30 July 2024
297-24

2nd Call for submissions – Proposal P1055

Definitions for gene technology and new breeding techniques

FSANZ has assessed a proposal to amend the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to clarify what foods are genetically modified (GM) foods for Code purposes. FSANZ has prepared a draft food regulatory measure extending across six standards and four schedules. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

FSANZ is consulting on this proposal using the FSANZ Consultation Hub, built on the Citizen Space platform. Submissions on this proposal should be made using the FSANZ Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on this proposal will be published on the FSANZ Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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 How to make a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send a hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 September 2024

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 a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting documents (SD)

The following documents are available on the FSANZ Consultation Hub[1] and FSANZ website[2]:

SD1	Updated compilation of regulatory approaches and definitions
SD2	Cost benefit considerations

[1] FSANZ consultation hub – https://consultations.foodstandards.gov.au/
[2] P1055 webpage – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed Proposal P1055 to amend the definitions for 'food produced using gene technology' and 'gene technology' in the Australia New Zealand Food Standards Code (the Code). Proposed changes will introduce a new definition for 'genetically modified food' to clarify what foods are genetically modified (GM) foods for Code purposes. All GM food available for sale in Australia and New Zealand must have been assessed for safety by FSANZ and expressly permitted by the Code.

A new Code definition for GM food is necessary to ensure regulation keeps pace with new techniques for genetic modification, collectively referred to as new breeding techniques (NBTs). NBTs can introduce a wide variety of genetic modifications, including changes that are like those from conventional breeding. This means a clear distinction between GM techniques and conventional breeding no longer exists. Our assessment has concluded that when a food derived using NBTs is equivalent in its characteristics to food derived through conventional breeding, it also presents the same low risk. Because of this low risk, a pre-market safety assessment by FSANZ is not needed, and such food should therefore not be GM food for Code purposes.

We completed a first round of statutory public consultation on this work in December 2021. Following consideration of submitter feedback and based on the available evidence and the reasons set out in this second call for submissions, FSANZ has revised its proposed approach and prepared a draft variation to the Code (Attachment A to this report).

The proposed approach has been revised to make it simpler and clearer, but has not changed in its intent, which is to:

- continue to require that GM foods be subject to pre-market assessment and approval;
- exclude certain foods from the new GM food definition, either because they are:
    - equivalent to conventional food and therefore do not require pre-market safety assessment, or
    - regulated under other parts of the Code and already subject to pre-market safety assessment and approval (e.g. food additives).

If approved, the draft variation would amend Standard 1.1.2 – Definitions used throughout the Code to repeal the current definitions for 'food produced using gene technology' and 'gene technology', replacing them with a new definition for 'genetically modified food'. The effect of the proposed change would be to redefine GM food as food derived from an organism (or cells) that contains novel DNA as an outcome of the genetic modification process. This differs from the current approach where food is considered GM food if it is derived using gene technology, irrespective of the outcome of that process.

The intent of the proposed amendments is to continue to protect public health and safety while also providing a clear definition for enforcement purposes, better harmonisation with regulatory approaches being adopted around the world and greater regulatory certainty for industry.

The draft variation also includes consequential changes to other standards and schedules in the Code as a result of the proposed new definition for GM food. The draft variation also includes consequential and clarifying changes to the labelling requirements including a minor change to remove certain labelling exemptions that would be redundant under the proposed new definition. These amendments do not change the existing approach to mandatory labelling of GM food.

Glossary

Term	Description
Cell culture	The practice of growing plant, animal or microbial cells in an artificial environment.
Cell-cultured food	Food derived from animal cell lines grown in cell culture and then further processed to resemble traditional meat or seafood products derived from an animal.
Cell line	A collection of cells grown in cell culture originating from a single cell.
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 its arrangement.
Conventional breeding	Use of traditional methods for developing new traits in plants or animals, without involving gene technology.
Conventional food	Food derived from plants or animals obtained through conventional breeding.
De novo	Anew, not pre-existing in nature.
DNA	**D**eoxyribo**n**ucleic **a**cid is the hereditary material for most living organisms. DNA is present in cells as two strands (double stranded) composed of a series of nucleotides.
Foreign DNA	DNA obtained from an unrelated species.
Gene technology	Recombinant DNA techniques that alter the heritable genetic material of living cells or organisms (specified in Subsection 1.1.2—2(3) of the Code). May also be called GM techniques.
Genetic modification (GM)	The process of altering the DNA of an organism.
Genetically modified organism (GMO)	An organism whose genome has been modified using gene technology.
Genome	The complete set of genetic material in a living cell or organism.
Genome editing	A group of techniques that make precise changes (edits) at targeted locations in the genome of an organism.
GM food	Food derived from organisms that have been modified using gene technology.
Grafted plant	A plant derived by joining the parts of different but compatible plants together (usually the vegetative part of one plant is joined to the rootstock of another plant) to create a composite plant.
Growth factors	Naturally occurring substances that stimulate the growth of living cells.
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.

Term	Description
NBT food	Food from an organism modified using a new breeding technique.
New breeding techniques (NBTs)	A wide range of new techniques used to modify the genomes of plants, animals and microorganisms.
Novel DNA	Has a similar meaning to foreign DNA. Please refer to the new proposed legal definition in section 3.3.
Novel food	See subsection 1.1.2—8 of the Code.
Novel protein	Protein encoded by novel DNA.
Null segregants	Progeny that have not inherited an introduced gene. Please refer to the new proposed legal definition in section 3.2.
Precision bred organisms or PBOs	Defined in England's *Precision Breeding Act 2023* as plants or vertebrate animals produced using precision breeding.
Precision breeding	A way of changing the genome of plants or animals in a precise way using genome editing techniques.
Precision fermentation	A technology that uses microorganisms to produce specific products such as proteins, human-identical milk oligosaccharides, vitamins or steviol glycoside sweeteners.
Recombinant DNA	*In vitro* laboratory techniques that are used to recombine or join DNA from two or more sources.
Transgenesis	Transfer of DNA between two different species, unable to normally breed or exchange DNA.
Transformation event	A unique genetic modification arising from the use of gene technology.

1 Introduction

1.1 The proposal

Proposal P1055 – Definitions for gene technology and new breeding techniques commenced in February 2020 with the aim of amending the definitions for 'food produced using gene technology' and 'gene technology' in the Australia New Zealand Food Standards Code (the Code). Together these definitions determine what foods are subject to pre-market assessment and approval as genetically modified (GM) foods under the Code.

The purpose of amending the definitions is to clarify, in light of technology developments, what foods are GM foods for Code purposes.

1.2 Reasons for preparing the proposal

FSANZ prepared the proposal following an earlier review[3] which concluded the definitions for 'food produced using gene technology' and 'gene technology' are no longer fit for purpose because they are unclear and do not reflect the diversity of techniques now in use, or that may emerge in the future.

Updating the definitions through this proposal will ensure:

- public health and safety continue to be protected as new technologies emerge
- a clear and predictable pathway to market for investors and developers, and
- better harmonisation with regulatory approaches being adopted by other countries around the world.

1.3 Proposal objectives

In undertaking its assessment, FSANZ must have regard to statutory objectives and other obligations set out in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). In addition to the statutory objectives and obligations, the following regulatory objectives were considered in the assessment of this Proposal:

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

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

2) **Better accommodate new and emerging genetic technologies**

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

3) **Regulate NBT foods in a manner commensurate with the risk posed**

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

1.4 Procedure for the proposal

This proposal is being assessed under the Major Procedure requirements of the FSANZ Act,

[3] NBT review (2017-2019) landing page – https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

which requires two statutory calls for submissions (CFS).

The 1st CFS released on 7 October 2021 sought feedback from interested parties on FSANZ's assessment and preliminary conclusion about whether to prepare a variation to the Code. It also included FSANZ's preferred regulatory approach.

This 2nd CFS now seeks submissions on FSANZ's approach, as revised following the 1st CFS, and the draft variation to the Code.

Submissions received in response to the 2nd CFS will inform FSANZ's decision on whether to approve, amend or reject the proposed draft variation. If approved by FSANZ, the draft variation will be referred to the Food Ministers' Meeting for consideration and endorsement.

1.5 Scope

Proposal P1055 includes consideration of the following:

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

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

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

1.6 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 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;
- 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.

[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.

For a GM food to be listed in Schedule 26 or permitted for use as either a food additive or a processing aid, an application must be made to FSANZ. Assessment of the application includes a pre-market safety assessment. The foods are assessed according to procedures in the FSANZ Application Handbook. These procedures are consistent with internationally agreed guidelines and principles developed by the Codex Alimentarius Commission[6] for conducting such assessments (Codex 2009).

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 food ministers 25 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)*.[7] The purpose of these labelling provisions is to provide 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. Several 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.[8]

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.

'Food produced using gene technology' is defined as:

> ***food produced using gene technology*** means a food which has been derived or developed from an organism which has been modified by gene technology.

'Gene technology' is defined as:

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

1.7 Consultation

1.7.1 Consultation prior to commencement of P1055

FSANZ has been considering NBTs since 2011, primarily through targeted consultation with scientific experts and the jurisdictions, but did not commence a formal review until 2017. This review included public consultation as well as engagement with an expert advisory group (EAG).[9] Submissions in response to the public consultation showed diverse views exist on the safety and regulation of NBT foods, but most agreed the current definitions are no longer fit for purpose and lack clarity. The review findings provided the impetus for the current proposal.

[6] The Commission is the international food standards setting body established by the United Nation's Food and Agriculture Organization and the World Health Organization
[7] Review of food labelling law and policy – https://webarchive.nla.gov.au/awa/20170215181007/http://foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic
[8] GM food labelling webpage – https://www.foodstandards.gov.au/consumer/gmfood/labelling
[9] Information on the expert advisory group – www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

1.7.2 1st Call for Submissions for P1055

Pursuant to section 72 of the FSANZ Act, FSANZ called for submissions to assist further consideration of the proposal and to inform its decision on whether to amend the definitions in the Code. The 1st CFS included a detailed safety assessment, FSANZ's preferred approach to amending the definitions, suggested criteria for excluding certain foods from revised definitions, and a preliminary cost benefit analysis.

As part of the assessment under P1055, and in developing the 1st CFS, FSANZ undertook further targeted consultation with the EAG, which had been reconvened for this purpose, and jurisdictional and other government representatives.

The 1st CFS was released for an 8 week public consultation period between 7 October and 3 December 2021. FSANZ received a total of 1736 submissions (Table 1).

The submissions reflect diverse views and raise a wide range of issues, some of which have been previously considered by FSANZ as part of the earlier NBT work (section 1.7.1). The submissions, and a report summarising major themes and feedback from submitters, were published on the FSANZ website in November 2022.[10]

FSANZ has carefully considered the feedback from submitters and has responded below to the key themes and issues raised. FSANZ's detailed submission responses are provided in Appendix 1 to this report.

[10] P1055 1st CFS Stakeholder feedback summary report – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Table 1. Submitters by sector

Sector	Name
Government (5)	• New South Wales Food Authority • New Zealand Ministry for Primary Industries • Queensland Health • United States Government • Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions (joint submission)
Individuals, community groups and NGOs (1704)	• Auckland GE-free Coalition • Consumers SA • Friends of the Earth and Gene Ethics (joint submission) • GE Free New Zealand • Institute of Health and Environmental Research Inc. • Physicians and Scientists for Global Responsibility • Sustainability Council of New Zealand • Sustainable Agriculture & Communities Alliance (SACA) • 5 private individuals • 1264 campaign submissions • 427 modified[11] campaign submissions
Research (7)	• Australian Academy of Science with Australian Academy of Technology & Engineering (joint submission) • Centre for Integrated Research in Biosafety, University of Canterbury • Commonwealth Scientific and Industrial Research Organisation (CSIRO) • La Trobe Institutional Biosafety Committee • Murdoch University, WA State Agriculture Biotechnology Centre • Plant & Food Research • The Life Sciences Network
Industry (20)	• Agcarm • Australian Beverage council • Australian Organic Limited • Australian Seed Federation • Barley Australia • BASF • Buy Pure New Zealand • Chr. Hansen • Confidential • CropLife Australia • EuropaBio • Fonterra Co-operative Group Limited • Grain Trade Australia • Horticulture New Zealand Incorporated • InterGrain • International Flavors & Fragrances Inc. • New Zealand Beverage Council • New Zealand Food and Grocery Council • NOVALAIT AOTEAROA LIMITED • Organic Industries of Australia Ltd

[11] These are campaign submissions where additional content was included by the submitter

2. Regulatory approach

2.1 Excluding low risk foods from a revised definition

In the 1st CFS, FSANZ proposed to revise the existing definitions to exclude certain NBT foods and refined ingredients from pre-market safety assessment and approval as GM food. The approach was based on the conclusions of a detailed safety assessment[12] that compared NBTs to other methods of genetic modification, including conventional breeding.

The key finding from the safety assessment was that some NBT foods and refined ingredients will be similar, and sometimes identical, in their product characteristics to conventional food. When NBT food and refined ingredients are equivalent to conventional food in terms of their characteristics they can also be considered to present the same low risk.

Based on this assessment, FSANZ concluded there would be justification in excluding the following food categories from pre-market safety assessment and approval as GM foods under revised definitions:

- food from null segregant organisms
- NBT food with equivalent product characteristics to conventional food
- refined ingredients where no novel DNA or novel protein is present in the food for sale.

It should be noted that exclusion from pre-market safety assessment and approval as a GM food under the Code does not exclude the food from other relevant Code provisions, or requirements under Food Acts that foods be safe and suitable.

2.1.1 Submitter feedback

While most submitters agreed with FSANZ that the definitions should be revised to improve clarity with respect to existing and emerging genetic technologies, views were divided on whether some NBT foods and refined ingredients should be excluded from pre-market assessment and approval.

Submitters who opposed excluding certain NBT foods and refined ingredients expressed concern about the safety of NBT food and disagreed with FSANZ's assessment that some NBT foods will be equivalent in risk to conventional food. Overall, they consider the risk from NBT foods to be equivalent to that from existing GM foods, with both requiring pre-market safety assessment. These submitters also do not trust biotechnology companies to self-determine the regulatory status of their products and believe excluding some NBT foods from pre-market scrutiny by FSANZ will lead to reduced confidence in the food regulatory system.

Submitters who supported excluding certain NBT foods and refined ingredients referred to the need for a regulatory approach that is risk proportionate, science-based and consistent in terms of regulatory outcomes. These submitters agreed with FSANZ's assessment that certain NBT foods and ingredients were equivalent in risk to conventional food and stated the current lack of clarity regarding the pathway to market for such products, combined with the disproportionate oversight for certain NBT applications, acts as a disincentive for investment and innovation in the biotechnology sector. They believe a more risk proportionate approach to the regulation of such products will reduce red tape and help farmers and consumers access safe NBT products and their benefits more quickly and will also provide economic

[12] P1055 SD1 Safety Assessment – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

benefits by promoting sustainable agricultural production and improving food security.

2.1.2 FSANZ response

Excluding NBT foods from revised definitions

While most submitters agree with FSANZ that the definitions are unclear and outdated and should be revised, divergent views exist regarding the level of risk posed by NBT foods, and whether all NBT foods should be subject to pre-market safety assessment and approval as GM food. FSANZ notes these are long held views and are consistent with those expressed in earlier consultations on NBTs.[13] Such views are also reflected in consumer research undertaken by FSANZ, although the results of that research indicate community attitudes are more nuanced and can vary depending on the intended purpose of the genetic modification (section 6).

In terms of the safety of NBTs and derived foods, FSANZ acknowledges the concerns expressed by many submitters to the 1st CFS and their strong opposition to the exclusion of any NBT foods from a revised definition. FSANZ has carefully considered the issues and concerns raised by these submitters, however no new information was provided by submitters, nor has FSANZ become aware of any new scientific evidence since the 1st CFS, that would cause FSANZ to alter its previous safety assessment or conclusions. FSANZ therefore maintains that sufficient scientific justification exists to exclude NBT foods and refined ingredients from pre-market assessment and approval as GM foods when they are equivalent in characteristics and of similar low risk as conventional foods.

FSANZ notes that most foods in our food supply are not subject to pre-market scrutiny, as the general provisions under the Code and food law are sufficient to protect public health and safety. Pre-market approval is typically reserved for those foods which, on evidence-based consideration, require an additional layer of public health and safety protection via a FSANZ safety assessment. For example, pre-market approval is required for novel foods.

Foods derived through conventional breeding do not typically trigger pre-market approval requirements under the Code (e.g. as novel foods). When a new food is developed through conventional breeding, it can be marketed without any involvement from FSANZ providing the new food is safe and suitable and complies with relevant provisions of the Code, including those relating to novel food.

By establishing that specific types of NBT foods should not be GM food for Code purposes, FSANZ is declaring that some applications of NBTs are equivalent to conventional breeding in terms of their outcome and should therefore not be subject to different treatment or requirements under the Code.

Regulatory oversight

FSANZ acknowledges the related issues raised by submitters regarding regulatory oversight, concerns about food developers self-determining if an application is required, and that this may reduce consumer trust/confidence in the food regulatory system.

It is important to note that it is the legal responsibility of those who trade in food to ensure their food is both safe and suitable, and complies with relevant provisions of the Code, including those relating to pre-market approval. The decision to apply to FSANZ for pre-market approval of a food therefore rests with the food business/developer. FSANZ does not oversee or police this process. This will continue to be the case once the GM food definitions

[13] Preliminary report: Review of Food Derived using New Breeding Techniques - Consultation outcomes (2018) https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

are amended. FSANZ notes that food businesses that do not comply with the Code may be subject to enforcement action by the relevant enforcement agency.

In relation to consumer trust in the food regulatory system, it is difficult to know whether the proposed approach will directly impact this. A recent consumer survey by FSANZ indicates GM foods are not currently a top three food safety issue for most consumers. While this could change in the future, more recent data shows this is a continuing trend (section 6).

Maintaining a high degree of consumer confidence in the quality and safety of food is one of the main goals of FSANZ under the FSANZ Act. In relation to GM food, the most critical action FSANZ can take is to ensure that GM foods are safe and regulated appropriately according to the risk they pose, and that the regulatory approach is based on sound science and evidence.

FSANZ notes there are other important actors in the system that also impact consumer trust and confidence. FSANZ's consumer research suggests that consumer support for GM foods will depend in large part on the GM food industry building and maintaining trust with consumers directly. Both qualitative and quantitative consumer studies suggest that building and maintaining consumer trust could include ensuring that scientists and producers are understood to be operating in good faith, and that products developed with GM techniques have an explicit benefit for wider society beyond industry (including the environment and/or animal welfare).

2.1.3 Conclusion

FSANZ stands by its conclusion from the 1st CFS that certain NBT foods and refined ingredients will be equivalent in risk to conventional foods and should not require pre-market assessment and approval as GM foods under the Code. FSANZ also confirms its decision to amend the definitions in the Code for GM food to give effect to the conclusion.

2.2 Definitional approach as proposed at 1st CFS

To achieve the regulatory outcome of excluding certain NBT foods and refined ingredients from a revised definition, FSANZ proposed a hybrid definition that included both process- and product-based elements. This approach involved expanding the process-based definition of 'gene technology' to capture a wider range of technologies and changing the definition for 'food produced using gene technology' to contain product-based exclusion criteria for NBT foods and refined ingredients. Refer to the 1st CFS for full details.[14]

The rationale for the hybrid approach was to provide the ability to capture future food products derived from new technologies, but only if the food had characteristics that would warrant an assessment by FSANZ to confirm safety.

2.2.1 Submitter feedback

There were mixed responses to the proposed definitional approach.

Some submitters supported the approach, noting that it contained elements that are broadly consistent with approaches being considered or adopted by other countries and that it provided a means to apply appropriate regulatory scrutiny of new technologies but in a risk proportionate way.

Many submitters were only in favour of expanding the 'gene technology' definition to capture

[14] P1055 1st CFS – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

a broader range of technologies and did not agree with excluding any NBT foods from pre-market assessment (see subsection 2.1.1 above for further context).

Other submitters expressed in-principal support for the approach, but considered the way FSANZ was proposing to achieve such an outcome was overly complex, open to misinterpretation and may also to lead to regulatory outcomes that would be inconsistent with FSANZ's own safety assessment.

In relation to expanding the 'gene technology' definition, these submitters were concerned this approach would be disproportionate to the level of risk and inconsistent with current scientific knowledge and policy. They also noted the additional criteria for expanding the 'gene technology' definition were highly technical and likely to trigger the need for further definitions, introducing even more complexity. These submitters also found the product-based exclusion criteria to be unclear and were concerned it would impose significant burden on product developers to demonstrate compliance, requiring them to generate large data sets for excluded products which they considered would be a perverse outcome.

Several submitters made very specific suggestions for revising the approach to make it simpler and clearer, including that revised definitions should be based on the presence of foreign DNA in the genome of the final organism used for food. They argued that basing the approach around the presence of foreign DNA was more likely to meet the stated proposal objectives. Some of these submitters also provided suggestions for how the current 'gene technology' definition could be changed to refer to foreign DNA, including how foreign DNA could be defined.

2.2.2 FSANZ response

Feedback from submitters indicates different views exist among stakeholders regarding the definitional approach proposed by FSANZ at the 1st CFS. While some submitters were generally comfortable with an expanded 'gene technology' definition being used in combination with product-based exclusion criteria, FSANZ notes the concerns raised by other submitters particularly around clarity, complexity, potential for inconsistent regulatory outcomes, and that the proposed approach would be onerous in terms of compliance.

FSANZ has carefully considered the issues raised and on reflection accepts that the proposed approach was unnecessarily complex and did not hit the mark in terms of meeting the specific intent and objectives of the proposal. Following further consideration, FSANZ also agrees the approach, as proposed at the 1st CFS, may produce unintended outcomes in terms of what foods would be considered GM food for Code purposes, and that some of these outcomes could potentially be inconsistent with FSANZ's own safety assessment, that is, capture foods with equivalent characteristics to conventional foods, which would be counter to the regulatory intent.

FSANZ has also had regard to the suggestion from some submitters that the approach be revised so definitions are based on the presence of foreign DNA in the genome, including how that could be drafted. FSANZ's assessment in response to these suggestions is that there would be merit in exploring a revised approach based on foreign DNA. FSANZ notes other countries have also used this approach (see SD1), and that it may help to simplify the new definitions and make them clearer and less onerous in terms of compliance, with benefits also for implementation and enforcement. Importantly, it is also FSANZ's assessment that such an approach will deliver more consistent outcomes in terms of excluding certain low risk foods from GM food regulation based on their risk equivalence to conventional foods.

2.2.3 Conclusion

Based on submitter feedback and further assessment, FSANZ has concluded the approach as proposed at 1st CFS should be revised to instead focus on the presence of foreign DNA in the genome as an outcome, rather than food product characteristics.

2.3 Revised approach

2.3.1 Key considerations

In considering a revised approach, FSANZ had regard to the specific suggestion made by some submitters to revise the 'gene technology' definition to include reference to foreign DNA and retain the current definition for 'food produced using gene technology' without change.

While FSANZ found the suggestions helpful, it was important to consider how to accommodate other aspects related to refined ingredients, how to account for innovations involving precision fermentation and cell-cultured food, and how the revised approach and definition based on the presence of foreign DNA would also fit with the GM labelling provisions in Standard 1.5.2.

As a result of these additional considerations and further assessment, FSANZ now proposes the following revised approach:

- a single outcomes-based definition for **genetically modified food**;
- a definition based on the presence of **novel DNA** in the genome of an organism**,** instead of foreign DNA;
- revised definitions for **novel DNA** and **novel protein**;
- explicit exemptions for food derived from null segregant organisms and grafted plants;
- explicit exemptions for substances regulated by other standards in the Code (food additives, processing aids and nutritive substances);
- an explicit exemption for substances used in cell culture to support the growth and viability of cells, and to process cells, for the production of cell-cultured food.

These changes are intended to deliver equivalent outcomes to those described in the 1st CFS, and to further clarify what is a GM food for Code purposes in light of recent developments in precision fermentation and cell-cultured food (Table 2).

Table 2. Comparison between proposed approaches in the 1st and 2nd CFS

Approach at 1st CFS	Approach at 2nd CFS
Hybrid definition (process + product)	Outcomes-based definition
Interacting definitions for *food produced using gene technology* and *gene technology*	Single definition for *genetically modified food*
Revised definitions for: • food produced using gene technology • gene technology	Repeal existing definitions for 'food produced using gene technology' and 'gene technology' New definitions for: • genetically modified food • null segregant • novel DNA • novel protein
Product-based exclusions for: • certain NBT foods • processed food ingredients and substances added to food	Explicit exemptions for: • food from null segregants and grafted plants • substances added to food • substances used in cell culture to support the growth and viability of cells, and process cells, for the production of cell-cultured food

The different elements of the revised approach and regulatory intent are described below.

2.3.2 Outcomes-based definition

In the 1st CFS, FSANZ considered the advantages and disadvantages of a process versus a product-based definition. For this analysis, FSANZ noted that product-based means the definitions are focussed on the outcome of a process, not the process itself, with outcome referring either to the genome change that has been introduced, or any resulting change to the derived food.

The 1st CFS and 2nd CFS approaches are both outcomes-based and intended to deliver equivalent outcomes in terms of what foods will be GM foods for Code purposes. They differ however in how they deliver that outcome. In the 1st CFS the approach was based on changes to the food itself (food product characteristics), whereas for the 2nd CFS the revised approach is based on the specific change to the genome (insertion of novel DNA into the genome).

The advantages of the 2nd CFS outcomes-based approach include:

- flexibility, to address technology developments and new breeding techniques
- stability, with the definition less likely to become outdated because it is not based on a specific technique or technology, and
- risk proportionality, supporting a focus on characteristics more relevant to risk.

FSANZ notes these advantages remain relevant to a definition based on the presence of novel DNA.

The disadvantages are that an outcomes-based approach can be more open to interpretation than a process-based approach and may be more onerous to implement if additional guidance is required to aid interpretation. FSANZ notes these disadvantages are more relevant to the approach proposed for the 1st CFS and its reliance on product-based exclusion criteria. They are less relevant for an approach based on the presence of novel DNA.

2.3.3 Presence of novel DNA

The overall intent of the revised approach is to continue to capture the types of foods that are listed in Schedule 26 of the Code, with some exceptions (see subsections 2.3.4 and 2.3.5 below). This is consistent with the original policy intent of Standard 1.5.2. Most of the organisms listed in Schedule 26 are transgenic[15] organisms, with a limited number being intragenic[16]. A presumption of greater risk exists with these types of genetic modifications because the transferred DNA may encode a novel protein, or other substance, and may not have a safe history of use in food. Hence the longstanding requirement that such products undergo pre-market safety assessment before being permitted for sale.[17]

As noted in subsection 2.3.1 above, several submitters suggested FSANZ base a revised definition on the presence of foreign DNA. While FSANZ agrees with the suggestion to adopt an outcomes-based definition, FSANZ prefers to use the term 'novel DNA' in preference to 'foreign DNA', which is commonly understood to mean DNA transferred from an unrelated species to create a transgenic organism. Based on FSANZ's previous safety assessment, the intent would be to capture food from both transgenesis and intragenesis, which is also consistent with the types of products listed in Schedule 26. Furthermore, FSANZ must also consider the possibility that DNA may be specifically designed and synthesised and not based on any naturally occurring or pre-existing DNA sequence. Using the term 'novel DNA' will also be compatible with the GM labelling requirements in Standard 1.5.2, which are partly based on the presence of novel DNA in food for sale.

Moving to an outcomes-based approach based on the presence of novel DNA in the organism from which the food for sale is derived provides a clear and objective measure to determine if a food is a GM food for Code purposes. Novel DNA is either present in the organism or it is not. This will assist product developers to comply with the Code and jurisdictions to implement, interpret and enforce Code requirements.

FSANZ's proposed new definition for novel DNA is discussed in section 3.3.

2.3.4 Specific food categories

Food derived using genome editing

In the case of food from genome editing, FSANZ has revised its approach to rely on other parts of the Code to achieve a regulatory outcome that is comparable to that proposed in the 1st CFS.

Under the revised approach, food from genome editing will only be GM food for Code purposes if the editing process results in the insertion of novel DNA into the genome of the organism from which the food is derived. This differs from the 1st CFS approach where, in the absence of novel DNA being inserted, the intent was to also capture food from genome

[15] Transgenic is where DNA from an unrelated organism is inserted into the genome, in any configuration.
[16] Intragenic means DNA from the same or cross-compatible species is rearranged before being inserted into the genome.
[17] This proposal does not seek to challenge the presumption of greater risk for such products, although it should be noted that no safety issues have been identified in any GM food assessed by FSANZ over the last 25 years.

editing if the editing process changed the characteristics of a food in a way that was outside the range expected for conventional food. Under the revised approach, such food will not be GM food for Code purposes. This outcome signals that food from genome editing that does not involve the insertion of novel DNA is equivalent in regulation to food derived from conventional breeding and will ensure greater consistency in regulatory outcomes.

It is important to note that food that is not GM food under the Code may still be subject to other Code provisions, including for novel food. This would be the case for food derived from conventional breeding, as well as food from genome editing that is not captured as a GM food. Either food could be captured as novel food should any changes to that food because of genome editing or conventional breeding be considered sufficient to warrant an assessment of public health and safety by FSANZ.[18] Novel food is defined in the Code[19] and is assessed via a separate application process.

Based on the types of food products that have been produced using genome editing to date, FSANZ expects the majority would not be considered novel food under the Code. This is because the types of changes being introduced are consistent with changes that have been introduced through conventional breeding, for example, hair coat modifications in cattle, changes to fatty acid profiles in oilseeds etc. Such foods are therefore likely to be considered equivalent to traditional food, or if considered non-traditional, to have characteristics that would not be considered to require an assessment of public health and safety.

Food derived using cisgenesis

The cisgenesis technique involves inserting DNA into the genome, however, to meet the criteria for cisgenesis, that DNA must be derived from the same or a cross-compatible species and be inserted without altering its sequence or configuration. The exclusion of food from cisgenic organisms is supported by FSANZ's safety assessment, which found the genetic changes introduced using cisgenesis would be equivalent to those introduced using cross breeding. FSANZ notes that no foods derived from cisgenesis are listed in Schedule 26.

In the 1st CFS, FSANZ had originally proposed to exclude such food from a revised definition using the product-based exclusion criteria. To achieve the same outcome under the revised approach, FSANZ has defined novel DNA in a way that does not include DNA from the same or cross-compatible species (refer to section 3.3).

Foods and ingredients derived using precision fermentation

Precision fermentation products were not explicitly considered in the 1st CFS but are included here given the increased attention this type of technology is receiving, along with the increase in the number and different types of products being brought forward for regulatory approval.

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[18] Novel foods are prohibited from sale unless expressly permitted and listed in Schedule 25 of the Code. Advice on whether a food is a novel food can be obtained from the Advisory Committee on Novel Foods which is made up of jurisdictional representatives and chaired by FSANZ. www.foodstandards.gov.au/business/novel

[19] Under section 1.1.2—8 of the Code, **novel food** means a non-traditional food that requires an assessment of the public health and safety considerations having regard to:

(a) the potential for adverse effects in humans; or

(b) the composition or structure of the food; or

(c) the process by which the food has been prepared; or

(d) the source from which it is derived; or

(e) patterns and levels of consumption of the food; or

(f) any other relevant matters.

Precision fermentation refers to the process of genetically modifying microorganisms to produce a range of ingredients for addition to food using longstanding fermentation technology. Such technology has been used for many years to produce enzymes that are used in the processing of food, flavouring compounds, and certain food additives such as steviol glycoside sweeteners. More recently, precision fermentation is being used to produce proteins and other dietary macro components (e.g. fats, oligosaccharides) which are then separated away or secreted from the microorganism and further purified. The genetic modification of these microorganisms typically involves the insertion of novel DNA that has been derived from an unrelated species. Such products are already captured under the current GM food definitions, and FSANZ expects this to continue under the proposed new definition for GM food. The exception to this will be if the precision fermentation product is intended to be used as a food additive, processing aid or nutritive substance. Under the revised approach, FSANZ proposes to exempt food additives, processing aids and nutritive substances from the proposed new GM food definition (further discussed in subsection 2.3.5 and section 3.2).

Cell-cultured food

Cell-cultured food also was not explicitly considered in the 1st CFS, but like precision fermentation, it is receiving significant interest and attention. Cell-cultured food products are now being brought forward for regulatory approval.

Cell-cultured food is made from isolated animal cell lines which are cultured *in vitro* and then further processed to resemble traditional meat or seafood products derived from an animal. In some cases, the cell lines that are used may be genetically modified to assist the cell culturing process (e.g. to induce immortalisation) or for some other purpose. It might also eventuate that a cell line is derived from a GM animal.

Under the revised approach, if a cell line used to produce a cell-cultured food contains novel DNA in its genome, the food derived from that cell line will be a GM food.

Processed food ingredients

In the 1st CFS, the intent was to use product-based exclusion criteria to exclude processed food ingredients that are identical in composition to an equivalent conventionally derived ingredient, and where no novel DNA or novel protein remains in the food for sale. Examples of processed food ingredients include sugar, starches, protein concentrates, amino acids, gelatine products, fats and oils.

FSANZ explored excluding these types of food ingredients under the revised approach but determined it would be technically challenging to develop clear and objective criteria that could be uniformly applied across a large and diverse product category without the risk of inconsistent and unintended regulatory outcomes in terms of what ingredients would or would not be captured as GM food. FSANZ therefore concluded it would not be practically possible to provide for such exclusions under the revised approach. As a result, processed food ingredients derived from organisms that contain novel DNA in their genome will be GM food for Code purposes.

2.3.5 Proposed exclusions from the new GM food definition

Under the approach proposed in the 1st CFS certain foods and substances added to food were intended to be excluded from a new GM food definition either through the application of the product-based exclusion criteria, or via explicit exemption.

Following submitter feedback on this approach, and in the interest of greater clarity, FSANZ

is now proposing to provide for all such exclusions through explicit exemptions under the proposed new definition for GM food. The foods and substances proposed to be exempted are discussed below.

Substances added to foods

The substances proposed to be explicitly exempted from a new GM food definition are food additives, processing aids and nutritive substances. It is important to note that being subject to an explicit exemption under the new GM food definition means such substances will be excluded even if the organism from which they are derived contains novel DNA in its genome.

The rationale for their exemption is that such substances are already appropriately regulated under other parts of the Code and subject to pre-market safety assessment. It is therefore unnecessary for protecting public health and safety to separately regulate such substances as GM food, as any assessment as a food additive, processing aid or nutritive substance will also consider the manufacturing process, including any genetic modification of the production organism. FSANZ notes other countries typically do not distinguish between GM and non-GM derived food additives and processing aids in their regulations.

Food from null segregant organisms

In the 1st CFS, FSANZ noted the current definition for 'food produced using gene technology' is ambiguous with respect to food from null segregants and concluded such food should not be GM food for Code purposes. This conclusion was supported by the safety assessment which found that food from null segregants will be equivalent in risk to conventional foods. Moreover, when the GM food standard was originally developed, it had not been the intent to capture such foods as GM foods. To remove any doubt regarding the regulatory status of food from null segregants, FSANZ proposed to include a specific exemption in a revised definition, and to also consider whether to specifically define 'null segregant'.

FSANZ has further considered null segregants under the revised approach, in particular whether an explicit exemption is still required given the change in definitional approach. While it is FSANZ's assessment the proposed new GM food definition will be clearer with respect to null segregants, FSANZ has decided to include an explicit exemption for food from null segregants, and to also define 'null segregant'. This will provide certainty to both product developers and food enforcement agencies.

FSANZ notes the exclusion of null segregants from the new GM food definition is consistent with recent changes to the *Gene Technology Regulations 2001* in Australia which clarified that null segregant organisms are not genetically modified organisms (GMOs).[20] The approach also aligns with the recent determination by the New Zealand Environmental Protection Authority that null segregants are not GMOs under the *Hazardous Substances and New Organisms Act 1996* (HSNO Act).[21]

Food from grafted plants

In the 1st CFS, FSANZ proposed to rely on the product-based exclusion criteria to exclude food from grafted plants, noting that foreign DNA would not be present in the part of the plant from which food is typically derived. Food from grafted plants would have also been required to meet the other exclusions relating to food product characteristics.

[20] Overview of changes to the Gene Technology Regulations 2001 – Overview of the status of organisms modified using gene editing and other new technologies

[21] Environmental Protection Authority determination on null segregants – https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204173

FSANZ has further considered food from grafted plants under the revised approach and has decided to include an explicit exemption for such food under the proposed new GM food definition.

Grafted plants represent an unusual case, where only part of the plant may be genetically modified to contain novel DNA. Furthermore, while novel DNA may be stably integrated into the genome of cells making up certain plant parts (e.g. the rootstock), and therefore is not mobile throughout the rest of the plant, the scientific literature indicates it is possible to engineer some proteins to move across the graft junction into tissues that have not themselves been directly genetically modified to contain novel DNA. As a result, FSANZ is proposing to exempt food from grafted plants from the GM food definition but only where that food is derived from the part of the plant that does not contain novel DNA or novel protein (protein encoded by the inserted novel DNA).

FSANZ is aware that substances other than proteins may also cross the graft junction and could potentially change the characteristics of a food product that is derived from the part of the plant that has not been directly modified itself to contain novel DNA (Haroldsen et al., 2012). Similar to food from genome editing, FSANZ notes that although excluded from regulation as a GM food, such foods may be subject to regulation as novel foods if the change to a food's characteristics are considered sufficient to warrant a safety assessment by FSANZ.

Substances used in cell culture

The culturing process used in the production of cell-cultured food can include a wide variety of components. The cell culture media, for example, can be used to supply nutrients such as carbohydrates, vitamins, amino acids, minerals, growth factors and hormones, as well as other components that are used to control pH and cellular osmotic pressure. Culture plates or flasks, as well as the media, can also contain other substances that are used to process cells during cell culture.[22] Some of these components (e.g. growth factors, enzymes, amino acids, vitamins) may be derived from GM organisms.

The media and culture vessels are used for the express purpose of facilitating the culture of the cells, which are then harvested and processed into a food product. Depending on any washing or cell dissociation steps that may occur at the harvesting stage, some residues of various cell culture components may be carried over to the harvested cells, and potentially may also be present in the final food.

As part of its assessment of a cell-cultured food, FSANZ considers the safety of any cell culture components that are present as residues on the harvested cells. FSANZ does not however consider the individual components to be food ingredients, as they are not added for that express purpose. FSANZ also does not consider such components, particularly the ones used to support cell growth and viability, to be food processing aids or food additives as they are not performing a technological function at the food processing stage or in the final food. Whether the components that are used to process the cells during cell culture are processing aids will need to be determined on a case by case basis in the context of an application to FSANZ. Nevertheless, FSANZ's assessment is that processing aids as a class of substances be exempt from the GM food definition.

Given the uncertainty that exists in relation to the regulatory status of such components under the Code, particularly for those that are derived from GM organisms, FSANZ proposes to include an explicit exemption under the proposed new GM food definition. This exemption

[22] For example: proteins or poly(amino acids) to promote cell adhesion; or enzymes to dissociate cells adhering to a culture vessels, scaffolds or other cells while in suspension or tissue culture by degrading cell adhesion components or DNA.

will clarify that substances that are used to support cell growth and viability during cell culture, or to process cells during cell culture, are not GM food for Code purposes. This will not exempt such substances from consideration under other parts of the Code.

3. Definitions

3.1 Background

In crafting the new definition, FSANZ had regard to the need for a clear definition that is not open to multiple interpretations. This reduces uncertainty for product developers about whether pre-market approval is required and supports them to comply with food regulations. A clear definition also facilitates effective and consistent implementation, interpretation and enforcement of food regulations by the jurisdictions. The ability to determine whether a food product in the food supply is non-compliant is critical to the enforceability of food regulations, which is essential for maintaining public confidence in the food regulatory system.

3.2 New definition for genetically modified food

The current definitions for 'food produced using gene technology' and 'gene technology' set out in subsection 1.1.2—2(3) of the Code will be repealed and replaced with the new definition for 'genetically modified food' set out below. The new definition includes: the primary definition; list of exempted foods and substances; and a definition for 'null segregant'.

(1) In this Code, ***genetically modified food*** means:

(a) a food that is:

(i) an organism that contains *novel DNA; or

(ii) derived from an organism that contains novel DNA; or

(iii) cells that contain novel DNA; or

(iv) derived from cells that contain novel DNA; and

(b) does not include any of the following:

(i) a *substance used as a food additive;

(ii) a *substance used as a processing aid;

(iii) a *substance used as a nutritive substance;

(iv) a substance used to:

(A) support the growth and viability of cells during cell culture; or

(B) process cells during cell culture;

(v) food that is derived from part of a grafted plant, where that part does not contain novel DNA or novel protein;

(vi) food derived from a null segregant.

(2) In this section, ***a null segregant*** means an organism, cell or cells that:

(a) is descended from an organism, cell or cells that contain *novel DNA: and

(b) does not contain novel DNA.

The rationale and regulatory intent of the different elements of the new definition are discussed in section 2.3 above. Table 3 below summarises the intended regulatory outcomes for different types of foods and substances.

Table 3. Intended regulatory outcomes under the revised approach at 2nd CFS

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

Consultation Question 1. Definition for ‘genetically modified food’

1a. Is the new definition for ‘genetically modified food’ clear? If not, which parts of the definition could be clearer?

1b. Will the new definition for ‘genetically modified food’ produce the intended regulatory outcomes, as described in section 3.2 and Table 3?

3.3 New definitions for novel DNA and novel protein

In response to the 1st CFS, several submitters suggested FSANZ should base the revised definitions on the presence of foreign DNA and suggested the following definition for 'foreign DNA'.

> ***foreign DNA*** means the stable integration into the genome of one or more genes that originate from outside the organism's cross-compatible gene pool and are inaccessible through conventional methods

While the term 'novel DNA' was adopted in preference to 'foreign DNA', as discussed in section 2.3.3, FSANZ had regard to the suggested definition for 'foreign DNA' when developing its definition for 'novel DNA'.

While the suggested 'foreign DNA' definition adequately conveys its meaning to those who are knowledgeable in plant breeding, FSANZ did not consider it suitable as a legal definition that could be readily interpreted and enforced. As previously discussed, there are also other aspects that need to be encompassed within the definition for 'novel DNA', such as ensuring both transgenesis and intragenesis come within its meaning, as well as DNA that has been artificially synthesised and is not based on any naturally occurring or pre-existing DNA sequence.

FSANZ is therefore proposing the following definition for 'novel DNA'.

> In this Code, ***novel DNA*** means DNA that:
>
> (a) a person has inserted into the genome of an organism, cell or cells; and
>
> (b) is:
>
> (i) from a species that has not previously been crossed or hybridised with the species of the organism, cell or cells; or
>
> (ii) from a species that has previously been crossed or hybridised with the species of the organism or cells, where the sequence or arrangement of the inserted DNA was changed prior to its insertion; or
>
> (iii) not from an existing species.

The intent is to capture food from both transgenic (subclause (b)(i)) and intragenic organisms (subclause (b)(ii)), while excluding food from cisgenic organisms. Subclause (b)(iii) is intended to capture DNA that has been *de novo* designed to contain nucleotide sequences or encode proteins that do not match with any naturally occurring or pre-existing DNA sequences.

Consultation Question 2. Definition for 'novel DNA'

2a. Is the new definition for 'novel DNA' clear? If not, which parts of the definition could be clearer?

2b. Will the new definition for 'novel DNA' produce the intended regulatory outcomes, as described in section 3.3 and Table 3?

FSANZ notes that when DNA is inserted, or when genome editing is used, other genome changes can occur that are associated with the process of DNA insertion[23], or are secondary to the intended change[24]. Some changes to DNA sequence are also made to facilitate expression of an encoded protein in a different species, but without changing the amino acid

[23] For example, restriction site sequences flanking inserted DNA or right and left border sequences from the Agrobacterium-mediated transformation process.

[24] For example, in the case of genome editing, the introduction of small insertions and deletions from non-homologous end joining of the double stranded break site.

sequence of the encoded protein (e.g. codon optimisation). It is not FSANZ's intent that these types of genome changes come within the meaning of 'novel DNA' as such changes are unimportant to safety.

The other aspect to note in relation to the new definition for 'novel DNA' is that it will also be used for labelling purposes, where it will replace the current definition for 'novel DNA' set out in subsection 1.5.2—4(5) of the Code.

In the case of labelling however, it is the presence of novel DNA in the food for sale that is relevant. This differs from its purpose when determining if a food is a GM food under the Code, where it is its presence in the genome of the organism from which food is derived that is relevant. Under the proposed definition for 'genetically modified food', a food can be a GM food without any novel DNA being present in the food for sale, for example a refined soybean oil. This is no different to the situation under current Code requirements for GM food.

A new definition for 'novel protein' is also proposed, primarily for labelling purposes, but will also apply in relation to the proposed exemption for food from grafted plants (see subsection 2.3.5 and section 3.2 above).

> ***Novel protein*** means a protein encoded by novel DNA.

Refer to Section 4 for further information regarding GM food labelling.

3.4 Consequential changes to the Code

In addition to the proposed new definitions, consequential changes to the Code are required to give effect to the new definitions or to clarify Code provisions that interact with the new definitions. The primary Code changes will be to Standard 1.1.2 – Definitions used throughout the Code, as discussed in sections 3.2 and 3.3 above, however a number of other standards and schedules require amendment as a result of the changes to Standard 1.1.2. These are:

- Standard 1.1.1 – Structure of the Code and general provisions
- Standard 1.2.1 – Requirements to have labels or otherwise provide information
- Standard 1.2.4 – Information requirements – statement of ingredients
- Standard 1.5.2 – Food produced using gene technology
- Standard 2.9.1 – Infant formula products
- Schedule 3 – Identity and purity
- Schedule 18 – Processing aids
- Schedule 26 – Food produced using gene technology
- Schedule 29 – Special purpose foods

A significant number of the consequential changes are minor in nature and do not require further discussion here but are set out in *Attachment A – Draft variations to the Australia New Zealand Food Standards Code*. More notable changes are discussed in subsections 3.4.1 and 3.4.2, except for those relating to the labelling requirements for GM food, which are discussed in section 4 below.

Further explanation of all the proposed Code changes is provided in *Attachment B – Draft Explanatory Statement*.

3.4.1 Changes to Schedule 26

Schedule 26 contains additional definitions that are not listed in Standard 1.1.2 – Definitions used throughout the Code. These include definitions for 'conventional breeding', 'line', and 'transformation event'.

Definition for conventional breeding under S26—2(2)

In the 1st CFS, FSANZ noted that a decision would need to be taken on whether to retain a specific definition for 'conventional breeding' once a new GM food definition was adopted. In response to this, some submitters stated it is no longer scientifically supportable to make a distinction between conventional breeding and other methods for genetic modification, as different tools can produce the same genome change. Other submitters however saw value in retaining the definition for 'conventional breeding' and suggested FSANZ consider developing a definition for 'conventional food', so the distinction between GM food and conventional food is clear.

FSANZ has further considered this issue in light of the revised approach, and the proposed new definition for 'genetically modified food' and does not consider an explicit definition for 'conventional breeding' would serve any useful purpose in terms of the implementation or interpretation of the new definition for 'genetically modified food'. FSANZ believes it is already clear that a food that is not a GM food will either be a conventional food, or equivalent to a conventional food. Furthermore, to be retained, the definition for 'conventional breeding' would need to be revised, as it is currently defined as *all methods used to produce plants, excluding techniques that use gene technology*. This would add further complexity, without providing any additional benefit in terms of clarity or the implementation of the new regulatory approach to GM food.

Definition for line under S26—2(2)

The definition for 'line' was not discussed in the 1st CFS but is provided below:

> ***line*** means:
>
> (a) a plant, the genetic material of which includes a transformation event or events; or
>
> (b) any plant, descended from the plant referred to in paragraph (a), that is the result of conventional breeding of that plant with:
>
> (i) any other plant that does not contain a transformation event or events; or
>
> (ii) any other plant that contains a transformation event or events, whether expressed as a line or event, that is listed in the table to section S26—3;
>
> (iii) but shall not be taken to mean any plant derived solely as a result of conventional breeding.

The definition for 'line' is intended to be read in conjunction with the table to subsection (4), which lists permitted GM foods of plant origin. Each entry refers to food derived from a specific line of GM plant (e.g. corn line DP915635). The purpose of the definition is to clarify that separate approval is not required for foods derived from a GM plant that is the result of conventional breeding between two or more GM plant lines which are already permitted in Schedule 26. In other words, permission for a 'food derived from……' also includes any progeny from the conventional breeding of the GM plant line with other approved GM plant lines, or conventional (non-GM) plant lines. Additional information about the regulatory status of breeding stacks is available from the FSANZ website.[25]

[25] Food derived from GM plants containing stacked genes – https://www.foodstandards.gov.au/consumer/gmfood/stackedgene

FSANZ's assessment is that the definition for 'line' should be retained, subject to minor changes to make the definition also applicable to animals. While FSANZ has yet to receive an application for food derived from a GM animal, or approve such food, this is likely to occur in the future.

Definition for transformation event under Subsection S26—2(2)

The definition for 'transformation event' was not discussed in the 1st CFS but is a term that is used in the definition for 'line'. There are no further references to transformation event elsewhere in the Code. Transformation event is currently defined as follows:

> ***transformation event*** means a unique genetic modification arising from the use of gene technology

FSANZ is proposing to retain this definition in the schedule and revise as follows to remove reference to 'gene technology':

> ***transformation event*** means a unique genetic modification arising from the insertion of novel DNA

Amendments to the tables to Subsection S26—3

FSANZ has considered the permitted foods of plant origin listed in the table to subsection S26—3(4) and has determined that all the listed foods are GM foods under the proposed new GM food definition. FSANZ therefore decided not to change this table, other than its title.

A similar analysis was undertaken for the permitted foods of microbial origin listed in the table to subsection S26—3(7), where it was determined that the only entry that should be retained is the one for soy leghemoglobin preparation. Soy leghemoglobin, which is a component of the preparation, is considered a nutritive substance as it acts as a source or iron when added to meat analogue products. Soy leghemoglobin itself would therefore not be considered a GM food under the proposed new definition. The preparation however meets the proposed new GM food definition; hence it is proposed to be retained as a permitted GM food in Schedule 26.

The remaining entries for various human identical milk oligosaccharides are exempt from the proposed new GM food definition as they are nutritive substances under the Code. These nutritive substances will be transferred to Schedule 29 – Special purpose foods, where they will be listed in a table for permitted forms and sources for nutritive substances used in infant formula products (see subsection 3.4.2 below for further information).

3.4.2 Changes to Standard 2.9.1 and Schedule 29

Standard 2.9.1 – Infant formula products and Schedule 29 – Special purpose foods set composition and labelling requirements for infant formula products. These requirements have been under review through Proposal P1028 Infant Formula. At the time of release of this P1055 2nd CFS, proposal P1028 is in its final stages with an amended Standard 2.9.1 and S29 expected to be gazetted and take effect in August 2024 subject to the endorsement of Food Ministers.

Standard 2.9.1 and S29 have been renumbered and restructured in the new standard. Given the above transition, proposed draft amendments to Standard 2.9.1 and S29 arising from P1055 changes have been drafted in the new infant formula standard.[26]

[26] The new infant formula standard is provided in the P1028 Approval Report (Attachment A & B - Approved primary and consequential draft variations to the Australia New Zealand Food Standards Code) –

The entries to the table to S26—3 for human identical milk oligosaccharides list permissions according to the substance, the source organism containing the gene to the enzyme processing aid to produce the substance, and any conditions of use. FSANZ is proposing to retain these requirements but transfer them to tables in S29—7, S29—8, S29—9, and S29––9a with some amendments to the table structure.

Additional minor amendments in Standard 2.9.1 are proposed so that the requirements for nutritive substances correctly reference the above permissions proposed to be listed in S29.

4. Labelling

As stated in section 1.5 of this report, the GM labelling approach is out of scope of Proposal P1055. However, submissions to the 1st CFS raised labelling issues for consideration (see submitter comments in Table E in Appendix 1) and changes to the labelling provisions in the Code are proposed to clarify existing labelling requirements or are consequential to the revised approach.

4.1 Approach and intent

4.1.1 Submitter comments

As with previous consultations about NBTs, the issue of whether GM food labelling would apply to NBT foods was a major concern for many submitters. Most submitters commented that all GM and NBT foods should be labelled for the following reasons: to preserve the high-level transparency of GM food; that based on evidence, most Australians do not want to consume GM foods; and clear labelling would enable consumers to make informed choices.

Two submitters commented that NBT food excluded from a pre-market safety assessment should not require GM labelling.

4.1.2 FSANZ response

FSANZ has noted previously that approved GM food is subject to the mandatory requirement to label with the words ‘genetically modified’ (subsection 1.6.2 of the 1st CFS). Labelling requirements are based on the food ‘product’ for sale rather than the ‘process’. Unless exempt, food must be labelled as ‘genetically modified’ if it contains novel DNA or novel protein, or it has a characteristic that is altered (e.g. a different fatty acid profile).

This labelling approach is retained under the proposed new definitions for ‘genetically modified food’ and ‘novel DNA’ (see section 2.3 in this report). Foods that meet the new definition of ‘genetically modified food’ (see section 3.2 in this report) and are approved for use will be subject to mandatory GM labelling requirements in the Code. The revised and new definitions in section 3 are intended to provide greater regulatory certainty about what foods are GM foods for Code purposes.

FSANZ acknowledges submitter comments that labelling should apply to all GM foods, including NBT foods and notes this view may stem from a desire for ‘process-based’ labelling to apply. Process-based labelling requires a food to be labelled when GM food has been used anywhere in the production process, irrespective of the presence of novel DNA or novel protein, or whether the nature of the food has changed compared to counterpart food not produced using gene technology. However, when Standard 1.5.2 was developed in 2000, food ministers adopted a labelling policy for informed consumer choice based on the final

https://www.foodstandards.gov.au/food-standards-code/proposals/P1028

food ‘product’ for sale i.e. labelling for the presence of GM material (novel DNA/novel protein or altered characteristics in the final food). The current ‘product-based’ labelling approach is a balance between the need for consumers to be provided with meaningful information to make informed choices with the need for such requirements to be practical and enforceable and reflects the policy intent set by ministers. Further, a process-based approach does not reflect how current labelling requirements operate, including that certain labelling exemptions may apply. For example, labelling is not required for foods where the accidental presence of a GM component is less than 10 g/kg (1%) per ingredient of the final food.

FSANZ considers this balance would be maintained by aligning the outcome-based revised approach for pre-market safety assessment and approval with the existing ‘product-based’ approach for labelling. For example, FSANZ notes food derived using genome editing that does not involve the insertion of novel DNA is equivalent to food derived from conventional breeding. FSANZ has outlined the rationale for the outcomes-based approach in section 2.3 in this report.

In regard to submitter comments that most Australians do not want to consume GM foods (see Table E in Appendix 1), the evidence indicates that Australian and New Zealand consumer attitudes towards GM foods are nuanced and can vary depending on the intended purpose; that attitudes towards NBTs are generally more positive compared to GM foods; and that the majority of consumers do not consider GM foods or food ingredients as a top food safety concern. Furthermore, FSANZ’s recent Consumer Insights Tracker (2024) indicates at least a third of Australian and New Zealand respondents say they would purchase and consume GM banana if it became available for sale (see section 6 in this report). As noted above, approved GM foods will continue to be labelled to enable informed consumer choice.

4.2 Proposed clarifications and consequential changes to labelling provisions

While the labelling approach is unchanged, FSANZ is proposing changes to clarify current labelling provisions to ensure they continue to capture the existing intent for product-based labelling (see section 4.2.1). Some changes are consequential to the revised approach. These proposed amendments are described below in section 4.2.2.

4.2.1 Specific clarifications

Changes in the draft variation to Standard 1.5.2 are proposed to clarify that:

- a food for sale that contains a GM food would be subject to labelling requirements if novel DNA or novel protein is present or the GM food has altered characteristics (paragraph 1.5.2—4(1)(a) of the draft variation).
- labelling requirements apply where the GM food is listed as an approved GM food (paragraph 1.5.2—4(1)(a) of the draft variation).
- labelling requirements apply where the GM food contains novel DNA or novel protein or has an altered characteristic (paragraph 1.5.2—4(1)(b) of the draft variation).
- if a GM food is subject to the labelling requirements, these requirements would apply to a GM food ingredient of a compound of ingredient. An example of a GM food ingredient of a compound ingredient has been included (subsection 1.5.2—4(4) of the draft variation).

Changes in the draft variation to Standard 1.2.4 are proposed to clarify that:

- information relating to GM food would apply to a GM food ingredient of a compound ingredient where that compound ingredient comprises less than 5% of the food for

sale (subparagraph 1.2.4—5(6)(b)(i) of the draft variation).

4.2.2 Amendments consequential to the revised approach

As noted in sections 3.2 and 3.3 of this report, the new definitions for 'genetically modified food', 'novel DNA' and 'novel protein' are proposed including for labelling purposes. The new definition for GM food explicitly excludes substances *used as a processing aid or *used as a food additive. Therefore, the following current labelling exemptions will be removed because they are redundant:

- the GM food is a substance *used as a processing aid or *used as a food additive in the food in accordance with this Code; where no novel DNA or novel protein from the substance remains present in the food.
- the GM food is a *flavouring substance[27] that is present in the food in a concentration of not more than 1 g of flavouring/kg of food.

The current labelling exemption for a highly refined GM food will also be removed. This exemption applies if the effect of the refining process is to remove novel DNA or novel protein, and the GM food is not listed in section S26—3 as being subject to the condition that its labelling must comply with section 1.5.2—4 of the Code. Paragraph 1.5.2—4(1)(b) of the draft variation achieves the same effect; that is, a GM food would not be subject to the labelling requirements in section 1.5.2—4 if it does not contain novel DNA or novel protein and is not listed in section S26—3.

5. Non-regulatory measures

5.1 Establishment of a new advisory committee

In the 1st CFS, FSANZ proposed to establish a new advisory committee to serve as a point of enquiry in situations where a product developer remained uncertain about whether their NBT food product would be a GM food under the Code, and therefore require an application to FSANZ. Consultation with the proposed advisory committee would be voluntary.

The advisory committee was proposed to be modelled on the Advisory Committee for Novel Foods (ACNF)[28] where membership is drawn from both the jurisdictions and FSANZ. The ACNF makes recommendations about whether a food is a novel food. Its recommendations are not legal advice and are not legally binding. The recommendations are only intended to help enquirers make their own decision about whether they should apply to seek an amendment to the Code.

5.1.1 Submitter feedback

There were mixed views from government, the research sector and industry submitters on the establishment of an advisory committee.

Some submitters from the government and research sector expressed support for an advisory committee, and made suggestions for its membership, as well as the development of a tool to assist the committee with applying a consistent assessment process in making a recommendation about whether a food is a GM food.

[27] **Flavouring substance** means a substance that is used as a food additive to perform the technological purpose of a flavouring in accordance with this Code (subsection 1.1.2—2(3) of Standard 1.1.2 Definitions used throughout the Code).
[28] Advisory Committee for Novel Foods – https://www.foodstandards.gov.au/business/novel/novelcommittee

In contrast, industry submitters did not support an advisory committee and raised a number of issues and questions relating to: the legal standing of the committee's recommendations; funding (i.e. would it be cost recovered?); the make-up and expertise of committee members; what data and information would need to be submitted; how confidential information would be managed; and whether the consultation process itself would be confidential, noting that some developers may not want this disclosed to their competitors. It was also noted that if FSANZ simplified its proposed approach to the definitions, as suggested by some submitters, this would eliminate or significantly reduce the need for an advisory committee.

5.1.2 FSANZ response

The advisory committee was proposed by FSANZ to support the implementation of revised definitions, and to assist product developers to navigate the product-based exclusion criteria proposed in the 1st CFS, which FSANZ acknowledges were complex.

While some submitters did express support for the establishment of an advisory committee, FSANZ notes the stakeholder group who the advisory committee was primarily intended to assist were not supportive and unlikely to use it. Now that FSANZ is proposing a simpler approach, with clear and objective criteria, there is less need for the establishment of an advisory committee.

Given the resources to establish and maintain an advisory committee, and that it is unlikely to provide any additional benefit to product developers, or be required given the revised approach, FSANZ has decided not to pursue the establishment of an advisory committee.

5.1.3 Conclusion

FSANZ has concluded a need no longer exists for an advisory committee.

5.2 Development of guidance material

In the 1st CFS, FSANZ proposed the development of guidance material, the primary purpose of which would be to assist product developers to comply with the Code, and to aid their interpretation of relevant exclusion criteria to determine if their product qualified for exclusion from the revised GM food definition. FSANZ proposed the guidance material would include information about:

- the intent of each of the proposed criteria;
- the types of analyses/data that would be needed to determine if a food meets each criterion, including what evidence should be retained to demonstrate compliance; and
- provide relevant examples for different types of organisms and food products.

5.2.1 Submitter feedback

There was support for the development of guidance material from the government, research, and industry sectors with suggestions being made about the types of information that would be useful to include. For example, the scientific rationale for each exclusion, requirements for compliance, examples of different scenarios, and decision trees. Product developers stated that clear and detailed guidance material would assist them to determine the compliance of their specific product without the need to consult with FSANZ or the proposed advisory committee.

5.2.2 FSANZ response

FSANZ notes the strong support for the development of guidance material from a range of

submitters, but questions the need for such guidance now the approach has been simplified to include clear objective criteria in the proposed new GM food definition, including explicit exemptions for certain foods and substances. In addition to providing a much clearer definition, this 2nd CFS also includes descriptions of the regulatory intent and the rationale for each of the elements of the proposed new definition (sections 2.3.2 – 2.3.5).

While one of FSANZ's functions under the FSANZ Act is to develop guidance to assist in the interpretation of the Code, it is not a statutory requirement or directive that FSANZ *must* do so. The purpose of this provision in the FSANZ Act is to assist in harmonising interpretation of the Code across jurisdictions, with the intent being that any such guidance would be issued on behalf of the jurisdictions once they had endorsed its content.

It is important to note that when FSANZ publishes a new or varied food regulatory measure, this will be accompanied by a plain English guide to the Code in the form of an explanatory statement. Such an explanatory statement is provided in Attachment B to this report.

The need for further explanatory information in the form of guidance directed to industry or regulators might be considered by the Implementation Sub-committee for Food Regulation (ISFR) once the Food Ministers Meeting has made a decision to endorse a draft food regulatory measure approved by FSANZ.

Should feedback indicate certain aspects remain unclear, FSANZ will consider whether to address this by further refining the proposed new GM food definition, providing additional clarifying information in the form of guidance (developed at the request or in consultation with and endorsed by jurisdictions), or both.

Consultation Question 3. Guidance material

3. Do you believe additional clarifying information would be helpful to accompany the proposed the new definitions? If yes, what additional information would be most helpful?

5.2.3 Conclusion

Given the change to the approach, FSANZ has yet to reach a conclusion about whether guidance material would be useful, and if so, what form that may take. FSANZ will undertake further assessment on the need for additional clarifying information once submitter feedback is received about the clarity or otherwise of the proposed GM food definition.

6. Consumer research

6.1 Overview of research

Maintaining a high degree of consumer confidence in the quality and safety of food is one of FSANZ's key objectives. In order to gain a greater understanding of general community attitudes towards NBTs and GM foods, FSANZ supplemented the information gained through the consultation process with three pieces of bespoke consumer research. These were:

- a systematic literature review on consumers' awareness, knowledge, risk perceptions and behaviours in relation to the use of NBTs, including genome editing, for food production;
- new empirical research using focus groups to investigate consumer awareness, knowledge, and attitudes to NBTs in Australia and New Zealand; and
- a nationally representative survey of consumers' perceptions of and attitudes towards GM foods and NBTs used in food production.

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

In the following section, the key findings from each of these pieces of research are briefly summarised, followed by overall conclusions from the consumer research.

6.2 Summary of findings

6.2.1 Systematic literature review (2021)

In July 2021, FSANZ commissioned the Australian National Centre for the Public Awareness of Science at the Australian National University to undertake a systematic literature review on consumers' response to the use of NBTs in the production of food. The review included 146 studies, the majority of which were based on populations outside of Australia and New Zealand. The full report is available on FSANZ's website.[29] Key findings are outlined below.

Knowledge and awareness

- Self-reported knowledge and awareness of NBTs is low in Australia, and has not been explored in New Zealand. Levels of knowledge and awareness of NBTs are lower than for GM. This is also the case in the international context.
- People who were younger and/or more highly educated were more likely to report knowing more about NBTs. Gender was not associated with reported knowledge.
- Australians trust government agencies (CSIRO, NHMRC[30] and FSANZ) to provide information about gene technology. Industry groups and overseas regulators were least trusted.

Attitudes, beliefs and perceptions

- There is little evidence available, however Australian attitudes towards NBTs appear more positive than attitudes towards GM. This is also the case internationally.
- Levels of acceptability differ depending on the technique. Cisgenesis (defined as "introducing the genes of a plant of the same species") and gene editing (defined as "making a small change to an existing gene within a plant") are considered most acceptable, while transgenesis (defined variously as "introducing the genes of… a plant of a different species / a bacterium / an animal") is considered less acceptable, with transgenesis from more distantly related donor species the least acceptable.
- The purpose to which NBTs are put also affects their level of acceptability. People are more accepting of uses that provide benefits for human health and the environment, and less accepting of uses that primarily benefit industry.
- There are inconsistent findings regarding the demographic characteristics most associated with support for NBTs. Age, gender and education have all been found to be both significant and non-significant predictors of support for NBTs.

Behavioural responses

- In Australia, one study found there was no significant difference between consumers' willingness to pay or consume NBTs vs GM foods. Consumers' willingness to

[29] Consumer responses to the use of NBTs in the production of food – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques
[30] NHMRC – The National Health and Medical Research Council

consume food produced using either NBTs or GM was driven by perceptions of safety, environmental benefits and previous experience.

- Internationally, consumers were willing to pay more for food produced using NBTs than GM, but less than for food produced using conventional means. This was true for both processed and whole foods.

6.2.2 Focus groups (2021)

In July 2021, FSANZ commissioned the Food Values Research Group at the University of Adelaide to undertake focus groups on consumers' responses to the use of NBTs in food production. Two asynchronous, online focus groups were undertaken over the course of three days with 79 participants (49 from Australia and 30 from New Zealand). The full report is available on FSANZ's website.[31] Key findings are outlined below.

Knowledge, information and awareness

- Self-reported knowledge and awareness of NBTs or GM is relatively low. Levels of knowledge and awareness of NBTs are lower than for GM.
- Australian participants reported a higher degree of knowledge about gene technology and NBTs than New Zealanders. New Zealand participants reported a higher degree of knowledge about GM than Australians.
- Participants wanted more information from independent, trusted sources about:
    - how NBTs would be used;
    - longer term effects on organisms, the environment, humans and the resulting food products;
    - whether conventional varieties of food would be maintained and/or whether the technologies would be reversible; and
    - whether the use of these technologies would result in increased costs to farmers or consumers.
- FSANZ was considered to be a trusted source of information, however to maintain credibility it was important for any information provided to be neutral.

Attitudes, beliefs and perceptions

- Participants did not view foods produced by NBTs as equivalent to conventional food, but on a spectrum with food produced using other forms of gene technology.
- The purpose for which NBTs are used matters. While participants raised general questions or concerns about the long-term effects of NBTs on the organisms, environment and humans, participants' attitudes differed according to the purpose, risks and benefits associated with a particular application of NBTs.
- The majority of participants were generally positive about the five potential applications of NBTs presented in the focus groups. Use of NBTs in crops (rather than in animals) and for health or environmental benefits (rather than cosmetic or purely economic benefits) tended to be the most accepted.
- There was, however, a level of distrust in the motivations of companies or producers that employ NBTs. Participants were concerned that some applications with potential environmental or animal welfare benefits could instead be used to increase yields or

[31] Focus groups on consumers' responses to the use of New Breeding Techniques in food production – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

profits in a way that is ultimately harmful to the environment or animals.

- There was also a strong feeling that NBTs did not present the answer to systemic issues such as climate change or broader concerns about current agricultural practice and that 'lower tech' solutions should be considered.

Attitudes towards regulation

- There was a lack of knowledge about current regulation of GM foods, and regulation was rarely spontaneously raised by participants. However, when directly asked, participants felt that more regulation was a desirable outcome to ensure that NBTs were used in a manner in line with public expectations.
- Some participants also occasionally spontaneously expressed a preference for clear labelling of gene technology-related products. However, not all participants thought it was necessary or desirable where there was a lack of novel DNA in the final product.

6.2.3 Consumer survey (2022)

In July 2022, FSANZ undertook a survey to test the findings of the literature review and focus groups on a large, nationally representative sample. The survey sampled 1,000 Australians and 500 New Zealanders aged 18+ years, and was nationally representative by age, gender, and (Australia only) location. As the literature review and focus groups found that consumers tended not to distinguish between GM and NBTs but instead see them on a spectrum, the survey used the term GM foods to enhance its understandability. The full report is available on FSANZ's website.[32] Key findings are outlined below.

Knowledge, information and awareness

- Consumers have relatively low self-reported levels of knowledge about GM foods. Being university-educated and from New Zealand were the strongest predictors of having a higher level of self-reported knowledge about GM foods.
- Of those who reported knowing something about GM foods, two-thirds defined GM using a description that most closely aligned to genome editing.
- Around half of respondents wanted more information about GM foods, with government websites and newspapers or news websites the preferred sources.

Attitudes, beliefs and perceptions

- GM foods are not a top-of-mind food safety issue for the vast majority of consumers. Only 20% selected it as a top 3 food safety issue out of 11 options, despite a substantial minority believing that GM whole foods are already for sale in Australia/New Zealand.
- However, when asked, nearly half of respondents had some level of concern regarding GM foods. Key concerns were safety to humans, the trustworthiness of GM producers or scientists, environmental impact and animal welfare.
- Support for GM foods as a concept was mixed, with 30% supportive, 30% neutral, and 40% opposed. However, the uses to which GM technology is put matters. Respondents' views on specific applications were often substantially more positive than their view on GM foods overall. Respondents tended to be more supportive of GM applications in crops (rather than in animals) and for health or environmental benefits (rather than purely economic benefits).

[32] Consumer Survey Report: Consumers' perceptions of and attitudes towards genetically modified foods – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

- While being younger, male and tertiary educated was associated with higher levels of support for GM foods, trust in GM producers and scientists was a much stronger predictor of level of support for GM foods.

6.2.4 Consumer Insights Tracker (2023 and 2024)

6.2.4.1 Wave 1 (2023) results

In April 2023, FSANZ undertook its inaugural CIT, an annual survey of a nationally representative sample of approximately 2,000 consumers (1,200 from Australia and 800 from New Zealand). In Wave 1 of the survey, respondents were asked about their awareness of and confidence in gene-edited (GE) fruit and vegetables and gene-edited meat and dairy, as well as their top food safety concerns, which included GM foods as a response option. The full report is available on the FSANZ website.[33] Key findings relevant to P1055 are outlined below.

- Consumers generally have low levels of awareness of GE fruit and vegetables, meat or dairy. 69% had either never heard of or knew little/nothing about GE fruit and vegetables, and 77% in respect of GE meat or dairy.
- Most consumers indicated they would not be confident in the safety of GE fruit and vegetables (57%) or GE meat or dairy (63%) if they became available for sale in Australia/New Zealand.
- GM foods or food ingredients was the second-least selected out of nine food safety concerns, with 20% of consumers selecting it as one of their top 3 concerns.

6.2.4.2 Wave 2 (2024) results

In April 2024, the second wave of the CIT was run. In Wave 2 of the survey, respondents were asked about their levels of awareness of and confidence in the GM banana that had recently been approved by FSANZ[34] and food produced from precision fermentation (which involves the genetic modification of yeast, bacteria or fungi). It is important to note that the GM banana was not for sale at the time of the survey. The question around food safety concerns that was asked in Wave 1 was also repeated. The full report is forthcoming. Preliminary findings relevant to P1055 are outlined below.

- Consumers generally have low levels of awareness of the GM banana or food produced from precision fermentation. 80% of consumers had either never heard of or knew little/nothing about the GM banana, while 77% of consumers had either never heard of or knew little/nothing about precision fermentation.
- Around half of consumers indicated they would not be confident in the safety of the GM banana (52%) or food produced using precision fermentation (45%) if they became available for sale in Australia/New Zealand.
- If the GM banana became available for sale, 34% of consumers said they would purchase and consume it, 40% said they would not, and 27% were unsure.
- GM foods or food ingredients remain one of the least selected out of nine food safety concerns, with 23% of consumers selecting it as one of their top 3 concerns.

[33] Consumer Insights Tracker 2023: Technical Report – https://www.foodstandards.gov.au/science-data/social-science

[34] Application A1274 – Food derived from disease-resistant banana line QCAV-4 – https://www.foodstandards.gov.au/food-standards-code/applications/A1274-Food-derived-from-disease-resistant-banana-line-QCAV-4

6.3 Conclusions

A number of common themes emerge across the findings from the three pieces of bespoke consumer research undertaken for P1055 (i.e. the literature review, focus groups, and consumer survey) as well as the data obtained from the CIT.

Australian and New Zealand consumers have low levels of awareness of and knowledge about NBTs

Australian and New Zealand consumers have consistently reported a low level of knowledge and awareness about NBTs across all of the research undertaken. The consistency evident across a range of different studies, including those with large, nationally representative samples, gives confidence in this finding.

However, while this level of knowledge has been reported as being lower than GM, it is important to consider this in the context of the lack of distinction that consumers tend to make between the definitions of NBTs and GM, seeing these as different forms of technology on a single spectrum (discussed further below). This may mean, as was evidenced in the consumer survey of perceptions around GM food, that people understand 'GM' in terms of techniques that are actually more aligned with NBTs (such as genome editing). The research reviewed has not generally asked consumers about their interpretation of these terms, and caution must therefore be taken in the reported *relative* level of knowledge and awareness of NBTs compared to GM, although the overall level of knowledge and awareness has generally been low for both.

Consumers tend to view NBTs more positively than older forms of GM, but do not see them as equivalent to conventional food

Findings from the literature review and focus groups suggest that most consumers currently have a process-based understanding of NBTs, seeing them on a spectrum with GM as a more targeted version of older GM techniques. While this tends to lead to more positive attitudes towards NBTs compared to GM, it also means that consumers generally do not perceive food produced using NBTs as equivalent to conventional food, even if the resulting product is similar to what could have been achieved through conventional means.

This perception follows through into the prospective behaviour of consumers towards food produced using NBTs versus GM food and food produced using conventional means. Internationally, five different studies found that consumers were willing to pay more for food produced using NBTs than GM, but less than food produced using conventional means.[35]

Australian and New Zealand consumers have a nuanced perspective on the use of NBTs in food production, with greater levels of support for applications with clear health and/or environmental benefits

A key finding across all three pieces of research was that the uses to which NBTs are put matters. Consumers had a nuanced perspective on the use of NBTs in food production, with their level of support differing according to the purpose and perceived risks and benefits (and their distribution) associated with a particular application of NBTs.

The research consistently found that consumers tended to be more accepting of the use of NBTs in crops rather than animals, and for health and/or environmental benefits rather than

[35] The systematic literature review found that, in Australia, there was no difference in consumers' willingness to pay for or consume NBT vs GM foods. However, this finding was based on only one study that examined willingness-to-pay in the context of glyphosate-resistant rice, and FSANZ's GM consumer survey found that glyphosate-resistance was not a trait that was highly valued by consumers (also see the finding on consumers' nuanced perspectives on use of NBTs in food production).

for cosmetic or economic benefits. However, the focus groups found that this general trend was nuanced by a certain level of distrust in the motivations of companies or producers that employ NBTs, which consumers thought may undermine apparent societal benefits.

The importance of trust in producers and scientists was also borne out in FSANZ's GM consumer survey, which found that people who had higher levels of trust in GM producers and scientists were more likely to be supportive of GM foods. It appears that consumer acceptance of food produced using NBTs may be in large part contingent upon scientists and producers ensuring they are understood to be operating in good faith, and in ways that have an explicit and realised benefit for wider society. In the focus groups, when directly asked, a majority of respondents suggested that regulation was desirable to ensure that NBTs were used in a manner in line with these kinds of public expectations. However, levels of understanding of current regulation of GM foods were consistently low across the research.

Although not a top-of-mind food safety issue, a substantial proportion of Australian and New Zealand consumers still have concerns about the long-term effects of using gene technology in food production

GM foods and food ingredients have consistently been one of the least selected food safety issues among a nationally representative sample of Australian and New Zealand consumers across three separate surveys (in 2022, 2023, and 2024). Across these surveys, 20-23% of respondents selected GM foods as a top three food safety issue out of 9 or 11 options.

However, this does not mean that Australian and New Zealand consumers do not have concerns about this technology. In the GM consumer survey, when directly asked, nearly half (46.7%) of respondents indicated that they had some level of concern about GM foods. Concerns were also raised during the focus group discussions, and around half of respondents in two separate waves of the CIT indicated a lack of confidence in in the safety of GE and GM food and food produced from precision fermentation if it became available for sale in Australia or New Zealand.

Key consumer concerns centre around the long-term safety for humans, the long-term environmental impact, the consequences for animal welfare and the trustworthiness of GM producers or scientists (see above finding on the latter).

Consumers want more information about food produced using gene technologies, and government agencies and websites are a trusted source of information

A substantial proportion of consumers appear to want more information about the use of gene technology, whether GM or NBTs, in food production. Key areas in which they wanted more information was: how NBTs would be used; the long-term effects on organisms, the environment, and humans; whether conventional varieties would be maintained or the technology would be reversible; and whether the technology would result in increased costs to farmers and/or consumers.

Government agencies, including FSANZ, were considered to be an independent and credible source of information about gene technology used in food production. However, it is critical for any information provided to be perceived as neutral rather than biased in favour of gene technology for that credibility to be maintained.

Overall conclusions

Proposal P1055 represents a paradigm shift away from the process-based understanding and regulation of gene technology used in food production to an outcomes-based approach. While consumers generally have quite low levels of awareness and knowledge about NBTs, it appears that current understandings tend to align more closely with a process-based

approach. Consumers tend to see food produced with NBTs on a spectrum with food produced using GM, rather than as being equivalent to conventional food. As a result of this process-based understanding, although not a top-of-mind food safety issue, a substantial proportion of consumers remain concerned about the long-term impact of these technologies on the environment, humans, animals, farmers' livelihoods and conventional food varieties.

Despite these concerns, consumers have a nuanced view of the use of NBTs in food production, with most consumers tending to support applications that have explicit benefits for human health and/or the environment. Long term acceptance of food produced using NBTs is thus likely to be contingent upon GM producers and scientists being understood to operate in good faith in ways that deliver these kinds of benefits broadly to society.

There appears to be an opportunity for consumer education. A substantial proportion of consumers want more information about the use of gene technology in food production, and consider FSANZ and other key government agencies such as CSIRO and the NHMRC to be trusted sources of information. It will be important to ensure any information provided is neutral, rather than biased in favour of gene technology, in order to maintain this trust and credibility.

It should also be noted when considering any form of consumer education that the scientific, outcomes-based understanding of food produced using NBTs as being potentially equivalent to conventional food may not find widespread agreement among the broader population, at least initially. It will therefore be important to consider attending to consumers' concerns about the long-term effects of using gene technologies from a process-based as well as an outcomes-based perspective.

7. Other relevant matters

7.1 Alignment of domestic regulations

The desire from stakeholders for alignment of domestic regulations related to gene technology has been a recurring theme throughout FSANZ's work on NBTs, including in response to the 1st CFS. Usually, the focus is on alignment between the definitions in the Code for GM food and the definitions for GMOs in the *Gene Technology Act 2000* (GT Act) and its regulations. FSANZ notes however that definitions in the HSNO Act and its regulations would also be a relevant consideration given Standard 1.5.2 applies in both countries.

In considering revised GM food definitions in the Code, FSANZ concluded the most appropriate approach would be to focus on managing potential food risks from GM food, as well as meeting FSANZ's obligations and statutory objectives under the *Food Standards Australia New Zealand Act 1991.*

7.1.1 Submitter feedback

Greater consistency and alignment of definitions between the Code, the GT Act and its regulations was again raised by some submitters in response to the 1st CFS. Submitters argued the lack of alignment of definitions in Australia has serious implications for industries dealing with products that may be classified as GM under the Code but not by the GT Act.

While some submitters raised this issue with the expectation that FSANZ would change its approach to align with the GT Act, there were other submitters who considered the FSANZ approach to be more risk proportionate. Some submitters therefore suggested the regulatory approach to GMOs should align with the direction FSANZ is taking.

7.1.2 FSANZ response

FSANZ acknowledges the legitimate desire for consistency between regulations in terms of what is captured as a GMO, and what is captured as a GM food, however cautions against consistency for consistency's sake, particularly if that produces outcomes that are not scientifically supportable.

FSANZ has previously concluded that aligning revised Code definitions for GM food to the definitions in the GT Act and its regulations would not be appropriate given the different objectives and risks to be managed under the GT Act and the Code. Alignment with the definitions under the GT Act is also not supported by the safety assessment undertaken by FSANZ as it would result in regulating some foods as GM on a process basis, even though the food is indistinguishable from conventional food.

FSANZ's approach to revising the definitions however shares the same high level aspirations being applied to modernising and future proofing the National Gene Technology Scheme in Australia. FSANZ also notes the New Zealand Government plans to update regulations for the use of gene technologies. This includes the establishment of an independent regulator within the Ministry of Business Innovation and Employment. The intent of the reform is to make the regulations risk-based and allow for greater use of genetic technologies within New Zealand.

As a result of these reforms, FSANZ expects the gene technology regulations in Australia and New Zealand, along with the GM food regulations that operate in both countries, will be brought into greater alignment progressively over time. FSANZ notes a process of gradual alignment over time is also occurring internationally (refer to section 7.2 below).

7.1.3 Conclusion

FSANZ is satisfied its objectives and approach to revising the GM food definitions are appropriate for managing potential food risks from GM food. FSANZ expects greater regulatory alignment will occur over time as relevant domestic regulations related to gene technology are progressively reformed.

7.2 International harmonisation and trade

As part of its assessment for the 1st CFS, FSANZ considered regulatory approaches to NBTs in other countries or regions. At that time, FSANZ noted the situation was highly dynamic but that there was an emerging trend towards regulatory approaches that allow for the exclusion of certain products from pre-market regulatory requirements. A common feature of these approaches was reliance on either similarity to the outcomes of conventional breeding, or the absence of foreign or recombinant DNA, as a basis for exclusion.

7.2.1 Submitter feedback

Several submitters stressed the importance of seeking alignment with international regulations, while recognising that complete international harmonisation is unlikely to be achievable. These submitters noted that a number of Australia's trading partners are either already excluding certain NBT products from regulation or are in the process of revising their regulations to take a more risk-proportionate approach to NBTs. Some of these submitters expressed concern that a lack of harmonisation with trading partners would stifle innovation in Australia and reduce its global competitiveness.

In contrast, some submitters expressed concern that taking a deregulatory approach to NBTs could negatively impact trade with partners who regulate NBTs as GMOs. One submitter expressed the view that the deregulation of NBT products in other countries should not

prevent Australia and New Zealand from continuing to regulate NBTs as GM foods, and that trade considerations should be deprioritised relative to consumer expectations.

7.2.2 FSANZ response

FSANZ has continued to monitor the situation internationally and notes that since the 1st CFS, a number of countries have either formalised their approach to NBTs or have provided updates on their direction. Worldwide, countries are opting to reduce or have no government oversight of NBT food with the same product characteristics as conventional food. This is wholly consistent with the direction being taken by FSANZ.

An overview of regulatory approaches around the world is provided in SD1, along with a detailed description of more recent developments that have occurred since the 1st CFS.

Key recent highlights include:

- *European Union* – In 2024 the European Parliament voted in favour of a European Commission proposal to introduce simpler and less onerous regulatory requirements (under EU Directive 2001/18/EC) for plants modified using new genomic techniques (NGTs; targeted mutagenesis and cisgenesis) including derived food and feed products. Under the proposal, plants derived using NGTs that could also occur naturally or by conventional breeding will be exempted from the requirements of the GMO legislation. This represents a significant change in approach following the 2018 European Court of Justice ruling that all genome edited organisms are GMOs.

- *United Kingdom* – The *Genetic Technology (Precision Breeding) Act* passed into law in England in 2023. The Act defines a precision bred organism (PBO) as a plant or vertebrate animal produced by precision breeding techniques such as gene editing, that could have been produced by traditional breeding processes. The main outcome of the Act is that PBOs are no longer subject to regulation as GMOs.

  Late in 2023, the Food Standards Agency (FSA) consulted on a policy proposal for a new framework for the regulation of PBOs used for food and feed under the new Act. Following the consultation, the FSA is proceeding with the implementation of secondary legislation that will include a two-tiered approach to the regulation of PBOs. For Tier 1 PBOs, where potential safety risks are understood, no application will be required although they will still need to be notified to the FSA. Tier 2 PBOs, which require more regulatory scrutiny, will require an application to the FSA. Both Tier 1 and Tier 2 PBOs for use in food and feed will however be subject to authorisation and required to be listed on a public register before they can be placed on the market.

- *United States* – In the United States, there is no Food and Drug Administration (FDA) pre-market approval requirement for new plant varieties (NPVs) as a class. Product developers of new GM plant varieties however routinely consult with the FDA under their voluntary pre-market consultation programme for foods from NPVs.

  In 2024, the FDA released new non-binding guidance for developers of foods derived from genome edited plants, outlining two voluntary processes that developers may use to inform the FDA of steps they have taken to ensure the safety of their product. The guidance recommends developers undertake either a pre-market consultation or a pre-market meeting. A pre-market consultation is recommended when genome editing results in changes that may raise safety questions or regulatory considerations that put the legal status of the food in question.[36] Where the genome editing does not raise safety questions according to the FDA guidance, they strongly

[36] Detailed examples of what changes would raise safety questions are provided in the guidance.

recommend that developers schedule a pre-market meeting to inform the FDA about the type of food that will be entering the market and the steps they have taken to ensure safety.

In relation to trade, the emerging global picture is that more and more countries are aligning their regulatory approaches, with FSANZ's proposed approach also aligning. In light of the continuing trend towards international alignment in regulatory approaches, any concerns raised about negative impacts on trade are increasingly becoming moot.

7.2.3 Conclusion

FSANZ's approach, as revised in this 2nd CFS, aligns internationally with regulatory approaches that have been adopted, or are proposed to be adopted, by other countries around the world.

8 Risk Communication

8.1 Consultation

Consultation is a key part of FSANZ's open and transparent standards development process. Targeted consultation with key stakeholders has informed assessment of this proposal and public submissions were called to assist consideration of the proposal and the proposed approach (see section 1.7).

Subscribers and interested parties were notified about the 1st CFS via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. In addition, a webinar about the proposed approach at the 1st CFS was held on 12 November 2021 to assist stakeholders make submissions. A similar approach will be taken for the release of this 2nd CFS, including a webinar to further engage interested parties.

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.

FSANZ is consulting on this proposal using the FSANZ Consultation Hub, built on the Citizen Space platform. Submissions on this proposal should be made using the FSANZ Consultation Hub (https://consultations.foodstandards.gov.au/). The consultation will be open for six weeks.

FSANZ has provided consultation questions in this CFS document and Supporting Document 2 to guide submissions. A consolidated list of consultation questions is presented at Appendix 2.

8.2 World Trade Organisation (WTO)

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures may be inconsistent with any existing or imminent international standards or where 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 repeal the definitions for 'food produced using gene technology' and 'gene technology' and replace them with a new definition for 'genetically modified food' 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.

Amending the Code to include a new definition for GM food is supported by a scientific assessment. While this amendment reflects regulatory approaches that have been adopted, or are proposed to be adopted, by other countries around the world, there may be differences with some countries.

Therefore, a notification has been made to the WTO in accordance with Australia's and New Zealand's obligations under both the Technical Barriers to Trade (TBT) and Application of Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO members to comment on the proposed amendments.

9 Obligations under the FSANZ Act

When assessing this proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

9.1 Section 59

9.1.1 Consideration of costs and benefits

The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59 (2)(a)).

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. This analysis considers the costs and benefits of revising the definitions for 'food produced gene technology' and 'gene technology' in the Code under the proposed approach.

For the full analysis, refer to Supporting Document 2 (SD2).

FSANZ will review its assessment of costs and benefits in light of the feedback received in response to this 2nd CFS and then prepare a Decision Regulation Impact Statement (DRIS). The DRIS will inform a final decision on whether to approve, amend or reject the draft variations proposed in this CFS. Before that final decision is made, the DRIS will be submitted to the Office of Impact Analysis (OIA) to confirm the quality and adequacy of the DRIS's analysis, and to review the DRIS for compliance under the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies (OIA, 2023).

The OIA exempted FSANZ from the need to prepare a formal Consultation RIS in relation to the regulatory change proposed (reference number OBPR22-03666). The OIA was satisfied with the consultation undertaken for this proposal.

Conclusions from cost benefit considerations in SD2

The food industry is expected to benefit from improved regulatory certainty provided in the proposed approach, including clear pathways to market for GM and NBT food which may incentivise investment and greater innovation. In the long term, consumers may benefit from cheaper and higher quality food products as food businesses compete to maintain market share.

FSANZ's assessment is that the benefits that would arise from the measures proposed by FSANZ are expected to outweigh the costs involving familiar with the changes in the Code. However, information received from this 2nd CFS may result in FSANZ arriving at a different conclusion.

9.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal.

9.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

9.1.4 Any other relevant matters

Other relevant matters are considered below.

9.2 Subsection 18(1)

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

9.2.1 Protection of public health and safety

The proposed approach protects public health and safety by continuing to require that GM foods are subject to pre-market safety assessment and approval under the Code.

The exclusion of low risk foods from pre-market assessment and approval as GM foods is supported by FSANZ's safety assessment and its conclusions. Excluded foods that are equivalent in risk to conventional foods are still required to be safe and suitable and comply with the relevant provisions of the Code. A food that is excluded from regulation as a GM food but has a change in characteristics, which is considered sufficient to warrant a safety assessment by FSANZ, may be subject to regulation as a novel food.

9.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Approved GM foods will continue to be subject to product-based mandatory GM labelling requirements to enable informed consumer choices (see section 4).

9.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues to date.

9.3 Subsection 18(2)

FSANZ has also had regard to:

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

FSANZ's risk analysis has considered the best scientific information currently available. FSANZ had regard to prior assessments undertaken as part of the previous NBT review (see subsection 1.7.1), the scientific assessment that was undertaken for the 1st CFS (see section 2.1), additional information obtained from submitters to the 1st CFS, and information obtained from consumer research (see section 6).

FSANZ has used this information to inform decisions regarding the proposed amendments set out in the draft variation (Attachment A).

- **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 7.2 and Supporting Document 1). FSANZ's approach, as revised in this 2nd CFS, aligns internationally with regulatory approaches that have been adopted, or are proposed to be adopted, by other countries around the world.

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

The proposed risk proportionate approach to the regulation of GM foods, which includes clear definitions and is aligned internationally, will contribute to a more efficient food industry by reducing regulatory uncertainty, facilitating innovation and supporting international trade in products.

Consistent with Australia's and New Zealand's obligations under the WTO, FSANZ will make a notification under the TBT and SPS agreements.

- **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[37] is relevant to NBTs, however it does not apply in the case of this proposal as the current approach to GM labelling is out of scope. Therefore, NBT food that is a 'GM food' will be subject to the same labelling requirements that currently apply to GM food.

10 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

11 Implementation

The draft variation is proposed to commence at gazettal.

The proposed variations to the six Standards and four Schedules are:

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

[37] Labelling of foods produced or processed using new technologies – https://www.foodregulation.gov.au/resources/publications/policy-guideline-labelling-food-produced-using-new-technologies

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

The variations related to Schedule 29 Special Purpose Foods relate only to those permissions for nutritive substances added to infant formula products that are currently defined as GM foods. The changes are administrative and there is no regulatory change to the permissions themselves. The transitional arrangements in place for changes to Schedule 29 under P1028 would apply.[38]

FSANZ is interested to receive feedback from submitters on whether the proposed approach to transitional arrangements presents any issues to food manufacturers or enforcement agencies.

12 References

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

Haroldsen VM, Szczerba MW, Aktas H, Lopez-Baltazar J, Odias MJ, Chi-Ham CL, Labavitch JM, Bennett AB, Powell AL (2012) Mobility of Transgenic Nucleic Acids and Proteins within Grafted Rootstocks for Agricultural Improvement. Front Plant Sci. Mar 2;3:39

Appendices

1. FSANZ response to issues raised in submissions to the 1st CFS
2. List of consultation questions

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

[38] See Section 7 of the Approval Report for P1028 - Infant Formula – https://www.foodstandards.gov.au/food-standards-code/proposals/P1028

Appendix 1: FSANZ response to issues raised in submissions to the 1st CFS

Table A lists all submitters to the 1st CFS.

Tables B-F compile submitter comments and FSANZ responses to issues raised.

List of tables

Table A. Submitters to the 1st CFS

Submitter	Abbreviation
Agcarm	ACM
Auckland GE-free Coalition	AGEFC
Australian Beverages Council Limited	ABCL
Australian Organic Limited	AOL
Australian Seed Federation	ASF
Barley Australia	BA
BASF	BASF
Buy Pure New Zealand	BPNZ
Chr. Hansen	ChrH
Consumers SA	CSA
Crop Life Australia	CLA
CSIRO	CSIRO
EuropaBio	EUB
Fonterra Co-operative Group Limited	FCG
GE Free NZ	GEFNZ
Grain Trade Australia	GTA
Horticulture New Zealand Incorporated	HortNZ
Institute of Health and Environmental Research Inc.	IHER
InterGrain	IG
International Flavors & Fragrances Inc.	IFF
Centre for Integrated Research in Biosafety	INBI
Joint submission Australian Academy of Science & Australian Academy of Technology and Engineering	Academies
Joint submission from Friends of the Earth and Gene Ethics	FoE & GE
Joint submission from Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	VicDoH & VicDJPR
La Trobe Institutional Biosafety Committee	LTIBC
Ministry for Primary Industries New Zealand	MPI
Murdoch University Perth	M.U
New South Wales Food Authority	NSWFA
New Zealand Beverage Council	NZBC
New Zealand Food and Grocery Council	NZFGC
Novolait Aotearoa Limited	NAL
Organic industries of Australia Ltd	OIA
Physicians and Scientists for Global Responsibility	PSGR
Plant and Food Research	PFR
Private Individuals	–
Queensland Health	QLDH
Sustainability Council of New Zealand	SCNZ
Sustainable Agriculture & Communities Alliance	SACA
The Life Sciences Network	LSN
U.S. Embassy, Canberra	USEC
Campaigns	–

Table B. Excluding low risk foods from a revised definition

Issue		Comments	Submitter(s)	FSANZ Response
Risk and safety				
1.	**Safety assessment of NBT foods**	These submitters stated that all NBT foods must undergo rigorous independent testing e.g. animal feeding studies, human trials, whole genome sequencing and/or additional 'omics' analyses before their safety can be determined.	FoE & GE; CSA; PSGR; SACA; BPNZ; GEFNZ; OIA; IHER; AGEFC; Private individuals – SF; SH	FSANZ acknowledges submitter concerns regarding the safety of NBT foods and their desire for rigorous independent testing. FSANZ does not agree however that "rigorous independent testing" of the type specified by the submitters is either necessary or appropriate to establish the safety of a food. FSANZ undertook a detailed a safety assessment of the types of genome changes that are introduced using NBTs, and found in many cases these would be equivalent to those introduced through conventional breeding or that occur in nature. In these cases derived food products can be considered as safe as those derived through conventional breeding. Since that assessment, FSANZ has not identified any new information that would justify all NBT foods being subjected to the type of testing suggested by the submitters. FSANZ notes such testing is also not considered necessary as part of its pre-market safety assessment of GM foods.
		This submitter expressed a desire for NBT foods to be subject to post-market surveillance for any potential effects on human or animal health (e.g., as part of an epidemiological study) and to subsequently withdraw	IHER	FSANZ considers it unnecessary and also impractical to undertake post market surveillance of NBT foods. FSANZ notes such surveillance is also not undertaken for existing approved GM foods.

Issue		Comments	Submitter(s)	FSANZ Response
		NBT foods which are found to be potentially dangerous. The mechanism for enabling this surveillance is labelling.		FSANZ undertook a comprehensive safety assessment which supports the exclusion of certain NBT foods from pre-market assessment and appoval as GM foods. This is because such foods are considered to be as safe as conventional food. In relation to an epidemiological study, FSANZ notes that many health effects have complex causes. It is unlikely observational epidemiological studies could establish causation against the background of health effects resulting from diets made up primarily of conventional foods.
		These submitters expressed the view that conventional foods are not a suitable benchmark to assess the risk of NBT foods.	INBI; CSA	The suitability of conventional foods as a benchmark for assessing the safety of NBT foods was considered in detail by FSANZ for this proposal.[39] In summary – the scientific literature shows us that a large number of substantial genetic changes (both natural and induced, intended and unintended) have occurred or have been introduced to organisms using conventional methods. Despite these significant changes to genomes, food derived from these organisms has a long history of safe human consumption. There is overwhelming scientific evidence to support FSANZ's conclusion that conventional food with a history of safe use is an appropriate benchmark against which to compare other foods. In considering this issue, it is also important to note that: • making comparisons to conventional food as a

[39] Please see SD1 and SD2 in the first call for submissions – consultation documents available on the P1055 webpage – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Issue		Comments	Submitter(s)	FSANZ Response
				basis for establishing safety is a concept that is routinely applied to GM food and has been widely adopted by regulatory agencies around the world; • NBT foods are typically derived from conventional organisms
2.	**General safety concerns about NBT foods**	These submitters raised one or more of the following safety concerns about NBTs: 1. NBTs result in changes that are fundamentally different from naturally occurring mutations and there is an absence of long-term history of safe use. 2. Impacts of 'off-target' effects/unintended changes e.g. deletions, rearrangements, insertions, or changes in gene expression, in food produced using gene editing techniques. 3. Lack of criteria to distinguish high-risk from low-risk gene edits, and the rapid and accessible modification possible with NBTs reduces the opportunity for detection and elimination of unintended effects, therefore increasing the potential for harm relative to conventional techniques.	FoE & GE; CSA; PSGR; SACA; BPNZ; GEFNZ; AGEFC; INBI; IHER; AOL; Private individuals; Campaigns	FSANZ notes submitters' concerns and provides the following responses: 1. FSANZ does not agree. FSANZ comprehensively examined the types of mutations that both NBTs and natural mechanisms can introduce to food organisms in its safety assessment at the 1st CFS. No evidence for novel or unique types of genetic changes, either intended or unintended, was found. Nor has any such evidence been provided or identified since the 1st CFS was issued, The types of genetic changes introduced using NBTs are directly comparable to those that happen naturally, which have a long history of safe use. 2. 'Off-target' effects / unintended changes were considered in FSANZ's safety assessment for the 1st CFS. We concluded such changes are no different to those that arise through conventional breeding, GM techniques, or changes that occur spontaneously. No evidence has been provided or identified since the 1st CFS was issued that would warrant a different conclusion. 3. It is not possible to categorise gene edits as low or high risk. Please refer to SD1 from 1st CFS for further details. There are established

Issue		Comments	Submitter(s)	FSANZ Response
				strategies to minimise the occurrence or impact of these changes (e.g. backcrossing, screening and construct design). This is irrespective of the methods used to genetically improve an organism or how rapid or accessible modifications can be made. The potential for harm will be equivalent to conventional methods.
3.	**Issues relating to the safety of GM foods**	These submitters highlighted that no evidence of safety risks of GM foods has been identified after 25 years of strict regulations enforced by various different countries around the world. Some submitters argued that the current approach to pre-market GM food safety assessments is not risk-proportionate.	ASF; CLA; CSIRO; LSN; MU; Private individual- PB	While FSANZ agrees that no plausible safety issues have been identified for any GM food assessed over the last 25 years, the general regulatory approach to GM foods, including the approach to safety assessment, is out of scope of this proposal.
		These submitters raised concerns about the safety of GM foods, including toxicity and allergic reactions; loss of nutrition compared to non-GM foods; and antibiotic resistance.	Campaigns; Private individuals	All GM foods must undergo safety assessment and be approved before they are allowed in the food supply. The safety assessment considers the potential toxicity and allergenicity of any new proteins introduced into the food as well as the nutrient composition of the food. There is no evidence to suggest that GM foods have reduced nutritional value compared to conventional food. Antibiotic resistance genes are sometimes used as selectable markers in the laboratory stages of the genetic modification process. FSANZ has assessed the safety of such genes and does not consider their use represents a safety concern. FSANZ also notes

Issue		Comments	Submitter(s)	FSANZ Response
				the antibiotic resistance genes that are used encode resistance to antibiotics that are rarely used clinically. Further information about GM food safety assessment is available on the FSANZ website.[40]
Exclusion of certain NBT foods and refined ingredients from pre-market safety assessment as GM food				
4.	**Revision of the definitions to exclude certain low risk foods**	These submitters expressed broad support for the approach of excluding certain NBTs and refined ingredients from a revised definition for one or more of the following reasons: • This represents a more risk-proportionate regulatory approach than the current definition. • The opportunity to achieve clarity and certainty on the regulatory status and assessment requirements. • The approach accommodates existing and emerging technologies. • The likely reduced costs to the food industry and regulatory agencies by providing a defined framework for the determination of food safety risk for food produced using NBTs.	NSWFA; MPI; VicDoH & VicDJPR; QLDH; USEC; CSIRO; Academies; LTIBC; FCG; ChrH; IFF; LSN; IG; ABCL; BASF; ACM; CLA; ASF; NAL; NZBC; NZFGC; GTA; EUB; MU; PFR; Private individual -PB	Noted. FSANZ is now proposing a simpler approach to deliver equivalent outcomes to those described in the 1st CFS. Refer to sections 2.3 and 3.
		These submitters did not agree with the approach of product-based	FoE & GE; CSA; PSGR; SACA; BPNZ;	FSANZ acknowledges a large number of submitters disagreed with the exclusion of any NBT foods from

[40] Safety assessments of GM foods – https://www.foodstandards.gov.au/consumer/gmfood/safety

Issue		Comments	Submitter(s)	FSANZ Response
		exclusions for certain NBT foods. These submitters want all GM and NBT foods to be regulated and subject to pre-market safety assessment.	GEFNZ; INBI; IHER; AGEFC; OIA; Private individual-SF	a revised GM food definition. However, FSANZ maintains that sufficient justification exists to exclude NBT foods that are equivalent in characteristics and risk to conventional foods. Furthermore, no new evidence has been provided or identified since the 1st CFS was issued that would warrant a different conclusion This is discussed in more detail in section 2.1 of this CFS.
		These submitters preferred the *status quo* (i.e. retaining the existing definitions) for the following reasons: • No evidence that the existing rules lack clarity. • Strongly against deregulation of NBT foods.	AOL; SCNZ, Private individual-ML; Campaigns	FSANZ disagrees with the statement that there is no evidence for the lack of clarity of the existing GM food definitions. Such evidence was documented and discussed as part of FSANZ's review of NBTs that was concluded in 2019.[41] One of the key findings of the review was that current definitions are unclear with respect to NBTs which results in regulatory uncertainty about what foods would be GM foods under the Code. This finding was one of the main drivers for preparing Proposal P1055. FSANZ also received many submissions in response to the 1st CFS agreeing as lack of clarity with the current definitions exists that needs to be addressed. FSANZ acknowledges the strong opposition to the exclusion of any NBT foods from a revised definition but notes no scientific justification exists for capturing NBTs foods for pre-market safety assessment as GM foods when they are equivalent to conventional foods.

[41] Food derived using new breeding techniques – review – https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

Issue		Comments	Submitter(s)	FSANZ Response
5.	**Costs and benefits of the proposed regulatory approach**	These submitters highlighted the range of likely benefits and beneficiaries resulting from implementing the proposed approach, including: • Consumers – greater choice of products and contribution to food security through fast and increased production. • The food industry – increased clarity, reduced cost via fewer pre-market safety assessments, increased opportunity for innovation, and expansion of sale domestically and internationally. • Government and regulatory agencies – more targeted allocation of resources to areas with substantial risks.	QLDH; NZFGC	Noted. FSANZ has revised its consideration of the costs and benefits of this proposal to include more detail. Refer to SD2.

Issue		Comments	Submitter(s)	FSANZ Response
		These submitters noted: • The opportunities that new technologies such as gene editing can bring to breeders, scientists, farmers, and consumers, e.g. enhanced crops at a faster rate, allowing farmers and consumers to access these products and their benefits more quickly. • That the reduction of regulatory burden can enhance innovation and competitiveness of the agricultural industry as well as contribute to increased productivity and economic growth.	USEC; CSIRO; BA; MU	Noted FSANZ's consideration of the costs and benefits of this proposal is provided in SD2.
		This submitter noted that the costs to stakeholders resulting from the proposed amendment would largely relate to adopting the regulatory changes into operational documentation, training etc.	NZFGC	Noted FSANZ's consideration of the costs and benefits of this proposal is provided in SD2.

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter expressed the view that there has been insufficient quantitation of the public benefits that would be expected to result from the proposed approach, and that the potential costs to international trade have not been adequately weighed against these benefits.	SCNZ	Noted FSANZ's consideration of the costs and benefits (SD2) notes the difficulty in placing monetary value on many of the impacts involved in P1055. FSANZ welcomes additional information (e.g. studies or data) from submitters that may enable FSANZ to undertake a more quantitative impact analysis for incorporation into the Decision RIS. Potential impact on international trade is discussed in subsection 7.2.2 of this CFS.
6.	**Other issues related to the exclusion of certain foods from pre-market assessment**	This submitter expressed the view that NBTs should not trigger novel food safety assessments due to modified processes when the resulting food is equivalent to the conventional counterpart.	CSIRO	It is not FSANZ's intent that any NBT foods excluded under a revised GM food definition would automatically be captured as novel foods under the Code. Based on the types of NBT food products that have been produced to date using genome editing for example, FSANZ expects the majority would not be considered novel food under the Code. This is because they would either be considered equivalent to a traditional food, or if considered non-traditional, to have characteristics that would not require an assessment of public health and safety. This issue is discussed further in subsection 2.3.4 of this CFS.

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter stated that food derived from organisms containing foreign DNA should only be captured for pre-market safety assessment if the final characteristics of the food warrant such an assessment and not based on the process that may be applied to produce the food.	LTIBC	Under the revised approach proposed in this CFS, the use of a genetic modification process will not automatically mean a derived food product is a GM food. It will only be a GM food if that genetic modification process results in the insertion of novel DNA The insertion of novel DNA may or may result in altered characteristics in the final food but this would also be the case for existing GM foods. The overall intent of the approach is to capture the types of foods that are listed in Schedule 26 of the Code, with some exceptions. This is consistent with the original policy intent of Standard 1.5.2 and will result in consistent outcomes.
		These submitters expressed the view that exemption from pre-market assessments should allow for modifications that could have been achieved with ‘conventional’ breeding methods, including harnessing allelic variation, spontaneous mutations, and chemical or radiation-induced mutagenesis.	CSIRO; Academies; LTIBC	The revised approach increases clarity with respect to what is a 'GM food' for Code purposes without the need to provide explicit exclusions for products that could have been achieved through conventional breeding. FSANZ notes it would be a significant challenge for compliance and enforcement purposes to determine what 'could have been achieved', as this is very subjective.
		This submitter suggested that it could be beneficial to develop a new definition for ‘conventional’ breeding to assist with determining which products could have been achieved using these tools.	LTIBC	FSANZ has determined that an explicit definition for ‘conventional breeding’ would serve any useful purpose for the implementation or interpretation of the proposed new GM food definition. FSANZ believes it is already clear that a food that is not a GM food will either be a conventional food, or equivalent to a conventional food. Refer to subsection 3.4.1 for further discussion.

Issue		Comments	Submitter(s)	FSANZ Response
Regulatory oversight				
7.	**Regulatory oversight of NBT products**	These submitters expressed concerns over what they perceive as a lack of government oversight under the proposed approach. They argue that: exempting NBT products from assessment as GM foods will result in increased misuse of the technology, and increased harm; and that there would be no absolute certainty of safety.	INBI; IHER; OIA; AOL; CSA; SCNZ, FoE & GE	FSANZ does not agree with the submitters that full government oversight in the form of pre-market assessment of all NBT foods is necessary to ensure safety. Foods that are proposed to be excluded from a revised definition have been determined to be equivalent to conventional food in terms of their risk. All foods, whether they are captured for pre-market assessment or not, are still subject to regulatory oversight, as they are required to comply with relevant food standards and be safe and suitable before they may be sold.
		In contrast, these submitters emphasised the need for risk-proportionate and pragmatic regulation of NBT foods to allow the societal and economic benefits of these technologies to be realised. They stressed that pre-market safety assessment should only be required when scientifically justified – i.e. where there is a plausible hypothesis of a food safety risk.	CSIRO; LTIBC; ASF; MU	Noted. As highlighted in subsection 2.1.2 of this CFS, pre-market approval is typically reserved for those foods which, on evidence-based consideration, require an additional layer of public health and safety protection via a pre-market safety assessment.

Issue		Comments	Submitter(s)	FSANZ Response
8.	**Trust and confidence**	These submitters expressed one or more of the following concerns about FSANZ's approach to this proposal: • FSANZ will lose public confidence, and there will be a perceived lack of transparency and safety without full regulation of foods produced using GM technology. • FSANZ has a pro-industry bias, and has been excessively influenced by advice from biotechnology companies and academics that have conflicts of interest in developing its approach. • FSANZ has already made a decision on how to regulate NBT foods, and is now attempting to retroactively validate this decision via a formal consultation process.	FoE & GE; AGEFC; Private individual - SF	FSANZ notes these concerns. Maintaining a high degree of confidence in the quality and safety of food is a key objective of FSANZ. In matters concerning GM food FSANZ accepts that diverse and strongly held views exist and therefore that full support for any proposed approach is unlikely to be achieved. The best way FSANZ can maintain confidence in the food supply is to ensure that GM foods are safe and regulated in an open and transparent way according to the risk they pose, and that the regulatory approach is based on sound science and evidence. This is the approach FSANZ has taken to assessing this proposal. FSANZ has been carefully considering the regulatory problem posed by the emergence of NBTs since 2011 and has engaged and consulted extensively with a wide range of stakeholders and technical experts, as well as commissioning and undertaking consumer research. This long period of consultation has progressively shaped our thinking, culminating in an approach that FSANZ has assessed as best meeting its statutory objectives, and the specific regulatory objectives of this proposal.
		These submitters expressed a lack of trust in self-assessments of products by developers. Some submitters raised examples of instances in which unintentional genetic changes in NBT organisms have not been detected by developers.	FoE & GE; GEFNZ; AGEFC; INBI; IHER; SACA; Private individuals - SF, SH	FSANZ notes these concerns but reiterates it is the legal responsibility of those who trade in food to ensure their food is safe and suitable, according to the Code, irrespective of whether or not the food has been subject to pre-market safety assessment by FSANZ. The proposed new definition for GM food includes clear and objective criteria on which to determine if a food is a GM food. This will assist product

Issue		Comments	Submitter(s)	FSANZ Response
				developers to comply with the Code and jurisdictions to enforce Code requirements. FSANZ notes that unintentional changes occur with all forms of genetic modification, including conventional breeding. FSANZ's experience assessing GM foods over the last 25 years is that such changes typically do not result in any food safety concerns. Further information is available in the 1st CFS safety assessment.[42] No evidence has been provided or identified since the 1st CFS was issued that would change this view.
9.	**Intellectual property and competition**	These submitters raised one or more of the following concerns: 1. NBT-created traits are frequently patented or created using patented technologies. As a result, the trait is distinct in its characteristics and not identical to a trait found in nature. 2. Large-scale adoption of patented NBT foods and technologies will monopolise the food industry and accelerate risk when compared to conventional foods. 3. Monopolisation of agriculture by biotech companies.	GEFNZ; INBI; Private individuals - SF, SH	FSANZ notes these concerns. In relation to point 1, FSANZ has not implied that unique traits are not possible using NBTs. Rather, FSANZ has stated that a range of genome modifications are possible using NBTs and that some of these modifications can be similar to those introduced through conventional breeding or that can occur in nature. Patentability does not mean the trait could not be achieved via conventional breeding. Some conventionally produced traits are also protected by intellectual property rights, such as plant breeder rights. Native traits and mutations produced by conventional mutagenesis can also be covered by patents (Kock 2021). In relation to point 2 and 3, the potential monopolisation of the food industry and agriculture as a result of the large-scale adoption of NBTs is not directly relevant to FSANZ's consideration of this

[42] 1st CFS Supporting Document 1 – Safety Assessment – https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1055%20SD1%20Safety%20Assessment.pdf

Issue		Comments	Submitter(s)	FSANZ Response
				proposal. The impacts of the proposed approach on the food industry are discussed in section 5.2 of SD2.
		In contrast, this submitter pointed to the potentially democratising power of reducing the regulatory burden on developers of NBT products. They provided an example of a country (Argentina) where NBTs have been deregulated, and emphasised that since this change there have been far more research institutions/small and medium enterprises relative to large multinational companies commercialising these products.	MU	Noted.
10.	**Traceability and monitoring**	These submitters stated it is critical to trace and distinguish NBT foods from conventional foods. They demanded the implementation of a traceability mechanism and that NBT food undergo at least 5 years of post-commercialisation monitoring.	FoE & GE; GEFNZ; SCNZ; Private individuals.	In the 1st CFS, FSANZ noted that some NBT foods will not contain any novel DNA and will be indistinguishable from conventional foods. The absence of novel DNA makes it challenging to trace and distinguish NBT foods from conventional food products. These challenges were highlighted in a working document published by the European Commission (EC),[43] as well as more recent papers (Guertler et al. 2023; Weidner et al. 2022). While detection methodologies exist to reliably detect small edits in a genome, they cannot determine how the edit was introduced, i.e. whether it was from genome editing,

[43] EC study on new genomic techniques – https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en

Issue		Comments	Submitter(s)	FSANZ Response
				conventional mutagenesis or natural mutation. Traceability systems[44] were also investigated as an alternative to analytical detection methods in the EC report 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. FSANZ's position regarding post-market surveillance is provided in issue 1 in this table.
		These submitters stated that all NBT foods must be registered and suggested that FSANZ should maintain a register.	BPNZ; PSGR; AGEFC; OIA; Private individuals	It is not part of FSANZ's statutory functions to maintain lists or registers of foods or substances, whether GM or not, that have not themselves been assessed by FSANZ and permitted under the Code.
		This submitter expressed support for preserving the current record of approved GM foods available on the FSANZ website.	NSWFA	FSANZ will continue to maintain a list of permitted GM foods in Schedule 26 of the Code.
11.	**Enforcement**	This submitter emphasised that deregulating NBT foods that are identical to conventional foods will help with enforcement.	MPI	Noted. Enforceability has been a key consideration for FSANZ in developing the new definition for GM food. The proposed approach based on the presence of novel DNA will provide clear and objective criteria for compliance and enforcement purposes.

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

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter argued that enforcement challenges should not be used to support deregulation of NBT foods.	OIA	FSANZ's safety assessment, based on scientific evidence, was used as the primary basis for proposing the exclusion of certain low risk NBT foods from a revised definition. Having decided on the most appropriate approach based on science FSANZ then had regard to issues such as enforceability in deciding how to define GM food.
		These submitters disagreed that NBT foods cannot be distinguished from conventional foods. They argued that rapid advances in the development of detection methodologies could be harnessed to enforce regulation of NBT foods.	FoE & GE; VicDoH & VicDJPR	Refer to FSANZ's response to issue 10 in this table.

Table C. Definitional approach as proposed at 1st CFS

Issue		Comments	Submitter(s)	FSANZ Response
12.	**FSANZ's proposed hybrid approach to revising the definitions: broadening the process-based definition for 'gene technology' and including product-based exclusion criteria for the 'food produced using gene technology' definition**	These submitters expressed support for both broadening the process-based definition for 'gene technology' and for including product-based exclusion criteria, though some submitters noted that they would prefer a purely product-based approach that does not consider the technology used to create a product.	NSWFA; MPI; VicDoH & VicDJPR; QLDH; NZFGC; FCG; MU; USEC; ABCL; CSIRO; LTIBC; LSN; ChrH; Academies	FSANZ acknowledges that a number of submitters supported the hybrid (process + product) definitional approach that was proposed in the 1st CFS. Given some of the issues raised, particularly in relation to the complexity and lack of clarity, it was decided to change to a fully outcomes-based definition, which enabled FSANZ to significantly simplify the approach, and make it clearer. The rationale for this change is discussed in sections 2.2 and 2.3 of this CFS.
		These submitters expressed support for broadening the definition for 'gene technology' but were opposed to product-based exclusions for certain NBT foods or refined ingredients. These submitters want all GM and NBT foods to be regulated.	FoE & GE; CSA; PSGR; BPNZ; GEFNZ; INBI; IHER; AGEFC; OIA; Private individuals; Campaigns	While a number of submitters supported expanding the definition for gene technology', FSANZ decided ultimately to pursue a different approach based on outcome, rather than process. See section 2.2 of this CFS for further discussion. Please refer to issue 4 in Table B for FSANZ's response to submitter feedback on the exclusion of certain NBT foods from a revised definition. This is also discussed in section 2.1 of this CFS.
		These submitters suggested that the proposed hybrid approach for NBT foods could also be used to exempt foods produced using older GM technologies, based on the characteristics of the product rather than the presence of 'foreign DNA'.	CSIRO	FSANZ agrees that product characteristics determine the hazard profile of foods, including GM foods. However, this proposal does not seek to challenge the presumption of greater risk for GM foods or change the current approach to pre-market GM safety assessment. As discussed in section 2.2 of this CFS, it is also very difficult to develop product-based exclusions without introducing complexity and ambiguity.

Issue		Comments	Submitter(s)	FSANZ Response
				While novel DNA in and of itself does not present a hazard, it provides a clear and objective measure to determine if a food is a GM food for Code purposes. Basing the definitions on the presence of novel DNA in the organism from which the food for sale is derived is also consistent with the types of foods that are listed in Schedule 26 of the Code (food derived from older GM technologies). It also ensures there are no regulatory gaps with respect to DNA that has been specifically designed (not based on any naturally occurring DNA sequences) and may encode a potentially new or altered hazard.
13.	**The proposed definition for 'gene technology'**	These submitters were concerned that the proposed definition for 'gene technology' is overly broad and would result in FSANZ's regulatory reach being effectively extended, and in developers needing to work through an overly onerous list of exclusion criteria.	IFF; CLA; BASF; ASF; GTA	FSANZ has revised the approach proposed in the 1st CFS, and is no longer pursuing a hybrid definition that involves expanding the existing 'gene technology' definition. Under its revised approach, FSANZ is proposing to adopt a single definition for 'genetically modified food' that is based on the presence of novel DNA in the organism from which the food is derived. The rationale for the change in approach and the use of the term 'novel DNA' in preference to 'foreign DNA' is discussed in sections 2.2 and 2.3 of this CFS.
		These submitters proposed a number of alternate definitions for 'gene technology'. Gene technology means: • 'genetic changes, or creation of novel genomes, directed through application of molecular biology techniques, excluding those meeting	CSIRO; LTIBC; CLA; ACM; BASF; ASF; Academies; LSN; IG; PSGR; GEFNZ	FSANZ acknowledges the lack of support for the proposed wording of a revised 'gene technology' definition. FSANZ made the decision to revise its approach so it no longer focusses on the gene technology process as a means to capture GM food, but appreciates the time taken by submitters to develop alternative suggestions for revising the 'gene technology'

Issue		Comments	Submitter(s)	FSANZ Response
		the criteria listed in a schedule.' (CSIRO) • 'techniques that modify or construct a genome by introducing foreign or recombinant DNA that remains in the final product used for food.' (LTIBC) • 'techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome.' (Academies) • 'techniques that directly use recombinant, synthesised or amplified nucleic acid to modify or create a genome.' (LSN) • 'all technology that can alter a pathway or molecule of an organism, that then changes/has potential to change chemical or biological traits of organisms, viruses or related replicating elements.' (PSGR) • 'techniques that modify a genome by introducing foreign DNA that remains in the final organism used for food.' (CLA; BASF; ASF; IG; ACM) • 'the scientific manipulation using molecular biology tools, which deletes, replaces, or inserts RNA/DNA molecular sequences (synthetic or natural), altering the heritable genetic material of living cells or organisms'. (GEFNZ)		definition.

Issue		Comments	Submitter(s)	FSANZ Response
		These submitters preferred 'foreign DNA' over 'recombinant DNA' as a more precise and less ambiguous term to describe introduced DNA.	CLA; BASF; ASF; LSN	Please refer to sections 2.3.3 and 3.3.
		These submitters proposed the following definition for 'foreign DNA', and stressed the importance of distinguishing foreign DNA from oligonucleotides or repair templates used in gene editing methods: '*Foreign DNA means the stable integration into the genome of one or more genes that originate from outside the organism's cross-compatible gene pool and are inaccessible through conventional methods*.'	CLA, BASF; ASF; IG	Please refer to section 3.3 for a discussion of the suggested definition for 'foreign DNA'. With regard to guide or repair DNA, FSANZ notes the new 'novel food' definition refers to DNA that has been 'inserted' into the genome.
		These submitters expressed concern over the use of technical terms that will require clear definitions and clarity, e.g.: • recombinant • synthesised • amplified • nucleic acid • modified	CLA; BASF; ASF	These terms are associated with the United States Department of Agriculture definition for 'genetic engineering'. At the 1st CFS, FSANZ proposed to adopt the language in the US definition into a revised Code definition for 'gene technology'. As stated above, FSANZ is no longer proposing to retain or revise the definition for 'gene technology'. Please refer to sections 2.3 and 3 of the CFS for further details. FSANZ notes that clarity was a key consideration in crafting new definitions. FSANZ purposely avoided the use of too many technical terms that would then need to be defined.

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter expressed the view that the revised definition of gene technology should include both chemical and radiation mutagenesis and gene silencing/RNA interference.	FoE & GE	Chemical and radiation mutagenesis are a form of conventional breeding. Since 1940, these methods have been used to improve a large variety of foods, which have a long history of safe human consumption, e.g. red grapefruit. These foods can be marketed without any involvement from FSANZ providing the new food is safe and suitable and complies with relevant provisions of the Code. Please see the 1st CFS's SD1 for further information.[45] No evidence has been provided or identified since the 1st CFS was issued that would warrant a different conclusion. The proposed new definition for GM food will continue to capture organisms containing novel DNA that encode RNA effector molecules used in gene silencing.
		These submitters stated that the revised definitions for 'gene technology' and 'food produced using gene technology' must continue to exclude food derived from animal or organism which has been fed food produced using gene technology.	NZFGC; FCG	The current definition for 'food produced using gene technology' includes a note which clarifies that the definition does not include food from animals or other organisms that been fed food produced using gene technology. Under the proposed draft amendments to the Code, FSANZ is intending to repeal this note, along with the repeal of the definition for 'food produced using gene technology', because the proposed new definition for 'genetically modified food' is sufficiently clear on this point. Notes in the Code also do not have a substantive legal effect. Their purpose is simply to explain certain

[45] P1055 SD1 Safety Assessment – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Issue		Comments	Submitter(s)	FSANZ Response
				matters to the reader.
14.	**The proposed exclusion criteria for NBT food that has the same characteristics as conventional food**	These submitters raised a number of issues related to both the clarity and content of the proposed exclusion criteria.	IFF; EUB; CSIRO; CLA; BASF; ASF; USEC; IG; LSN; Academies	FSANZ accepts submitters' concerns that the exclusion criteria lack clarity. FSANZ has since revised its approach and the exclusion criteria set out in the 1st CFS are no longer applicable. Please refer to section 2.2 and 2.3 for further information.
		This submitter raised several questions relating to the definition of cisgenesis: • Would this definition disqualify combining a strong promoter with an open reading frame that naturally has a weak promoter by considering this a change in arrangement? • How would codon optimization be handled? • Can the difference in assessment for cisgenesis and intragenesis be clarified?	EUB	The 1st CFS described what cisgenesis and intragenesis means, but these were not legal definitions. The intent under the proposed new definition for 'novel DNA' is to include intragenesis within its meaning, but exclude cisgenesis. FSANZ considers changing promoters would be a form of intragenesis, therefore food derived from such an organism would be a GM food under the proposed new definition. The reason for capturing intragenesis but not cisgenesis is that the insertion of DNA that retains its native sequence and configuration is equivalent to what may be achieved using cross-breeding. The changing of regulatory elements, such as promoters, is less likely to occur via cross-breeding. FSANZ notes food derived from a number of intragenic organisms are permitted as GM foods in Schedule 26 of the Code. FSANZ has provided a clear statement in section 3.3 of this CFS that the intent is not to include codon optimisation within the meaning of 'novel DNA'.

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter stated that clear differences need to be established between 'food produced using gene technology' and 'conventional food', and suggested that a definition for 'conventional food' be developed.	NSWFA	FSANZ does not consider an explicit definition for 'conventional breeding' would serve any useful purpose in terms of the implementation or interpretation of the new definition for 'genetically modified food'. FSANZ believes it is already clear that a food that is not a GM food will either be a conventional food, or equivalent to a conventional food. This is discussed further under subsection 3.4.1 of this CFS.
		These submitters considered greater clarity is needed if the 'altered characteristics' criteria that currently apply for labelling are intended to align with the proposed criteria for "new or altered characteristics" in relation to pre-market safety assessment.	FCG; Private individual – MH	The criteria, set out in the 1st CFS, which intended to capture NBT food that has new or altered characteristics compared to conventional food (ii-v) are no longer applicable in relation to whether a food is a GM food now that FSANZ has revised its approach. FSANZ notes the labelling approach to GM foods with altered characteristics has not changed.
15.	**The proposed exclusion of refined ingredients, nutritive substances, food additives and processing aids where no novel DNA or novel protein is present in the food for sale**	These submitters expressed the view that the presence of novel DNA or protein in refined ingredients are not valid indicators of risk, and that enforcement of a requirement for 'no novel DNA or protein' could be very complex.	IFF; EUB; USEC	FSANZ has moved to an outcomes-based approach based on the presence of novel DNA in the organism from which the food for sale is derived. This provides a clear and objective measure to determine if a food is a GM food for Code purposes; novel DNA is either present in the organism or it is not. Please refer to subsection 2.3.3 for more information.
		These submitters supported the proposed exclusion of refined ingredients that are chemically equivalent to those derived from conventional sources.	Academies; CSIRO; ABCL	Under the revised approach set out in this CFS, it is FSANZ's assessment that it would not be practically possible to provide for such exclusions. It would be technically challenging to develop clear and objective criteria that could be uniformly applied across a large and diverse product category without the risk of

Issue		Comments	Submitter(s)	FSANZ Response
				inconsistent and unintended regulatory outcomes in terms of what ingredients would or would not be captured as GM food. Please refer to subsection 2.3.4 – Processed food ingredients for more information.
		This submitter expressed concern that the use of the term 'novel DNA' in relation to exclusion of refined ingredients is not sufficiently clear, and would result in regulatory ambiguity for these products.	ChrH	FSANZ notes the concern. Under the revised approach, any potential ambiguity in relation to the term 'novel DNA' should no longer be an issue.
		These submitters suggested that, for ingredients produced using fermentation, an absence of viable GM microorganisms, rather than novel DNA/protein, would be a preferable criterion.	EUB; IFF	Under the revised approach, FSANZ is proposing to explicitly exempt food additives, processing aids and nutritive substances from a new GM food definition. Many of these substances are produced using microbial fermentation. Other substances produced using fermentation that are not food additives, processing aids or nutritive substances, will be captured by the GM food definition if the microorganism has been modified to contain 'novel DNA'. The presence or absence of a viable microorganism will be irrelevant.
16.	**The exclusion of food from grafted plants**	These submitters were concerned about exclusion of food products derived from GM rootstock grafting. They expressed the view these products should not be excluded, arguing that the risks arising from this technique are equivalent to those from transgenesis.	FoE & GE; IHER	FSANZ has further considered food from grafted plants and has decided to include an explicit exemption from the proposed new GM food definition. Please see subsection 2.3.5 for more information.

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter supported the exclusion of foods produced GM rootstock grafting, but noted that cultivation of such grafted plants in Australia would still require approval by the OGTR.	CSIRO	
17.	**The proposed exclusion of food from null segregants**	These submitters expressed mixed views in relation to the proposed exclusion of food from null segregants from the revised definition – some submitters were strongly opposed to its exclusion, and stated that a full safety assessment should be required to confirm the absence of GM DNA. Other submitters supported the exclusion, and noted that it is scientifically appropriate as well as being aligned with the *Gene Technology Act 2000*.	FoE & GE; IHER; FCG; Academies; MU	FSANZ does not have the power to require assessment of food derived from a null segregant organism without first capturing it as GM food. FSANZ notes the exclusion of null segregant organisms from GM regulations is standard practice around the world, as well as under the *Gene Technology Regulations 2001* in Australia and the *Hazardous Substances and New Organisms Act 1996* (HSNO Act) in New Zealand. Under the proposed new definition, an organism that contains novel DNA cannot be a null segregant. Food derived from such an organism, were it put into the food supply, would not comply with the Code. It is the legal responsibility of those who trade in food to ensure their food is both safe and suitable, and complies with relevant provisions of the Code, including those relating to pre-market approval.

Table D. Non-regulatory measures

Issue		Comments	Submitter(s)	FSANZ Response
Advisory committee				
18.	**Establishment of a new advisory committee**	These submitters supported the establishment of an advisory committee on NBT foods	NSWFA; MPI; CSIRO; FCG; QLDH; NZFGC; Academies; ABCL; Private individual – PB	FSANZ notes the mixed views for the establishment of a new advisory committee on NBT foods and that most of the concerns that were raised in response to the suggestion were from the stakeholder group who the advisory committee was primarily intended to assist.
		This submitter suggested that the OGTR and TGA should be part of the advisory committee, and that potentially a tool to assist in applying assessment procedures consistently could also be developed.	NSWFA	Given the proposed new definition for 'genetically modified food' FSANZ has decided an advisory committee is no longer needed. Refer to section 5.1 of this CFS for further information.
		These submitters either did not support the establishment of an advisory committee, or questioned the value of such a committee. Some of these submitters suggested that in place of an advisory committee, it would be preferable for FSANZ to provide clear and consistent advice on the regulatory status of NBT foods. They requested that more detail be provided on the proposed committee, and raised one or more of the following concerns: • scope of responsibility, composition, and source of funding for the advisory committee.	LTIBC; IG; CLA; BASF; ASF; LSN; ACM	

Issue		Comments	Submitter(s)	FSANZ Response
		• legal status of the advice provided by the committee, confidentiality of the consultation process, and management of CCI. • clarity of requirements for applicants regarding engagement with the committee. • timeline for the provision of advice. • practicality of the advisory committee, fearing that it will create more red tape and increased regulatory burden.		
Guidance material				
19.	**Development of guidance and consumer education materials**	These submitters supported the development of industry guidance material. Some of these submitters also provided suggestions for the guidance materials, including that they should: • Be clear and detailed to enable food developers to assess their products without the necessity to consult FSANZ or the advisory committee. • Provide clarity on when a declaration requirement applies and the appropriate disclosure method for pre-market safety assessment.	NSWFA; MPI; QLDH; CSIRO; Academies; IG; BASF; CLA; LTIBC; NZFGC; GTA; ASF; FCG; ABCL; Private individual – PB	FSANZ notes the support for the development of guidance materials and the suggestions from submitters about what information would be useful to include. FSANZ will make a decision about whether guidance material would be useful, and what form that should take, once feedback has been received from submitters on the proposed new definitions, particularly in relation to clarity. Refer to section 5.2 of this CFS for further information.

Issue		Comments	Submitter(s)	FSANZ Response
		• Be developed in consultation with industry stakeholders to ensure its practicality. • Include examples of all organisms, not just plants. • Include the criteria against which food will be assessed as well as provide a wide range of scenarios/example assessments. • Include a 'decision tree(s)' to assist developers in making a determination about their products. • Include testing methods that food developers can use to demonstrate the absence of novel DNA/protein or indistinguishability to conventional food. • Provide more clarity on how cisgenic and intragenic-derived foods will be screened for pre-market safety assessment. • Highlight the risk-proportionate and product-based assessment process as well as provide a scientific rationale for the exclusion of some NBT foods from pre-market safety assessment. • Provide information on how FSANZ will assess trait stacking (i.e. NBTs		

Issue		Comments	Submitter(s)	FSANZ Response
		generated trait introduced into an already approved GM plant). • Include guidance on who will retain the data and for how long should the data be retained. These submitters suggested the guidance materials be prepared in consultation with industry stakeholders.		
		This submitter suggested that public education materials already available for the proposal should be expanded to include: • Definitions of scientific terminologies & methodologies in simple language • Information on risks presented by GM food • A general description of pre-market safety assessment • A figure illustrating the relationship between GM organisms, foods and labelling • Examples of how NBTs and conventional breeding techniques might overlap	QLDH	FSANZ notes the submitter's useful suggestions, which will be considered when developing communication material at the next stage of this proposal.

Table E. Labelling

Issue		Comments	Submitter(s)	FSANZ Response
Labelling and consumer choice				
20.	**Labelling of NBT foods**	These submitters expressed the view that all GM and NBT foods should be labelled for one or more of the following reasons: • To preserve the high-level transparency of GM food. • Polling shows that most Australians and global citizens do not want to eat GM foods. • To assist consumers to make informed choices.	Private individuals; Campaigns; FoE & GE; IHER; AGEFC; CSA; VicDoH & VicDJPR; BPNZ; SACA; OIA, AOL; GEFNZ; SCNZ	FSANZ notes GM labelling is out of scope of this proposal. Refer to section 4 of this CFS for FSANZ's response.
		These submitters were concerned that the proposal would result in some NBT foods that would be exempt from pre-market assessment being subject to GM labelling.	BASF, CLA	NBT foods that are not captured by the proposed new GM food definition, would not be subject to pre-market assessment and approval as a GM food. Only those GM foods that have been assessed and approved for sale are listed in Schedule 26. Paragraph 1.5.2—4(1)(a) of the draft variation specifies that the labelling requirements apply to 'a food for sale that contains, or consists of, a *genetically modified food that is listed in Schedule 26.' Refer to section 4 of this CFS.

Table F. Other relevant matters

Issue		Comments	Submitter(s)	FSANZ Response
Process				
21.	**Consultation**	These submitters stated that there was a lack of time for public consultation at the first call for submissions.	Private individuals	FSANZ does not agree. FSANZ's standard public consultation process for proposals and applications is 6 weeks. However, for this proposal, FSANZ extended the public consultation period to 8 weeks due to the number of consultation documents and increased stakeholder interest.
Regulatory harmonisation				
22.	**Alignment of domestic regulations**	These submitters raised concerns about a lack of harmonisation in the definition of 'gene technology' between the *Gene Technology Act* and the Code. Some of these submitters noted that a lack of alignment could result in uncertainty/confusion for industry, such how ingredients or products that may be defined as GM by the Gene Technology Act but not under the Code, or *vice versa*, will be treated.	VicDoH & VicDJPR; CSIRO; Academies; BA; MU; LTIBC	The alignment of domestic regulations related to GMOs and GM food is discussed in section 7.1 of this CFS. While acknowledging these concerns, FSANZ considers that aligning revised Code definitions for GM food to the definitions for GMOs in Australia and New Zealand would not be appropriate given the different objectives and risks to be managed under the relevant regulations. FSANZ expects however that the regulations for GMOs in Australia and New Zealand, along with the GM food regulations that operate in both countries, will be brought into greater alignment progressively over time.
		These submitters raised a number of issues related to the regulation of GMOs in New Zealand and the current proposal, including: • The view that New Zealand's stance on GE crops should not	MU; LSN; SCNZ; FCG; ACM	FSANZ has undertaken this proposal with the intent that, if approved, the proposed new definition for 'genetically modified food' would be adopted and apply in both countries. FSANZ has kept in close contact with relevant Australian and New Zealand Government agencies throughout this work. The differences between Australia and New Zealand with respect to the regulation of GMOs are well known, as are the

Issue		Comments	Submitter(s)	FSANZ Response
		stifle Australia's food industry growth, and that Australia and New Zealand could potentially have separate regulations for NBT foods to allow Australia to benefit from new technologies. • That a collective and evidence-based approach to GM foods in both Australia and New Zealand should be applied by FSANZ. • Concern that the proposed approach would create regulatory asymmetry with New Zealand's approach to GMOs under the HSNO Act and potentially prompt the NZ government to opt out of any changes to the Code. • Acknowledgement of the difficulty in aligning definitions between Australia and New Zealand, particularly regarding the difference in approach to environmental issues, which are not in scope for FSANZ.		differences in definitions between GM food and GMOs. While having regard to these differences, FSANZ has concluded the proposed new definition is appropriate for managing potential food risks from GM food in both countries. Ultimately, the adoption in New Zealand of the proposed new definition for GM food is a matter for the New Zealand Government.
23.	**International harmonisation and trade**	These submitters stated that the definitions for 'gene technology' and 'food produced using gene technology' should be consistent with international definitions to facilitate global trade and innovation.	LTIBC; CLA; GTA; MU; NAL	As discussed in subsection 7.2.2 of this CFS, FSANZ is observing an increasing trend towards regulatory alignment between countries in relation to NBTs.

Issue		Comments	Submitter(s)	FSANZ Response
		This submitter noted that while the harmonisation of international regulations is desirable, it could ultimately be unachievable given the divergence in regulations across international jurisdictions.	CSIRO	
		These submitters were concerned about the impact of excluding NBT foods from GM food regulation on trade and on the organic industry, due to one or more of the following issues: • Cross-contamination of non-NBT products, with NBT products, resulting in loss of export opportunities to countries where NBT products are regulated and labelled, particularly those in the EU. • The risk of losing accreditation of organic certification due to unintentional contamination of Australian organic foods with unregulated GM foods. • The risk of damage to Australia's brand reputation.	OIA; AOL; SCNZ	FSANZ notes the submitters' concerns. Most jurisdictions around the world have updated, or are in the process of updating, their regulations for NBT foods. FSANZ's proposed approach to exclude certain foods from regulation as GM foods based on their equivalence to conventional food is in alignment with approaches being adopted elsewhere in the world. Refer to SD1 in this CFS for further information about where different countries stand, and also subsection 7.2.2 of this CFS for a full discussion. FSANZ notes that matters related to cross-contamination of agricultural commodities, organic certification, and 'Australia's brand reputation' are outside FSANZ's remit. FSANZ does not anticipate however that the adoption of the proposed new definitions would affect existing stewardship practices used by the agricultural sector.

Issue		Comments	Submitter(s)	FSANZ Response
Environment and sustainability				
24.	**Issues related to the environmental and sustainability impact of GM crops.**	These submitters raised one or more of the following concerns about GM crops and the environment: • The use of GM crops has increased the use of herbicides and pesticides, resulting in negative environmental effects such as increased weediness and the prevalence of superbugs. • There are better ways to manage the issues surrounding climate change rather than the use of GM crops. • GM crops intended to kill pests also kill beneficial soil microbes and beneficial insects that are essential pollinators.	Private individuals; SACA	FSANZ notes all submitters' views. Environmental issues are outside FSANZ's authority and expertise.
		In contrast, these submitters emphasised the contribution of GM crops to a more sustainable agriculture industry and improved economic growth. They expressed the view that inconsistent and unnecessary regulatory burdens around the world have hampered the realisation of these benefits.	CLA, CSIRO	

References – Appendix 1

Guertler P, Pallarz S, Belter A, Eckerman K, Grohmann L (2023) Detection of commercialized plant products derived from new genomic techniques (NGT) - Practical examples and current perspectives. Food Control. 109869. 10.1016/j.foodcont.2023.109869

Kock MA (2021) Open intellectual property models for plant innovations in the context of new breeding technologies. Agronomy 11(6):1218. https://doi.org/10.3390/agronomy11061218.

Weidner C, Edelmann S, Moor D. *et al.* (2022) Assessment of the Real-Time PCR Method Claiming to be Specific for Detection and Quantification of the First Commercialised Genome-Edited Plant. Food Anal. Methods **15**, 2107–2125. https://doi.org/10.1007/s12161-022-02237-y

Appendix 2: Consultation questions

Definition for ‘genetically modified food’ (Section 3.2)

1a. Is the new definition for ‘genetically modified food’ clear? If not, which parts of the definition could be clearer?

1b. Will the new definition for ‘genetically modified food’ produce the intended regulatory outcomes, as described in section 3.2 and Table 3?

Definition for ‘novel DNA’ (Section 3.3)

2a. Is the new definition for ‘novel DNA’ clear? If not, which parts of the definition could be clearer?

2b. Will the new definition for ‘novel DNA’ produce the intended regulatory outcomes, as described in section 3.3 and Table 3?

Guidance material (Section 5.2)

3. Do you believe additional clarifying information would be helpful to accompany the proposed new definitions? If yes, what additional information would be most helpful?

Consideration of costs and benefits (SD2)

4. Do you have any information (e.g. studies or data) that may be able to quantify the impacts to consumers that may arise from the proposed changes?

5. Have all the major impacts to consumers from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence (where possible) to support the inclusion and magnitude of other impacts.

6. Do you have any information (e.g. studies or data) that may be able to quantify the impacts to the food industry that may arise from the proposed changes?

7. Have all the major impacts to the food industry from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence such as studies or data to support the inclusion and magnitude of other impacts.

8. Have all the major impacts to government from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence such as studies or data to support the inclusion and magnitude of other impacts.

Attachment A – Draft variations to the Australia New Zealand Food Standards Code

Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 1.1.1 – Structure of the Code and general provisions

[1] Section 1.1.1—2

Omit "Food produced using gene technology" (wherever occurring), substitute "Genetically modified food".

[2] Section 1.1.1—10

Omit "*food produced using gene technology" (wherever occurring), substitute "*genetically modified food".

[3] Section 1.1.1—10 (Note 1)

Omit "food produced using gene technology", substitute "genetically modified food".

Standard 1.1.2 – Definitions used throughout the Code

[4] Subsection 1.1.2—2(3) (definition for food produced using gene technology)

Repeal the definition.

[5] Subsection 1.1.2—2(3) (definition of gene technology)

Repeal the definition.

[6] Subsection 1.1.2—2(3)

Insert:

Genetically modified food—see section 1.1.2—16.

[7] Subsection 1.1.2—2(3) (entry for novel food)

Repeal the entry, substitute:

Novel DNA—see section 1.1.2—17.

Novel food—see section 1.1.2—8.

Novel protein means a protein encoded by novel DNA.

[8] After section 1.1.2—15

Add:

1.1.2—16 Definition of genetically modified food

(1) In this Code, ***genetically modified food*** means:

(a) a food that is:

(i) an organism that contains *novel DNA; or

(ii) derived from an organism that contains novel DNA; or

(iii) cells that contain novel DNA; or

(iv) derived from cells that contain novel DNA; and

(b) does not include any of the following:

(i) a substance *used as a food additive;

(ii) a substance *used as a processing aid;

(iii) a substance *used as a nutritive substance;

(iv) a substance used to:

(A) support the growth and viability of cells during cell culture; or

(B) process cells during cell culture;

(v) food that is derived from part of a grafted plant, where that part does not contain novel DNA or *novel protein;

(vi) food derived from a null segregant.

(2) In this section, ***a null segregant*** means an organism, cell or cells that:

(a) is descended from an organism, cell or cells that contain *novel DNA; and

(b) does not contain novel DNA.

1.1.2—17 Definition of novel DNA

In this Code, ***novel DNA*** means DNA that:

(a) a person has inserted into the genome of an organism, cell or cells; and

(b) is:

(i) from a species that has not previously been crossed or hybridised with the species of the organism, cell or cells; or

(ii) from a species that has previously been crossed or hybridised with the species of the organism, cell or cells, where the sequence or arrangement of the inserted DNA was changed prior to its insertion; or

(iii) not from an existing species.

Standard 1.2.1 – Requirements to have labels or otherwise provide information

[9] Paragraph 1.2.1—8(1)(k)

Omit "*foods produced using gene technology", substitute "*genetically modified food".

[10] Paragraphs 1.2.1—9(3)(b) and (ba)

Omit "foods produced using gene technology", substitute "*genetically modified food".

[11] Paragraph 1.2.1—15(f)

Omit "foods produced using gene technology", substitute "*genetically modified food".

Standard 1.2.4 – Information requirements – statement of ingredients

[12] Paragraph 1.2.4—5(6)(b)

Repeal the paragraph, substitute:

(b) if the compound ingredient comprises less than 5% of the food for sale—the following ingredients:

(i) any ingredient of the compound ingredient that is required to be listed in accordance with section 1.2.3—4 or section 1.5.2—4; and

(ii) any substance *used as a food additive in the compound ingredient which performs a technological purpose in the food for sale.

Standard 1.5.2 – Food produced using gene technology

[13] Standard title

Omit "Food produced using gene technology", substitute "Genetically modified food".

[14] Standard title (Note 3)

Repeal the Note, substitute:

Note 3 Paragraphs 1.1.1—10(5)(c) and (6)(g) provide that a food for sale must not consist of, or have as an ingredient or a component, a genetically modified food, unless expressly permitted by this Code. This Standard contains the relevant permissions. Schedule 26 provides definitions of the terms 'line' and 'transformation event', and lists approved genetically modified foods and any conditions for use of the food.

[15] Section 1.5.2—1

Omit “Food produced using gene technology”, substitute “Genetically modified food”.

[16] Section 1.5.2—2 (Notes 1 to 3)

Repeal the Notes, substitute:

Note 1 In this Code (see section 1.1.2—16):

genetically modified food means:

(a) a food that is:
  (i) an organism that contains *novel DNA; or
  (ii) derived from an organism that contains novel DNA; or
  (iii) cells that contain novel DNA; or
  (iv) derived from cells that contain novel DNA; and
(b) does not include any of the following:
  (i) a substance *used as a food additive;
  (ii) a substance *used as a processing aid;
  (iii) a substance *used as a nutritive substance;
  (iv) a substance used to:
    (A) support the growth and viability of cells during cell culture; or
    (B) process cells during cell culture;
  (v) food that is derived from part of a grafted plant, where that part does not contain novel DNA or *novel protein;
  (vi) food derived from a null segregant.

a null segregant means an organism, cell or cells that:

(a) is descended from an organism, cell or cells that contain *novel DNA; and
(b) does not contain novel DNA.

Note 2 In this Code (see section 1.1.2—17):

novel DNA means DNA that:

(a) a person has inserted into the genome of an organism, cell or cells; and
(b) is:
  (i) from a species that has not previously been crossed or hybridised with the species of the organism, cell or cells; or
  (ii) from a species that has previously been crossed or hybridised with the species of the organism, cell or cells, where the sequence or arrangement of the inserted DNA was changed prior to its insertion; or
  (iii) not from an existing species.

Note 3 In this Code (see section 1.1.2—2)

novel protein means a protein encoded by novel DNA.

Note 4 Definitions for the terms ‘line’ and ‘transformation event’ are in Schedule 26.

[17] Section 1.5.2—3

Repeal the section, substitute:

1.5.2—3 When genetically modified food is permitted for sale

A food for sale may contain, or consist of, a *genetically modified food if that genetically modified food is:

(a) listed in Schedule 26; and
(b) complies with any corresponding conditions listed in that Schedule.

[18] Section 1.5.2—4

Repeal the section, substitute:

1.5.2—4 Requirement to label food as ‘genetically modified’

(1) This section applies to a food for sale:

(a) that contains, or consists of, a *genetically modified food that is listed in Schedule 26: and

(b) where that genetically modified food:

(i) contains novel DNA or novel protein; or

(ii) is listed in section S26—3 as subject to the condition that its labelling must comply with this section; and

(c) is not a food listed in subsection (2).

(2) The following are listed foods:

(a) a food for sale that contains a *genetically modified food that is:

(i) unintentionally present in the food for sale; and

(ii) present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient;

(b) a food for sale that is:

(i) intended for immediate consumption; and

(ii) prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).

(3) For the labelling provisions, the information relating to genetically modified food is the statement 'genetically modified' used in conjunction with the name of the genetically modified food.

Note The labelling provisions are set out in Standard 1.2.1. Labelling provisions apply to both packaged and unpackaged genetically modified food.

(4) If the genetically modified food is an ingredient (including an ingredient of a compound ingredient), the information may appear in the label other than in the statement of ingredients.

Example Standards 1.2.1 and 1.2.4 require the labelling of certain foods for sale to include a statement of ingredients. For the purposes of section 1.5.2—4, genetically modified corn meal that is used as an ingredient of a crumbed fish compound ingredient that is in turn used in a mixed ingredient food could be declared in the statement of ingredients for that mixed ingredient food as: Ingredients: *Crumb coating (wheat flour, water, canola oil, corn meal (genetically modified), salt, sugar, egg white)*. Alternatively, the name of the genetically modified ingredient could be declared in the statement of ingredients (eg,: *corn meal*) in accordance with Standard 1.2.4, with the information required by section 1.5.2—4 appearing elsewhere on the label (eg, *contains genetically modified corn meal*).

Standard 2.9.1 – Infant formula products

[19] Section 2.9.1—10

Repeal the section, substitute:

2.9.1—10 Required forms and sources for nutritive substances

A substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 must:

(a) if a vitamin, mineral or electrolyte—be added in a permitted form listed in the table to section S29—23; and

(b) in any other case—be:

(i) added in a permitted form listed in in Column 2 to the table to section S29—9; and

(ii) derived from a corresponding source, if any, specified in Column 3 of that table.

[20] Paragraph 2.9.1—10A(1)(c)

Repeal the paragraph, substitute:

(c) derived from a source listed in Column 2 of that table for that substance.

[21] Subsection 2.9.1—10A(2)

Omit the words “substance in that permitted form.”, substitute “substance.”.

[22] Section 2.9.1—38

Repeal the section, substitute:

2.9.1—38 Required forms and sources for nutritive substances

A substance used in a special medical purpose product for infants in accordance with section 2.9.1—36 or section 2.9.1—37 must:

(a) if a vitamin, mineral or electrolyte—be added in a permitted form listed in the table to section S29—23; and

(b) in any other case—be:

(i) added in a permitted form listed in Column 2 of the table to section S29—9; and

(ii) derived from a corresponding source, if any, specified in Column 3 of that table.

[23] Subparagraph 2.9.1—49(1)(c)(i)

Omit “foods produced using gene technology”, substitute “*genetically modified food”.

Schedule 3 – Identity and purity

[24] Subsection S3—35(2)

Omit “protein engineered enzymes” (wherever occurring), substitute “enzymes”.

[25] Subsection S3—35(2)

Omit “a protein engineered enzyme” (wherever occurring), substitute “an enzyme”.

Schedule 18 – Processing aids

[26] Subsection S18—4(2) (Note 3)

Repeal the Note.

[27] Table to subsection S18—4(5)

Omit “, protein engineered variant” (wherever occurring).

[28] Table to subsection S18—9(3)

Omit “, protein engineered variant,” (wherever occurring).

[29] Table to subsection S18—9(3)

Omit “Protein engineered enzyme” (wherever occurring), substitute “Enzyme”.

[30] Table to subsection S18—9(3)

Omit “Protein engineered enzymes”, substitute “Enzymes”.

[31] Table to subsection S18—9(3) (Note)

Repeal the Note.

Schedule 26 – Food produced using gene technology

[32] Standard title

Omit “Food produced using gene technology”, substitute “Genetically modified food”.

[33] Standard title (Note 1)

Repeal the Note, substitute:

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code.* See also section 1.1.1—3.

Genetically modified food is regulated by paragraphs 1.1.1—10(5)(c) and (6)(g) and Standard 1.5.2. This standard lists genetically modified food, and corresponding conditions, for paragraph 1.5.2—3(a).

[34] Section S26—1

Omit “Food produced using gene technology”, substitute “Genetically modified food”.

[35] Subsection S26—2(2) (definition for *conventional breeding*)

Repeal the definition.

[36] Subsection S26—2(2) (definition for *line*)

Repeal the definition, substitute:

line means an animal or plant that:

(a) has genetic material which includes a transformation event or events; or

(b) is descended from an animal or plant described in paragraph (a) and that is the result of conventional breeding of that animal or plant with:

(i) any animal or plant that does not contain a transformation event or events; or

(ii) any other animal or plant that contains a transformation event or events, whether expressed as a line or event, that is listed in the table to section S26—3;

(iii) but shall not be taken to mean any animal or plant derived solely as a result of conventional breeding

[37] Subsection S26—2(2) (definition for *transformation event*)

Repeal the definition, substitute:

transformation event means a unique genetic modification arising from the insertion of novel DNA.

[38] Section S26—3 (title)

Omit “food produced using gene technology”, substitute “genetically modified food”.

[39] Subsection S26—3(1)

Omit “food produced using gene technology”, substitute “genetically modified food”.

[40] Subsection S26—3(4) (Table heading)

Omit “Food produced using gene technology”, substitute “Genetically modified food”.

[41] Subsection S26—3(7)

Repeal the subsection, substitute:

(7) The table for this subsection is:

Genetically modified food of microbial origin

Substance	*Source*	*Conditions of use*
1 Soy leghemoglobin preparation	*Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*	1. May only be added to a meat analogue product to enable the use in that product of soy leghemoglobin as a nutritive substance in accordance with Standard 1.3.2. 2. Must comply with the specifications set out in section S3—42.

Schedule 29 – Special purpose foods

[42] Table to section S29—7

Omit “permitted for use by Standard 1.5.2” (wherever occurring).

[43] Table to section S29—8

Omit “permitted for use by Standard 1.5.2” (wherever occurring).

[44] Section S29—9

Repeal the section, substitute:

S29—9 Permitted forms and sources of nutritive substances in infant formula products

For paragraphs 2.9.1—10(b) and 2.9.1—38(b), the table is set out below.

Permitted forms and sources for nutritive substances used in infant formula products

Column 1	***Column 2***	***Column 3***
Substance	*Form*	*Source*
2′-fucosyllactose	2′-fucosyllactose	(a) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori* (b) *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126 (c) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* (d) *Escherichia coli K-12* containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*
3′-sialyllactose sodium salt	3′-sialyllactose sodium salt	(a) *Escherichia coli* K-12 containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*
6'-sialyllactose sodium salt	6'-sialyllactose sodium salt	(a) *Escherichia coli* K-12 containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*
A combination of 2′-fucosyllactose and difucosyllactose	2'-fucosyllactose and difucosyllactose	(a) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*
A combination of: 2′-fucosyllactose and lacto-N-neotetraose	2′-fucosyllactose and lacto-N-neotetraose	(a) For the 2′-fucosyllactose— *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori* (b) For the lacto-N-neotetraose— *Escherichia coli* K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,4-galactosyltransferase from *Helicobacter pylori*

Adenosine-5′-monophosphate	Adenosine-5′-monophosphate	
L-carnitine	L-carnitine L-carnitine hydrochloride L-carnitine tartrate	
Choline	Choline chloride	
	Choline bitartrate Choline Choline citrate Choline hydrogen tartrate	
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate	
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate	
	Guanosine-5′-monophosphate sodium salt	
Inosine-5′-monophosphate	Inosine-5′-monophosphate	
	Inosine-5′-monophosphate sodium salt	
Lactoferrin	Bovine lactoferrin	
Lacto-N-tetraose	lacto-N-tetraose	(a) *Escherichia coli* K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,4-galactosyltransferase from *Helicobacter pylori*
Lutein	Lutein from *Tagetes erecta L.*	
Inositol	Myo-inositol	
Taurine	Taurine	
Uridine-5′-monophosphate	Uridine-5′-monophosphate sodium salt	

Note Section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products.

[45] Table to section S29—9A

Repeal the table, substitute:

Conditions of use for certain permitted nutritive substances

Column 1	***Column 2***	***Column 3***
Substance	*Source*	*Conditions of use*
3′-sialyllactose sodium salt	(a) *Escherichia coli* K-12 containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. During the exclusive use period, may only be sold under the brand GlyCare 3SL 9001. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1265 – 2′-FL/DFL, LNT, 6′-SL sodium salt and 3′-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Column 1	***Column 2***	***Column 3***
Substance	*Source*	*Conditions of use*
6'-sialyllactose sodium salt	(a) *Escherichia coli* K-12 containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. During the exclusive use period, may only be sold under the brand GlyCare 6SL 9001. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
2′-fucosyllactose	(a) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*	1. During the exclusive use period, may only be sold under the brand 2′-FL-Inbiose. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1277 – 2'-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) in infant formula products) Variation* and ending 15 months after that date.
A combination of 2′-fucosyllactose and difucosyllactose	(a) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*	1. During the exclusive use period, may only be sold under the brand GlyCare 2′-FL/DFL 8001. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
Lacto-N-tetraose	(a) *Escherichia coli* K-12 containing the gene for beta-1,3- N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,3-galactosyltransferase from *Helicobacter pylori*	1. During the exclusive use period, may only be sold under the brand GlyCare LNT8001. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
Lactoferrin		1. During the exclusive use period, may only be sold under the brand Synlait. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation* and ending 15 months after that date.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1055 to amend definitions of terms used in the Code relating to genetic technologies, to make new terms clearer and better reflect existing and emerging genetic technologies including new breeding techniques. The Authority considered the proposal in accordance with Division 2 of Part 3 and has prepared a draft variation – the *Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or

instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the draft variation to amend definitions of terms used in the Code relating to genetic technologies, to make new terms clearer and better reflect existing and emerging genetic technologies including new breeding techniques. The draft variation also sets out other amendments to the Code as a consequence of the amendments proposed to those definitions.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1055 will include two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

The first call for submissions was issued on 7 October 2021 and ended on 3 December 2021.

Targeted consultation with an Expert Advisory Group (EAG) and government representatives was undertaken from April 2020 to April 2023.

The EAG was established to provide ongoing technical and scientific advice to the Authority regarding the proposed amendments to definitions of terms used in the Code relating to genetic technologies.

Following this second call for submissions, the Authority will consider whether to approve, amend or reject the draft variation, having regard to all submissions received.

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a formal Consultation Regulation Impact Statement in relation to the regulatory change proposed (reference number OBPR22-03666). The OIA was satisfied with the consultation undertaken for this proposal. A Decision Regulation Impact Statement (DRIS) will be prepared by the Authority following the second call for submissions.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'the variation' in this section are taken to be references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the amendment will commence on the date of gazettal of the instrument.

8. Schedule to the variation

Standard 1.1.1 – Structure of the Code and general provisions

Items [1] – [3] of the Schedule to the draft variation would amend Standard 1.1.1 of the Code. In particular:

Item [1] would amend section 1.1.1—2 by omitting 'Food produced using gene technology' (wherever it occurs), and substituting the omitted term with 'Genetically modified food'.

Item [2] would amend section 1.1.1—10 by omitting '*food produced using gene technology' (wherever it occurs), and substituting the omitted term with '*genetically modified food'.

An asterisk placed immediately before a term in the Code means that the term either is defined, or has an entry stating where it is defined in Standard 1.2.1, in subsection 1.1.2—2(3).

Item [3] would amend Note 1 of section 1.1.1—10 by omitting 'food produced using gene technology', and substituting the omitted term with 'genetically modified food'.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

If approved, the effect of these amendments would be that:

- the terms used throughout Standard 1.1.1, which relate to genetic technologies, reflect the proposed amendments in **items [4]** – **[8]** below, and
- that 'genetically modified food' (GM food), according to the new definition proposed in **item [8]** below, is prohibited from sale, and from being used as an ingredient or a component of a food for sale, unless expressly permitted by the Code.

Standard 1.1.2 – Definitions used throughout the Code

Items [4] – [8] of the Schedule to the draft variation would amend Standard 1.1.2 of the Code. In particular:

Items [4] - **[7]** would amend subsection 1.1.2—2(3) as follows:

Item [4] would repeal the definition for 'food produced using gene technology' in that subsection.

Item [5] would repeal the definition for 'gene technology' in that subsection.

Item [6] would insert the following new entry into that subsection:

'***Genetically modified food***—see section 1.1.2—16.' (see **item [8]** below).

Item [7] would repeal the entry for 'novel food' in that subsection, and substitute it with the following entries arranged in alphabetical order:

'***Novel DNA***—see section 1.1.2—17.

Novel food—see section 1.1.2—8.
Novel protein means a protein encoded by novel DNA.'

The entries for 'Novel DNA' and 'Novel protein' are new, but the existing entry for 'Novel food' remains unchanged.

The amendments in **items [6]** and **[7]** are consequential to the amendment in **item [8]** below.

Item [8] would insert two new provisions into Standard 1.1.2 after section 1.1.2—15, each of which sets out a new definition that would apply throughout the Code. The proposed new provisions are sections 1.1.2—16 and 1.1.2—17.

Section 1.1.2—16 sets out the new definition for GM food.

Subsection 1.1.2—16(1) provides that in the Code, GM food means:

(a) a food that is:
  (i) an organism that contains novel DNA; or
  (ii) derived from an organism that contains novel DNA; or
  (iii) cells that contain novel DNA; or
  (iv) derived from cells that contain novel DNA; and
(b) does not include any of the following:
  (i) a substance used as a food additive;
  (ii) a substance used as a processing aid;
  (iii) a substance used as a nutritive substance;
  (iv) a substance used to:
    (A) support the growth and viability of cells during cell culture; or
    (B) process cells during cell culture;
  (v) food that is derived from part of a grafted plant, where that part does not contain novel DNA or novel protein;
  (vi) food derived from a null segregant.

Subsection 1.1.2—16(2) defines a 'null segregant' for the purposes of section 1.1.2—16 as meaning an organism, cell or cells that:

(a) is descended from an organism, cell or cells that contain novel DNA; and
(b) does not contain novel DNA.

The term 'novel protein' would be defined in subsection 1.1.2—2(3) of the Code (see **item [7]** above).

The terms 'used as a food additive', 'used as a nutritive substance' and 'used as a processing aid' are defined in sections 1.1.2—11, 1.1.2—12 and 1.1.2—13 of the Code respectively.

The term 'novel DNA' would be defined in proposed new section 1.1.2—17 (see below).

The intent of **paragraph 1.1.2—16(1)(a)** is to ensure that food from all organisms (plants, animals, and single cell organisms) and cells (cells isolated from a multicellular organism that are then grown in culture) can be captured for pre-market assessment and approval as GM food under the Code if those organisms or cells have been modified to contain novel DNA.

Paragraph 1.1.2—16(1)(b) lists certain foods that are excluded from the list of what constitutes GM food in paragraph 1.1.2—16(1)(a) for the following reasons:

- Food additives, processing aids and nutritive substances – such substances are already regulated by other parts of the Code where they are subject to pre-market assessment and approval.
- Substances used to support the growth and viability of cells or process cells in culture as part of the production of cell-cultured food – these substances are not added for the express purpose of being an ingredient of the food.
- Food from grafted plants, where it is derived from the part of a grafted plant that does not contain novel DNA or novel protein – such food will be equivalent to food derived through conventional breeding approaches.
- Food derived from a null segregant – such food will be equivalent to food derived through conventional breeding approaches.

The intent of the definition for 'null segregant' in subsection 1.1.2—16(2) is to remove any doubt that food from a null segregant organism, cell or cells is excluded from the proposed new definition for GM food, as this has been a point of ambiguity with the existing GM food definition. It has never been the intent to capture food from a null segregant organism, cell or cells as GM food under the Code.

If approved, the overall effect of the new definition of GM food would be to reframe the regulatory approach to GM food, where food is proposed to be considered GM food based on the presence of novel DNA in the genome of the organism or cells from which food is derived. This represents a change from the current approach where food is considered to be GM food if it is derived using gene technology, irrespective of the outcome of that genetic modification process.

The intent is to only regulate foods as GM foods under the Code when the outcome of the genetic modification process is different to what could be achieved through conventional breeding approaches. This will ensure GM foods are regulated in a way that is commensurate with risk, and also remove ambiguity about what foods are GM foods for the purposes of the Code.

Section 1.1.2—17 sets out the new definition for 'novel DNA'. This definition provides that in the Code, 'novel DNA' means DNA that:

(a) a person has inserted into the genome of an organism, cell or cells; and
(b) is either:
    (i) from a species that has not previously been crossed or hybridised with the species of the organism, cell or cells; or
    (ii) from a species that has previously been crossed or hybridised with the species of the organism, cell or cells, where the sequence or arrangement of the inserted DNA was changed prior to its insertion; or
    (iii) not from an existing species.

Paragraph 1.1.2—17(a) refers specifically to a person inserting novel DNA into the genome of an organism, cell or cells. This aims to avoid the unintentional capture of foods as GM foods under the Code in circumstances where insertion of 'novel DNA' has occurred through a natural process, without intervention by a person.

Paragraph 1.1.2—17(b) lists three types of DNA that will be considered 'novel DNA' under the new definition.

The intent of **paragraph 1.1.2—17(b)** is to limit the scope of what constitutes GM food to those foods that could not otherwise be produced using conventional breeding methods. The

emphasis in the definition of 'novel DNA' is therefore on whether or not the DNA is obtained from a species that has been crossed or hybridised with the species from which the food is derived, and whether the DNA has been modified prior to insertion. In particular:

- subparagraph 1.1.2—17(b)(i) would capture DNA as 'novel DNA' if it is from a species that is unrelated (i.e., not able to be crossed or hybridised) to the species from which food is derived;
- subparagraph 1.1.2—17(b)(ii) would capture DNA as 'novel DNA' if it is from the same or a closely related species (i.e., able to be crossed or hybridised) to the species from which food is derived, but where that DNA been rearranged or changed in its sequence prior to insertion;
- subparagraph 1.1.2—17(b)(iii) would capture DNA as 'novel DNA' if the sequence of the DNA cannot be attributed to an existing species - this would encompass DNA that has been computationally designed de novo.

The intent of the new definition for 'novel DNA' is to clarify what types of DNA would be considered 'novel DNA' for the purposes of the new definition for GM food. The new definition for 'novel DNA' would also be relevant for the purposes of labelling (see **item [18]** below).

Standard 1.2.1 – Requirements to have labels or otherwise provide information

Items [9] – [11] of the Schedule to the draft variation would amend Standard 1.2.1 of the Code. In particular:

Item [9] would amend paragraph 1.2.1—8(1)(k) by omitting '*foods produced using gene technology', and substituting the omitted term with '*genetically modified food'.

Item [10] would amend paragraphs 1.2.1—9(3)(b) and (ba) by omitting 'foods produced using gene technology', and substituting the omitted term with '*genetically modified food'.

Item [11] would amend paragraph 1.2.1—15(f) by omitting 'foods produced using gene technology', and substituting the omitted term with '*genetically modified food'.

An asterisk placed immediately before a term in the Code means that the term either is defined, or has an entry stating where it is defined in Standard 1.2.1, in subsection 1.1.2—2(3).

Those provisions in Standard 1.2.1 specify how information relating to specific types of food must be provided as follows:

- food for retail sale that is both packaged and required to bear a label because of section 1.2.1—6— on the label of the packaged food;
- food for retail sale that is not required to bear a label because of section 1.2.1—6 (irrespective of whether or not the food is packaged)—on labelling that either accompanies the food, or is displayed in connection with the display of the food;
- food sold to a caterer which is packaged and required to bear a label because of section 1.1.2—12— on the label of the packaged food;
- food sold to a caterer which does not have to bear a label because of section 1.1.2—12—on labelling provided to the caterer with the food.

If approved, the effect of the amendments in **items [9]** – **[11]** would be that labelling and information requirements in Standard 1.2.1 would apply to GM food as per the new definition

proposed in **item [8]** above.

Standard 1.2.4 – Information requirements – statement of ingredients

Item [12] of the Schedule to the draft variation would amend Standard 1.2.4 of the Code by repealing paragraph 1.2.4—5(6)(b), and substituting it with:

> '(b) if the compound ingredient comprises less than 5% of the food for sale—the following ingredients:
>
> (i) any ingredient of the compound ingredient that is required to be listed in accordance with section 1.2.3—4 or section 1.5.2—4; and
>
> (ii) any substance *used as a food additive in the compound ingredient which performs a technological purpose in the food for sale.'

Subparagraph 1.2.4—5(6)(b) (as amended) would include a reference to section 1.5.2—4 (see **item [18]** below).

Paragraph 1.2.4—5(6)(b) relates to the listing of a compound ingredient in a statement of ingredients when the compound ingredient comprises less than 5% of the food for sale. Existing paragraph 1.2.4—5(6)(b) requires an ingredient of a compound ingredient to be listed (in brackets) in a statement of ingredients if the ingredient is required to be listed in accordance with section 1.2.3—4 (i.e. certain foods that are food allergens) only, and any substance used as a food additive in the compound ingredient which performs a technological purpose in the food for sale.

The term 'used as a food additive' is defined in section 1.1.2—11 of the Code.

If approved, the effect of the amendment proposed in **item [12]** would be that the requirement to label a compound ingredient when it comprises less than 5% of the food for sale would also apply to GM food that contains novel DNA or novel protein, or where that GM food has been determined by the Authority to have an altered characteristic that is listed in section S26—3 of the Code.

Standard 1.5.2 – Food produced using gene technology

Items [13] – [19] of the Schedule to the draft variation would amend Standard 1.5.2 of the Code. In particular:

Item [13] would amend the title of Standard 1.5.2 by omitting 'Food produced using gene technology' from the title and substituting the omitted term with 'Genetically modified food'.

If approved, the effect of this amendment would be to rename the Standard as Standard 1.5.2 – Genetically modified food.

Item [14] would amend Note 3 to the title of Standard 1.5.2 by repealing Note 3 and substituting the Note with a new Note 3.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

New Note 3 would explain the following to the reader:

- Paragraphs 1.1.1—10(5)(c) and (6)(g) provide that a food for sale must not consist of, or have as an ingredient or a component, a GM food, unless expressly permitted by this Code.

- Standard 1.5.2 contains the relevant permissions.
- Schedule 26 provides definitions of the terms ‘line’ and ‘transformation event’; and lists approved GM foods and any conditions for use of the food.

Amendments proposed in **items [13]** and **[14]** are consequential to amendments proposed to definitions in Standard 1.1.2 in **items [4] – [8]** above; and Schedule 26 in **items [35]** – **[37]** below.

Item [15] would amend section 1.5.2—1 by omitting ‘Food produced using gene technology’ and substituting the omitted term with ‘Genetically modified food’.

Section 1.5.2—1 sets out the name of the Standard.

This proposed amendment is consequential to the amendment proposed in **item [13]** above.

Item [16] would amend Notes 1 - 3 in section 1.5.2—2 by repealing those Notes and substituting them with new Notes 1 - 4.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

New Note 1 sets out a copy of the definitions of GM food and ‘null segregant’ in proposed new section 1.1.2—16 of the Code (see **item [8]** above).

New Note 2 sets out a copy of the definition of ‘novel DNA’ in proposed new section 1.1.2—17 of the Code (see **item [8]** above).

New Note 3 sets out a copy of the definition of ‘novel protein’ proposed in section 1.1.2—2 of the Code (see **item [7]** above).

New Note 4 explains to the reader that definitions of the terms ‘line’ and ‘transformation event’ are in Schedule 26.

The amendments proposed in **item [16]** are consequential to amendments proposed to definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [35]** – **[37]** below.

Item [17] would amend section 1.5.2—3 by repealing the section and substituting it with a new section 1.5.2—3.

Existing section 1.5.2—3 sets out when ‘food produced using gene technology’ is permitted for sale and provides that:

> ‘A food for sale may consist of, or have as an ingredient, a *food produced using gene technology if the food produced using gene technology:
> (a) is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule; or
> (b) is a substance that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3.’

New section 1.5.2—3 sets out when GM food is permitted for sale and provides that:

> ‘A food for sale may contain, or consist of, a *genetically modified food if that genetically modified food is:

(a) listed in Schedule 26; and
(b) complies with any corresponding conditions listed in that Schedule.'

An asterisk placed immediately before a term in the Code means that the term either is defined, or has an entry stating where it is defined in Standard 1.2.1, in subsection 1.1.2—2(3).

This amendment would:

- remove the reference in section 1.5.2—3 to 'a substance that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3', as these substances would be specifically excluded from the new definition for GM food proposed in **item [8]** above;
- substitute the term 'food produced using gene technology' with 'genetically modified food'.

If approved, the overall effect of this amendment would be to permit a food for sale to contain or consist of a GM food, if both of the following conditions are met:

- the GM food is listed in Schedule 26; and
- the GM food complies with any corresponding conditions in that Schedule.

Item [18] would amend section 1.5.2—4 by repealing the section and substituting it with a new section 1.5.2—4. The new section sets out the labelling requirements for GM food, proposed as a consequence of the amendments to the definitions in Standard 1.1.2 proposed in **items [4]** – **[8]** above; and Schedule 26 in **items [35]** – **[37]** below.

In particular, for an explanation of the proposed new definition of GM food, see **item [8]** above.

New subsection 1.5.2—4(1) sets out the type of food to which section 1.5.2—4 applies. According to new subsection 1.5.2—4(1), the section applies to a food for sale that meets the following conditions:

- the food for sale contains, or consists of, a GM food that is listed in Schedule 26: and
- that GM food either:
  - contains novel DNA or novel protein; or
  - is listed in section S26—3 of the Code as being subject to the condition that its labelling must comply with this section, and
- the food for sale is not a food listed in subsection (2).

GM food is listed in S26—3 where the Authority has determined that the food has altered food characteristics as a result of the genetic modification.

New subsection 1.5.2—4(2) sets out the listed foods for the purposes of paragraph 1.5.2—4(1)(c), i.e. food for sale to which requirements in subsection 1.5.2—4 do not apply. The listed foods are as follows:

- a food for sale containing GM food where the GM food is both:
  - unintentionally present in the food for sale; and
  - present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient; or

- a food for sale that is both:
  - intended for immediate consumption; and
  - prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).

New subsection 1.5.2—4(3) sets out the requirements applying specifically to GM food for the purposes of the labelling provisions in Standard 1.2.1. According to new subsection 1.5.2—4(3), for those labelling provisions, the information relating to GM food is the statement 'genetically modified' used in conjunction with the name of the GM food.

The new Note to subsection 1.5.2—4(3) explains to the reader that:

- the labelling provisions referred to in subsection 1.5.2—4(3) are set out in Standard 1.2.1; and
- the labelling provisions apply to both packaged and unpackaged GM food.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

New subsection 1.5.2—4(4) provides that if the GM food is an ingredient (including an ingredient of a compound ingredient), the information may appear in the label other than in the statement of ingredients.

An example of how to meet the above requirements is provided. Standards 1.2.1 and 1.2.4 of the Code require the labelling of certain foods for sale to include a statement of ingredients. In this example, GM corn meal that is used as an ingredient of a crumbed fish compound ingredient that is in turn used in a mixed ingredient food could be declared in the statement of ingredients for that mixed ingredient food as:

> '*Crumb coating (wheat flour, water, canola oil, corn meal (genetically modified), salt, sugar, egg white)*'.

Alternatively, the name of the GM ingredient could be declared in the statement of ingredients (for example: '*corn meal*') in accordance with Standard 1.2.4, with the information required by section 1.5.2—4 appearing elsewhere on the label as, for example: '*contains genetically modified corn meal*'.

If approved, the effects of this amendment would be to:

- simplify and clarify the current labelling provisions under the proposed new definitions for GM food and 'novel DNA';
- remove reference to substances used as a food additive and substances used as a processing aid, as these substances would be specifically excluded from the new definition for GM food proposed in **item [8]** above;
- remove current labelling exemptions and requirements that specifically relate to substances used as a food additive (including flavouring substances), and substances used as a processing aid, as such exemptions and requirements would become redundant as a consequence of the amendments to definitions proposed in **items [4]** – **[8]** above.

The term 'flavouring substance' is defined in subsection 1.1.2—2(3) of the Code.

The terms 'used as a food additive' and 'used as a processing aid' are defined in sections 11 and 13 of the Code respectively.

Standard 2.9.1 – Infant formula products

Items [19] – [23] of the Schedule to the draft variation would amend Standard 2.9.1 of the Code.

The proposed amendments to Standard 2.9.1 are based on amendments proposed in the *Food Standards (Proposal P1028 – Infant Formula) Variation* (the Infant Formula Variation) and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation* (the Infant Formula Consequential Amendments Variation)[46], which were approved by the Authority and are being considered by the FMM. If endorsed by the FMM, it is expected that both variations would be gazetted and take effect in late August 2024.

The particular amendments proposed to Standard 2.9.1 in this variation are as follows:

Item 19 would amend Standard 2.9.1 by repealing section 2.9.1—10, and substituting it with a new section 2.9.1—10 (including a new title for the section).

In the Infant Formula Variation, section 2.9.1—10 (titled 'Required forms for nutritive substances') requires nutritive substances used in infant formula or follow-on formula in accordance with section 2.9.1—8 (Required nutritive substances) or 2.9.1—9 (Optional nutritive substances) to be added in a permitted form listed in:

- if a vitamin, mineral or electrolyte—the table to section S29—23; and
- in any other case— the table to section S29—9.

New section 2.9.1—10 (titled 'Required forms and sources for nutritive substances') would set out the following requirements for those nutritive substances:

- if the substance is a vitamin, mineral or electrolyte – the substance must be added in a permitted form listed in the table to section S29—23 of the Code;
- in any other case – the substance must comply with both of the following requirements: be added in a permitted form listed in Column 2 to the table to section S29—9; and be derived from a corresponding source, if any, specified in Column 3 of that table (see also **item [44]** below).

The term 'used as a nutritive substance' is defined in section 1.1.2—12 of the Code.

It is intended that the requirements for nutritive substances in section 2.9.1—10 would reflect the corresponding permissions proposed to be listed in Schedule 29 (see **item [44]** below). The existing table to subsection S26—3(7) lists permitted food produced using gene technology of microbial origin and their corresponding conditions.

It is also intended that this amendment would:

- preserve the existing permissions and conditions of use for nutritive substances currently listed in Schedule 26;
- enable new permissions and conditions of use to be included for future nutritive substances derived via genetic modification.

Item [20] would amend paragraph 2.9.1—10A(1)(c) by repealing the paragraph, and substituting it with a new paragraph 2.9.1—10A(1)(c).

[46] See Attachments A and B of the Approval Report for P1028 - Infant Formula at: https://www.foodstandards.gov.au/sites/default/files/2024-06/Approval%20Report%20-%20Proposal%20P1028%20Infant%20Formula.pdf

In the Infant Formula Variation, section 2.9.1—10A requires that the substances to which the section applies must comply with any conditions of use that are set out in Column 3 of the table to section S29—9A.

In that Variation, subsection 2.9.1—10A(1) provides that section 2.9.1—10A applies to a substance that meets all of the following conditions – the substance is:

(a) used as a nutritive substance in an infant formula product; and

(b) listed in Column 1 of the table to section S29—9A; and

(c) in a permitted form listed in Column 2 of that table for that substance.

New paragraph 2.9.1—10A(1)(c) refers to nutritive substances that are *derived from a source* that is listed in Column 2 of the table to section S29—9A, instead of being *in a permitted form* listed in Column 2.

If approved, the effect of this amendment would be that section 2.9.1—10A would apply to a substance that is:

- used for a nutritive purpose in infant formula products; and
- listed in the Column 1 of the table to S29—9A; and
- derived from a source listed in Column 2 of that table (see also **item [45]** below).

Item [21] would amend subsection 2.9.1—10A(2) by omitting the words 'substance in that permitted form.', and substituting the omitted text with 'substance.'.

In the Infant Formula Variation, subsection 2.9.1—10A requires a substance to which subsection 2.9.1—10A(1) applies (see **item [20]** above) to comply with any conditions specified in Column 3 of the table to section S29—9A for that substance *in that permitted form*.

The intent of this amendment is to remove what would be redundant language as a consequence of other amendments proposed in the Schedule to the draft variation e.g. **item [20]** above and **item [45]** below.

Item [22] would amend section 2.9.1—38 by repealing the section and substituting it with a new section 2.9.1—38 (including a new title for the section).

In the Infant Formula Variation, section 2.9.1—38 (titled 'Required forms for nutritive substances') requires substances used in a special medical purpose product for infants in accordance with section 2.9.1—36 (Required nutritive substances) or 2.9.1—37 (Optional nutritive substances) to be in a permitted form listed in:

- if the substance is a vitamin, mineral or electrolyte—the table to section S29—23; and
- in any other case—the table to section S29—9.

The term 'special medical purpose product for infants' would be defined in subsection 1.1.2—3(2) of the Code.[47]

New section 2.9.1—38 (titled 'Required forms and sources for nutritive substances') would

[47] See Attachment B of the Approval Report for P1028 – https://www.foodstandards.gov.au/sites/default/files/2024-06/Approval%20Report%20-%20Proposal%20P1028%20Infant%20Formula.pdf

require such substances to:

- if the substance is a vitamin, mineral or electrolyte—be added in a permitted form listed in the table to section S29—23; and
- in any other case—be added in a permitted form listed in Column 2 of the table to section S29—9; and be derived from a corresponding source, if any, specified in Column 3 of that table (see also **item [44]** below).

It is intended that the requirements for nutritive substances in section 2.9.1—38 would reflect the corresponding permissions proposed to be listed in Schedule 29 (see **item [44]** below).

Item [23] would amend subparagraph 2.9.1—49(1)(c)(i) by omitting 'foods produced using gene technology' from the subparagraph, and substituting the omitted term with '*genetically modified food'.

Section 2.9.1—49 sets out the mandatory labelling requirements for special medical purpose products for infants.

If approved, the effect of the amendment would be that this provision refers to GM food, instead of food produced using gene technology, as a consequence of amendments to definitions of terms used in the Code relating to genetic technologies proposed in **items [4]** – **[8]** above.

The intent of this amendment is to ensure that labelling requirements applying to GM food (both existing requirements and requirements proposed to be amended) would apply, where relevant, to special medical purpose products for infants.

Schedule 3 – Identity and purity

Items [24] and **[25]** of the Schedule to the draft variation would amend Schedule 3 of the Code. In particular:

Item [24] would amend subsection S3—35(2) by omitting 'protein engineered enzymes' (wherever occurring) from the subsection, and substituting the omitted term with 'enzymes'.

Item [25] would amend subsection S3—35(2) by omitting 'a protein engineered enzyme' (wherever occurring) from the subsection, and substituting the omitted term with 'an enzyme'

Those amendments are proposed as a consequence of the amendments to definitions of terms used in the Code relating to genetic technologies proposed in **items [4]** – **[8]** above.

If approved, the effect of the amendments set out in **items [24]** and **[25]** would be to remove references to 'protein engineered' from Schedule 3 as this term would become redundant given the exclusion of substances used as a processing aid from the new definition for GM food proposed in **item [8]** above.

'Protein engineered' is a term used to convey that the enzyme processing aid has an amino acid sequence that is not found in nature and therefore is not subject to the labelling exemption in subsection 1.5.2—4(5). As processing aids would be specifically excluded from the GM food definition, labelling requirements for GM food would no longer apply to processing aids. Consequently, if the draft variation is approved, the term 'protein engineered' would no longer serve a purpose in the Code.

Schedule 18 – Processing aids

Items [26] – **[31]** of the Schedule to the draft variation would amend Schedule 18 of the Code. In particular:

Item [26] would amend Note 3 to subsection S18—4(2) by repealing the Note.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

Note 3 to subsection S18—4(2) relates to protein engineered variants of enzymes, which are identified in section S18—4 as processing aids permitted to perform any technological purpose if the enzyme concerned is derived from the corresponding source specified in the table.

Item [27] would amend the table to subsection S18—4(5) by omitting ', protein engineered variant' (wherever occurring) from the table.

Item [28] would amend the table to subsection S18—9(3) by omitting ', protein engineered variant,' (wherever occurring) from the table.

Item [29] would amend the table to subsection S18—9(3) by omitting 'Protein engineered enzyme' (wherever occurring), and substituting the omitted term with 'Enzyme'

Item [30] would amend the table to subsection S18—9(3) by omitting 'Protein engineered enzymes', and substituting the omitted term with 'Enzymes'.

Item [31] would amend the Note to the table to subsection S18—9(3) by repealing the Note.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

The Note to the table to subsection S18—9(3) relates to protein engineered variants of enzymes, which are listed in the table as processing aids permitted to be used for specific technological purposes.

If approved, the effect of the amendments in **items [26]** – **[31]** would be to remove terms in Schedule 18 which include references to 'protein engineered' because the term 'protein engineered' would become redundant given the exclusion of substances used as a processing aid from the new definition of GM food proposed in **item [8]** above.

'Protein engineered' is a term used to convey that the enzyme processing aid has an amino acid sequence that is not found in nature and therefore is not subject to the labelling exemption in subsection 1.5.2—4(5). As processing aids would be specifically excluded from the GM food definition, labelling requirements for GM food would no longer apply to processing aids. Consequently, if the draft variation is approved, the term 'protein engineered' would no longer serve a purpose in the Code.

Schedule 26 – Food produced using gene technology

Items [32] – **[41]** would amend Schedule 26 of the Code. In particular:

Item [32] would amend the title to Schedule 26 by omitting 'Food produced using gene technology' from the title of the Schedule, and substituting the omitted term with 'Genetically modified food'.

Item [33] would amend Note 1 to the title of Schedule 26 by repealing the Note, and

substituting it with a new Note 1.

Notes in the Standard do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

New Note 1 would explain to the reader that (among other things):

- paragraphs 1.1.1—10(5)(c) and (6)(g), and Standard 1.5.2, of the Code regulate GM food; and
- Schedule 26 lists GM food, and their corresponding conditions for the purposes of paragraph 1.5.2—3(a) of the Code (for an explanation of new section 1.5.2—3, see **item [17]** above).

Item [34] would amend section S26—1 by omitting 'Food produced using gene technology' from the section, and substituting the omitted term with 'Genetically modified food'.

Section S26—1 states the name of Schedule 26.

The amendments proposed in **items [32]** – **[34]** above are consequential to the amendments to definitions of terms used in the Code relating to genetic technologies proposed in **items [4]** – **[8]** above.

The intent of the amendments proposed in **items [32]** – [**34]** above is to ensure that the relevant provisions refer to the term 'genetically modified food' instead of 'food produced using gene technology', as the latter term would become redundant as a consequence of amendments to definitions proposed in **items [4]** – **[8]** above.

Item [35] would amend subsection S26—2(2) by repealing the definition for 'conventional breeding' in the subsection.

The reason for the proposed amendment is that the definition for 'conventional breeding', which refers to 'gene technology', would become redundant as a consequence of amendments to definitions proposed in **items [4]** – **[8]** above.

Item [36] would amend subsection S26—2(2) by repealing the definition for 'line' in the subsection, and substituting it with a new definition for 'line'.

If approved, the effect of the new definition for 'line' would be to broaden its scope to both plants and animals. The existing definition for 'line' refers only to plants.

Item [37] would amend subsection S26—2(2) by repealing the definition for 'transformation event' in the subsection, and substituting it with a new definition for 'transformation event'.

The existing definition for 'transformation event' refers to 'a unique genetic modification arising from the use of gene technology'.

The new definition refers instead to 'a unique genetic modification arising from the insertion of novel DNA'.

The reason for this proposed amendment is remove reference to 'gene technology', and refer instead to 'novel DNA', to be consistent with the proposed new definition for GM food in **item [8]** above. The term 'gene technology' would become redundant as a consequence of amendments to definitions proposed in **items [4]** – **[8]** above.

Item [38] would amend the title of section S26—3 by omitting 'food produced using gene

technology' from the title, and substituting the omitted term with 'genetically modified food'.

Item [39] would amend subsection S26—3(1) by omitting 'food produced using gene technology' from the subsection, and substituting the omitted term with 'genetically modified food'.

Item [40] would amend the heading of the table to subsection S26—3(4) by omitting 'Food produced using gene technology' from the heading, and substituting the omitted term with 'Genetically modified food'.

If approved, the effect of the amendments set out in **items [38]** – [**40]** would be that these provisions refer to GM food instead of 'food produced using gene technology', as the latter term would become redundant as a consequence of amendments to definitions proposed in **items [4]** – **[8]** above.

Item [41] would amend subsection S26—3(7) by repealing the subsection which includes a table listing permitted food produced using gene technology of microbial origin, and substituting it with a new subsection S26—3(7) that would include a table listing permitted GM food of microbial origin.

If approved, this proposed amendment would:

- replace the reference to 'Food produced using gene technology' in the title to the table with a reference to 'Genetically modified food'; and
- remove the entries in the table relating to permitted human identical milk oligosaccharides, as these entries would be transferred to Schedule 29 of the Code (see **items [44]** and **[45]** below).

However, the new table to subsection S26—3(7) would retain the existing entry for 'soy leghemoglobin preparation', as the preparation would fall within the new definition for GM food proposed in **item [8]** above.

Schedule 29 – Special purpose foods

Items [42] – **[45]** would amend Schedule 29 of the Code.

The proposed amendments to Schedule 29 are based on amendments proposed in the Infant Formula Variation and the Infant Formula Consequential Amendments Variation[48], which were approved by the Authority and are being considered by the FMM. If endorsed by the FMM, it is expected that both variations would be gazetted and take effect in late August 2024.

The particular amendments proposed to Schedule 29 are as follows:

Item [42] would amend the table to section S29—7 by omitting 'permitted for use by Standard 1.5.2' (wherever occurring) in the table.

Item [43] would amend the table to section S29—8 by omitting 'permitted for use by Standard 1.5.2' (wherever occurring) in the table.

If approved, the effect of the amendments proposed in **items [42]** and **[43]** would be that the

[48] See Attachments A and B of the Approval Report for P1028 - Infant Formula at: https://www.foodstandards.gov.au/sites/default/files/2024-06/Approval%20Report%20-%20Proposal%20P1028%20Infant%20Formula.pdf

relevant nutritive substances would be regulated by Standard 2.9.1 instead of Standard 1.5.2, as those substances would no longer fall within the new definition for GM food proposed in **item [8]** above.

Item [44] would amend section S29—9 by repealing the section (including the table and Note to the section), and substituting it with a new section S29—9 (including a new table and Note to the section).

Notes in the Schedule do not have a substantive legal effect. Instead, their purpose is simply to explain certain matters to the reader.

Section S29—9 has been amended to accommodate nutritive substances derived via genetic modification that are permitted for use in infant formula products, which are not vitamins, minerals or electrolytes.

In particular:

- the new section and table headings would refer to 'Permitted forms and sources' (of nutritive substances) instead of simply 'Permitted forms';
- the new table to the section would no longer refer to 'permitted for use by Standard 1.5.2' and instead, would include permissions for human identical milk oligosaccharides and their source organisms that are currently listed in the table to S26—3(7); and
- the new table would have a third column listing the source of the permitted nutritive substance.

These proposed amendments correspond to the amendments proposed to paragraphs 2.9.1—10(b) and 2.9.1—38(b); and the table to subsection S26—3(7), in **items [19]**, **[22]** and **[41]** respectively above.

Item [45] would amend the table to section S29—9A by repealing the table, and substituting it with a new table to section S29—9A .

The new table to section S29—9A would:

- include the permitted human identical milk oligosaccharides, and their corresponding conditions of use, which are listed in the current table to S26—3(7) (this proposed amendment is related to the amendment proposed to subsection S26—3(7) in **item [41]** above); and
- remove entries for those permitted human identical milk oligosaccharides where the exclusive use period has now expired (exclusive use periods for human identical milk oligosaccharides are currently listed as a 'condition of use' in the table to S26—3(7)).

If approved, the effect of this proposed amendment would be to group all the permitted nutritive substances with their corresponding conditions of use into a single table in Schedule 29.

The primary purpose of the amendments in **items [42] – [45]** is to preserve the existing permissions for nutritive substances currently listed in Schedule 26, and to enable new permissions to be included for future nutritive substances derived via genetic modification.