered at the next stage of the assessment. If necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Application of Sanitary and Phytosanitary Measures (SPS) Agreements, or both. This will enable other WTO members to comment on any proposed amendments.

# 6. Obligations under the FSANZ Act

The *Food Standards Australia New Zealand Act 1991* (FSANZ Act) contains requirements applying to the development or variation of standards. Under section 18 (Objectives of the Authority) of the FSANZ Act, when developing or reviewing a standard we must meet the objectives outlined below.

## 6.1 FSANZ objectives

### 6.1.1 Subsection 18(1)

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

***a) Protection of public health and safety***

FSANZ has assessed the relevant scientific evidence on the risks to public health and safety arising from NBT foods (see Supporting Document 1) as well as risk management measures currently in place for GM food and their applicability and relevance to NBT food. The assessment indicates that some NBT foods and certain refined ingredients will be equivalent in risk to conventional food and therefore do not require a pre-market safety assessment by FSANZ before they may be sold. The assessment also indicates that some NBT food may have new or altered characteristics compared to conventional food, in which case a pre-market safety assessment by FSANZ would be warranted.

These assessment findings have informed our preferred approach to amending the definitions in the Code for 'food produced using gene technology' and 'gene technology'. The preferred approach protects public health and safety by limiting the potential for regulatory gaps in coverage to occur as technology develops and continuing to capture food for pre-market assessment and approval where that is justified based on risk.

***b) The provision of adequate information relating to food to enable consumers to make informed choices***

The current labelling approach for GM food was put in place to provide labelling information to assist consumers to make informed choices about the food they buy (Section 2.1). FSANZ did not change the current approach to labelling as part of this proposal.

### *c) The prevention of misleading or deceptive conduct*

FSANZ has not identified any relevant issues to date.

### 6.1.2 Subsection 18(2) considerations

FSANZ also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's risk analysis considered the best scientific information currently available. FSANZ had regard to prior assessments undertaken as part of the previous NBT review (see also Section 2.3.2) as well as further assessment undertaken as part of the current proposal (Supporting Document 1). Additional information will be sought from stakeholders through this and a second call for submissions to further inform FSANZ's risk analysis.

FSANZ will build upon these findings to inform decisions regarding appropriate amendments to the definitions for 'food produced using gene technology' and 'gene technology' in the next stage of this work.

- **the promotion of consistency between domestic and international food standards**

There are no relevant international food standards relating to GM food or NBT food.

The assessment considered developments in the regulation of NBT foods in other countries (Section 4.1.5 and Supporting Document 3). FSANZ notes however that considerable variation exists between countries in regulations for NBTs and their products. A number of countries have recently introduced or are proposing to introduce new or revised regulations to take account of NBTs or genome editing, including allowing for certain products to be excluded from pre-market safety assessment.

- **the desirability of an efficient and internationally competitive food industry**

Clarification of the regulatory requirements for NBT food will encourage an efficient and competitive food industry.

FSANZ does not anticipate any significant negative impacts on efficiency and international competition from revising the definitions for 'food produced using gene technology' and 'gene technology'. This issue will be fully considered at the next stage of the assessment and notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreements, as necessary.

- **the promotion of fair trading in food**

FSANZ has not identified any issues to date.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There is no policy guideline for GM food *per se* as the standard pre-dated the development of explicit policy guidelines. The Ministerial Policy Guideline *Labelling of foods produced or processed using new technologies* is relevant to NBTs, however it does not apply in the case of this proposal as FSANZ is not proposing to change the current approach to GM labelling. NBT food that is a 'food produced using gene technology' will be subject to the same

labelling requirements that currently apply to GM food.

## 6.2 Section 59

### *6.2.1 Consideration of costs and benefits*

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs that would arise from a food regulatory measure developed or varied as a result of this proposal (e.g. the options, including the preferred approach discussed above) outweigh the direct and indirect benefits to the community, government or industry that would arise from the development or variation of the food regulatory measure. The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the options. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential costs and benefits of moving away from the status quo to:

- Option 2: Non-regulatory approaches, and
- Option 3: Amend the definitions in the Code.

***Option 2: Non-regulatory approaches***

FSANZ's preliminary assessment found it is unlikely this option would be effective at resolving the problem this Proposal is attempting to address because it would not provide legal certainty. This would potentially result in sub-optimal levels of investment, inefficient enforcement and other costs. The other disadvantage identified with this option is that it would only apply to the current definitions, which the previous NBT review concluded are no longer fit for purpose (see Section 4.2). Therefore, it has been concluded this option will most likely result in higher costs and lower benefits than Option 3.

***Option 3: Amend the definitions in the Code***

Outdated definitions may result in regulatory gaps with products intended to be subject to pre-market safety assessment not being captured. Updated definitions for GM food will ensure public health and safety continues to be protected as new technologies are developed.

Regulatory uncertainty can deter investment in new technologies, potentially delaying or stifling innovation. Having clear and updated definitions for GM food will provide a clear and predictable pathway to market for investors and developers. NBTs are useful tools that may contribute to more sustainable food production, cheaper food and innovative food products which benefits the food and agriculture sectors as well as consumers.

The specific costs and benefits for industry, regulators and consumers are as follows:

*Industry*
Increased legal certainty and clearer administrative pathways will make investment decisions clearer and potentially encourage investment in innovation. Increased innovation has the potential to result in increased profits, exports and competiveness.

*Regulators*
Updated definitions will provide legal certainty for regulators to more efficiently and effectively manage risk across a broader range of technologies.

*Consumers*
Option 3 will potentially allow additional cheaper, higher quality and new products to consumers that they value. It will also provide broader regulatory oversight to a wider range of technologies better managing potential risks. Some consumers may still have concerns the new definitions will not result in the risks being sufficiently managed. However, it is likely risk will be better managed under Option 3 than the status quo whilst not unnecessarily limiting potential benefits.

FSANZ welcomes any general comments, data, or information to assist us in a more detailed consideration of costs and benefits. If information of sufficient quality and volume is obtained through consultation, it may be possible to undertake a more quantitative impact analysis of the proposed options.

***Questions about costs and benefits:***

1. What costs and benefits do you believe should be taken into account when assessing Options 2 and 3?
2. Can you provide any reports, papers, data or any other evidence to support the importance and the potential magnitude of any costs or benefits you have identified?

### *6.2.2 whether other measures would be more cost-effective than development of or a variation to a standard and could achieve the same end*

FSANZ's view is that a variation to the Code is required as continuation of the status quo will only serve to exacerbate the current uncertainty, and may not adequately protect public health and safety. FSANZ has also not identified other measures that would be more cost-effective than varying the Code for addressing the problem.

### *6.2.3 any relevant New Zealand standards*

No relevant New Zealand standards have been identified.

### *6.2.4 any other relevant matters*

No other relevant matters have been identified.