18 June 2025
345-25

Approval Report – Proposal P1055

Definitions for gene technology and new breeding techniques

FSANZ has prepared and 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.

On 30 July 2024, FSANZ sought submissions on a draft food regulatory measure extending across six standards and four schedules and published an associated report. FSANZ received 1485 submissions.

After having regard to the submissions received and the relevant matters as set out in this report, FSANZ approved draft variations on 4 June 2025. The Food Ministers' Meeting was notified of FSANZ's decision on 18 June 2025.

This report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991*.

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Supporting documents

The following document(s) which informed the assessment of this proposal are available on the FSANZ website[1]:

SD1	Safety assessment: full technical report
SD2	Safety assessment: plain English summary
SD3	Consumer research (*at approval*)
SD4	Decision Regulation Impact Statement
SD5	Updated compilation of regulatory approaches and definitions (*at approval*)

The published submissions from the call for submissions can be found on the P1055 Consultation Hub page.

[1] P1055 landing page – 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 approved changes to definitions for genetically modified (GM) food in the Australia New Zealand Food Standards Code (the Code). They are necessary to keep pace with technology developments, including the emergence of new breeding techniques (NBTs), and ensure regulatory requirements remain appropriate and proportionate to risk.

The primary change introduces new definitions for 'genetically modified food' and 'novel DNA' to replace the old process-based definitions for 'food produced using gene technology' and 'gene technology'. Unlike the old definitions, the new definitions focus on the outcome of the genetic modification process which is more relevant to risk.

A food will be a GM food under the Code if it is from an organism or cells containing novel DNA as an outcome of the genetic modification. Novel DNA is defined to exclude the types of genetic modifications introduced through conventional breeding or are naturally occurring.

Our comprehensive safety assessment confirmed many genetic modifications introduced using NBTs will be the same as those introduced through conventional breeding or occur naturally. Food from conventionally bred organisms with these changes has a long history of safe use. If a NBT is used to introduce the types of genetic modifications made through conventional methods, the food is just like any other conventional food and does not need to be assessed by FSANZ.

The new definition for 'genetically modified food' also clarifies, through explicit exemptions, that certain other foods and substances are not GM foods. Food from null segregants and food from grafted plant parts without novel DNA and novel protein are exempt because the foods will be indistinguishable from, and just as safe as, conventional food. Food additives, processing aids and substances used in cell culture are exempt as they are regulated by other parts of the Code.

A range of other approved changes to the Code give effect to the new definitions, remove redundant provisions or clarify provisions that interact with the new definitions. These changes are minor and consequential in nature.

In considering the totality of these changes, FSANZ had regard to the best available scientific evidence, existing policy related to GM foods, input from both public and targeted consultation, consumer research, international developments in the regulation of NBTs and an analysis of the costs and benefits.

The changes are consistent with regulatory approaches already adopted or being considered internationally and also will bring GM food regulations into closer alignment with domestic gene technology regulations.

The new definitions do not alter the overall regulatory approach to GM food, including how it is labelled. Foods that are GM foods under the new definitions will continue to require an application to FSANZ for pre-market safety assessment and approval. If approved and listed in the Code, GM foods will continue to be subject to mandatory GM labelling requirements.

Glossary

Term	Description
Cell culture	The practice of growing plant, animal or microbial cells in an artificial environment.
Cell-cultured food	A food obtained by culturing cells isolated from any of the following sources: livestock; poultry; game; seafood (including fish); an egg or an embryo of any of the former.
Cell line	A collection of cells that are derived from a single source that was prepared under specific culture conditions. Cell lines have a uniform composition and are intended for use in the production of a cell mass.
Cisgenesis	A process in genetic modification where 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 e.g. cross breeding, classical mutagenesis.
Conventional food	Food derived from plants or animals obtained through conventional breeding.
De novo	A term used in biology to describe a process or thing that is completely new, 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.
Food additives	A substance added to the food to perform a technological purpose (specified in section 1.1.2—11 of the Code).
Gene technology	Recombinant DNA techniques that alter the heritable genetic material of living cells or organisms (as specified in subsection 1.1.2—2(3) of the Code prior to this proposal). May also be called GM techniques.
Genetic modification (GM)	The process of altering the DNA of an organism.
Genetically modified organism (GMO)	Defined by the *Gene Technology Act 2000* as 'an organism that has been modified by gene technology'.
Genome	The complete set of genetic material in a living cell or organism.
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 whose genome has novel DNA. This proposal contains a new Code definition for 'GM food' (refer to section 3.4.1).
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.

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.
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	A term FSANZ has adopted to define DNA that is considered 'foreign' to an organism. That is, from a source that is unrelated to that organism, or DNA that is unlikely to be produced using conventional breeding methods or that does not occur naturally. This proposal contains a new Code definition for 'novel DNA' (refer to section 3.4.2).
Novel food	A non-traditional food that requires an assessment of public health and safety considerations (specified in section 1.1.2—8 of the Code).
Novel protein	Protein encoded by novel DNA. This proposal contains a new Code definition for 'novel protein'.
Null segregants	Progeny that has not inherited novel DNA. Please refer to the new proposed Code definition in section 3.4.1.
Nutritive substances	A substance added to food to achieve a nutritional purpose (specified in section 1.1.2—12 of the Code).
Precision fermentation	A technology that uses genetically modified microorganisms to produce specific products such as proteins, human-identical milk oligosaccharides, vitamins or steviol glycoside sweeteners.
Processing aids	A substance used during the course of food processing to (1) perform a technological purpose in the course of processing and (2) not perform a technological purpose in a food for sale (specified in section 1.1.2—13 of the Code)
Recombinant DNA	*In vitro* laboratory techniques are used to recombine or join DNA from 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 insertion of novel DNA

1 Introduction

1.1 The proposal

Proposal P1055 – Definitions for gene technology and new breeding techniques (NBTs) 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[2] which concluded the definitions for 'food produced using gene technology' and 'gene technology' are no longer fit for purpose. The review found the definitions are unclear, outdated and do not reflect the diversity of techniques now in use, or that may emerge in the future. It also concluded there may be a case, based on risk, for some NBT foods to be excluded from the requirement for pre-market safety assessment.

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
- 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). The following regulatory objectives were considered in addition to FSANZ Act requirements 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 NBTs.

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

1.4 Procedure for assessment

This proposal is being assessed under the Major Procedure requirements of the FSANZ Act. This requires two public calls for submissions (CFS) which have now been completed.

The 1st CFS released on 7 October 2021 sought feedback 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 released on 30 July 2024 sought feedback on FSANZ's regulatory approach (as revised following the 1st CFS) and draft variations to six standards and four schedules in the Code. It also sought information to support the consideration of costs and benefits, and the preparation of a Decision Regulatory Impact Statement (DRIS).

The submissions received in response to the 2nd CFS, as well as feedback from additional targeted consultations with stakeholders prior to the finalisation of the approval report, have informed FSANZ's decision on whether to approve, amend or reject the proposed draft variations.

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
- any consequential amendments to the Code that may be necessary to give effect to revised definitions or to clarify other Code provisions that interact with 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 intent or regulatory approach to GM food, including how it is labelled. Foods that are GM foods under amended definitions will continue to require an application to FSANZ for pre-market safety assessment and approval. If approved and listed in the Code, GM foods will be subject to mandatory GM labelling requirements.

1.6 Decision

Following consideration of submissions and for the reasons set out in this report and supporting documents, FSANZ decided to:

- approve the draft variations to the following standards without amendments:
    - 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
    - Schedule 3 – Identity and purity
    - Schedule 18 – Processing aids

- approve the draft variations to the following standards with amendments:
    - Standard 1.1.2 – Definitions used throughout the Code
    - Standard 1.5.2 – Food produced using gene technology
    - Schedule 26 – Food produced using gene technology
    - Standard 2.9.1 – Infant formula products
- reject the draft variations to the following standards:
    - Schedule 29 – Special purpose foods

FSANZ also amended the drafting proposed at the 2nd CFS to include a variation to the following standard:

- Standard 1.3.3 – Processing aids.

The new variation to Standard 1.3.3 is minor in nature and relates to a single Note. The Note was repealed to be consistent with variations to Schedule 3 and 18, removing reference to 'protein engineered'.

The approved draft variations are at Attachment A. The variations take effect on gazettal.

The related 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.

The draft variations on which submissions were sought at the 2nd CFS are at Attachment C.

2 Overview of the proposal to date

2.1 Current Code requirements for GM foods

2.1.1 Pre-market assessment and approval

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a 'food produced using gene technology'.[3] Standard 1.1.2 defines a 'food produced using gene technology' for this purpose.

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

The effect of the above is to require pre-market approval of a GM food before it can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment.

Standard 1.5.2 sets out the permission and conditions for sale of a food that is, or has as an ingredient, a GM food. Permitted GM foods are listed in Schedule 26 of the Code. Standard 1.5.2 also provides that a GM food that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3 is also a permitted GM food for the purposes of Standard 1.5.2.

[3] See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g).

P1055 aims to revise and update the definitions for GM food to clarify what NBT foods should be subject to pre-market assessment and approval as GM foods under the Code.

2.1.2 Labelling

Approved GM foods are subject to mandatory labelling under section 1.5.2—4 of Standard 1.5.2. Mandatory GM labelling reflects the policy intent 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)*.[4]

The purpose of GM 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. The requirement for product labelling is based on the presence of novel DNA or novel protein, or an altered characteristic (see Box 1), in the food for sale. Several exemptions to labelling may apply (e.g. the exemption for highly refined foods or ingredients). Further information about GM food labelling is available on the FSANZ website.[5]

Box 1. Altered characteristic

An **altered characteristic** is when, for example, the GM food has an altered composition or nutritional profile compared to the existing non-GM counterpart food. Approved GM food with an altered characteristic must be labelled 'genetically modified' irrespective of the presence of novel DNA or novel protein in the food for sale

2.2 Assessment summary

FSANZ has undertaken comprehensive assessments of all relevant issues, some of which pre-date the commencement of P1055 but provide key background to the proposal. To assist this work, FSANZ established an Expert Advisory Group (EAG) to provide expert technical advice on NBTs.[6] FSANZ engaged with the EAG on multiple occasions for both the earlier NBT review and P1055.

2.2.1 Previous FSANZ considerations

FSANZ hosted two expert technical workshops in 2012 and 2013 to enhance FSANZ's understanding of emerging techniques. The workshops discussed scientific and technical issues related to derived food products, including how such products might compare to GM foods. Reports from both workshops are available online.[7]

In June 2017, FSANZ commenced a review of food derived using new breeding techniques to consider how the Code should apply to NBT foods. That review examined whether the definitions for 'food produced using gene technology' and 'gene technology' are fit for

[4] 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

[5] GM food labelling webpage – https://www.foodstandards.gov.au/consumer/gmfood/labelling

[6] Information on the expert advisory group – www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

[7] NBT workshops landing page – https://www.foodstandards.gov.au/consumer/gmfood/New-plant-breeding-techniques-in-the-spotlight

purpose given the emergence of NBTs, and whether pre-market safety assessment of NBT foods would be justified based on risk.

The main finding of the review was that the current definitions in the Code are no longer fit for purpose in that they lack clarity, are outdated and do not reflect the diversity of techniques now in use. In addition, it was concluded there may be a case, based on risk, for some NBT foods to be excluded from the requirement for pre-market safety assessment.

The review considered whether options were available, other than amending the Code, to address the problem. Some of these options included the development of guidance or a code of practice to clarify interpretation of the current definitions in the Code. The review found it was unlikely such approaches would be effective at addressing the problem because they would not provide legal certainty. Any such guidance would also only apply to the current definitions, which the review concluded are not fit for purpose. It was therefore recommended that FSANZ prepare a proposal to amend the definitions in the Code.

Key reports (available online[8]) for the NBT review are:

- Consultation paper: Food derived using new breeding techniques (February 2018)
- Preliminary report: Food derived using new breeding techniques – consultation outcomes (August 2018)
- Final report: Review of food derived using new breeding techniques (December 2019).

2.2.2 P1055 evidence assessment

The assessment for P1055 included a comprehensive safety assessment that compared NBTs to other methods of genetic modification, including conventional breeding. The safety assessment was published as a supporting document to the 1st CFS and is also appended to this approval report (Supporting Document 1 (SD1)). A plain English summary is provided in SD2.

The key finding from the safety assessment was that some NBT foods will be equivalent in their product characteristics to conventional food and will therefore present the same low risk. Because of this low risk, FSANZ concluded pre-market safety assessment is not needed and such food should not be GM food for Code purposes.

Conclusions from the safety assessment were considered by FSANZ and informed the proposed approach to exclude certain NBT foods from the new definition based on their equivalence to conventional foods.

Consumer research was also undertaken to gain a greater understanding of general community attitudes towards NBTs and GM foods, with supplementary information being received through the public consultation process. A summary of this research is provided in SD3 to this report. The consumer research reports are also available online (links provided in SD3).

A DRIS was prepared for decision makers to inform their decision on whether to approve the proposed changes and contains the impact analysis (including the consideration of costs and benefits) of the proposed changes. The DRIS is provided in SD4 to this report.

[8] Key NBT review reports – https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies.

2.2.3 CFS summary

The 1st CFS sought views on FSANZ's assessment, including a comprehensive safety assessment, and FSANZ's preferred regulatory option based on that assessment. The preferred option was to amend the definitions to exclude certain NBT foods and refined ingredients from regulatory capture as GM foods based on their equivalence in characteristics and risk to conventional food with a history of safe use. To achieve this outcome, FSANZ proposed to expand the definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding. It also proposed to amend the definition for 'food produced using gene technology' to include specific product-based criteria for excluding certain foods and ingredients from pre-market safety assessment and approval as GM food. A preliminary cost benefit analysis was also included.

After carefully considering submissions in response to the 1st CFS and undertaking further assessment, a 2nd CFS was released in July 2024. The 2nd CFS:

- summarised FSANZ's assessment following the 1st CFS
- provided a revised approach to amending the definitions, including a proposed new definition for 'genetically modified food'
- provided the reasons for FSANZ's decision to prepare each draft variation
- gave the rationale for the proposed measures contained in each variation.

FSANZ sought submissions to inform its decision on whether each proposed draft variation should be rejected, approved, or approved with amendments.

The approach to amending the definitions was revised to make it simpler and clearer. This did not change the overall intent presented in the 1st CFS, which was to exclude certain NBT foods from regulatory capture as GM foods based on their equivalence to conventional foods. The revised approach included redefining 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 old definitions where food is considered GM food if it is derived using gene technology, irrespective of the outcome of that process.

The key reports (available online[9]) for P1055 are:

- 1st Call for Submissions (October 2021), including 3 supporting documents
- Stakeholder feedback summary report (November 2022);
- 2nd Call for Submissions (July 2024), including 2 supporting documents.

2.3 Submissions received to the 2nd CFS

FSANZ received a total of 1485 submissions to the 2nd CFS (see Table 1 below). The submissions are publicly available on the P1055 Consultation Hub page. FSANZ also had regard to late comments.

[9] P1055 landing page – 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 • South Australian Department for Health and Wellbeing • Victorian Departments of Health and Energy, Environment and Climate Action
Individuals (1386)	• 693 private individuals • 693 campaign submissions
NGOs and community groups (18)	• Auckland GE-free Coalition • Children's Heath Defense Australia Chapter • Friends of the Earth New Zealand • Gene Ethics • GE Free New Zealand • GE Free Tai Tokerau • HEART Party • Institute of Health and Environmental Research Incorporated • New Zealand Outdoors and Freedom Party • New Zealand Health Trust • OGM Dangers • Physicians and Scientists for Global Responsibility • Seniors' Voice, Otamatea • Takahiwai Maori Committee • Te Pūtahitanga o Te Waipounamu • The Non-GMO Project • Voices for Freedom • World Council for Health Australia
Organic sector (29)	• Australian Organic Limited • Biodynamic Research Institute • BioGro New Zealand Limited • Buy Pure New Zealand • Ceres Organics Limited • Chantal Shop • Commonsense Organics Limited • Foundation on Future Farming (Zukunftsstiftung Landwirtschaft) • Incafe Organic Coffee • Kete Ora Trust • Lux Organics Limited • Milla Saber Clothing • Natural Grocers (USA) • Natural Sugars New Zealand Limited • Organics Aotearoa New Zealand • Organic Consumers Association of Australia Incorporated • Organic Dairy and Pastoral Group • Organic Farm New Zealand • Organic Industries of Australia Limited • Organic and Regenerative Investment Co-operative • Organic Winegrowers New Zealand • Santos Organics • Soil and Health Association of New Zealand • Southern Organic Group • Te Waka Kai Ora • Thames Organic Shop • Maple Street Co-op • The Organic Food Chain Proprietary Limited • Waiheke Herbs

Environment and health groups (7)	• Agrownomics • Healthy Food Systems Australia • Manu Waiata Restoration and Protection Society Secretariat • Permaculture International College	• Watershed Landcare Incorporated • WePlanet Australia • World of Wellness International
Research (8)	• AgResearch Limited • Agrifood Innovation Institute • ARC Centre of Excellence in Plants for Space • ARC Training Centre for Accelerated Future Crops Development	• Commonwealth Scientific and Industrial Research Organisation • Food and Beverage Accelerator • Life Sciences Network Incorporated • The New Zealand Institute for Plant and Food Research Limited
Industry and peak bodies (32)	• All G Foods Proprietary Limited • Animal Medicines Australia • Australian Beverages Council Limited • Australian Food and Grocery Council • Australian Grape and Wine Incorporated • Australian Institute of Food Science and Technology • Australian Seed Federation • AUSVEG • BASF Australia Limited • BioTech New Zealand • Cellular Agriculture Australia • Cotton Australia • CropLife Australia • Danisco New Zealand Limited, on behalf of International Flavors and Fragrances Incorporated • EuropaBio	• Fonterra Co-operative Group Limited • Food Frontier Institute Limited • GrainGrowers • Grain Trade Australia • Horticulture New Zealand • Infant Nutrition Council • InterGrain Proprietary Limited • Miruku Limited • New Zealand Beverage Council • New Zealand Food and Grocery Council • National Farmers Federation • Nestlé • Noumi Limited • Novozymes Australia Proprietary Limited • SPS International Incorporated • T&G Global Limited • The Australasian Association and Register of Practicing Nutritionists

3 Discussion of key issues from the 2nd CFS

The sections below discuss key issues raised by submitters to the 2nd CFS and FSANZ's response. Issues not covered below are addressed in Appendix 1.

3.1 Regulatory approach

FSANZ proposed an outcomes-based regulatory approach based on the presence of novel DNA in the organism from which food is derived, with the intent of excluding foods that are equivalent in risk to conventional foods. This approach was based on the conclusions of FSANZ's detailed safety assessment and subsequently refined through the submission process.

The rationale for an outcomes-based approach based on the presence of novel DNA is that it 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 cells, or it is not. This will assist product developers to comply with the Code and jurisdictions to implement, interpret and enforce Code requirements. An outcomes-based approach is also less likely to become outdated because it is not based on a specific technique or technology.

Submitter feedback

Submitters were divided on the proposed regulatory approach at the 2nd CFS.

Many submitters representing NGOs, community groups, the organic sector including peak bodies, as well as a large number of private individuals, were strongly opposed to the proposed approach. They expressed general concerns regarding GM and NBT foods, advocating for a process-based approach where all foods derived from gene technology undergo pre-market safety assessment. These concerns have been raised in previous consultations.

Other submitters from peak industry bodies representing the food and grain sectors, biotechnology and research sectors, and government (i.e. jurisdictions) generally supported a risk proportionate outcomes-based approach based on the presence of novel DNA, including the explicit exemptions. They generally agreed this had simplified the approach initially proposed at the 1st CFS. Many of these submitters also provided detailed feedback on various aspects of the new GM food definition, including concerns regarding the proposed exemption for nutritive substances, and suggestions for how the wording of the definition could be made clearer.

FSANZ response

FSANZ has carefully considered all submitter views on the proposed regulatory approach and acknowledges the ongoing concerns with, and opposition to, the exclusion of any NBT foods from a revised definition among particular stakeholder groups.

In considering the opposing submissions, FSANZ notes no new information, including scientific evidence, was provided that would alter its previous safety assessment, conclusions or proposed regulatory approach to exclude certain NBT foods from regulatory capture as GM food. FSANZ's further assessment following the 2nd CFS also did not identify any new information that would alter these conclusions. Consequently, FSANZ maintains that sufficient scientific justification exists to exclude NBT foods from pre-market assessment and approval as GM foods when they are equivalent in characteristics and of similar low risk to conventional foods.

FSANZ also has carefully considered the feedback and suggestions from submitters on various aspects of the definition itself. This feedback is addressed in the following sections, and also in Appendix 1 and 2 of this report.

Decision

FSANZ reaffirms its previous conclusions from the 2nd CFS that certain NBT foods 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 has decided to maintain the outcomes-based approach based on the presence of novel DNA in the organism from which food is derived.

3.2 Specific food categories

In proposing the outcomes-based approach at the 2nd CFS, FSANZ considered how the new definition relates to specific food categories and technologies. The following subsections discuss specific issues raised by submitters in relation to these food categories.

3.2.1 Excluded foods and the novel food standard

In the 2nd CFS report, FSANZ stated that under the new GM food definition, certain NBT foods would not be GM food for Code purposes.[10] This means that, for the purposes of food regulation, excluded foods are no different to conventional food.

FSANZ noted excluded foods may still be subject to other Code requirements, including those for novel foods, which is also the case for food derived from conventional breeding. Such food may be considered a novel food if it has characteristics that warrant a safety assessment by FSANZ, having regard to criteria set out in section 1.1.2–8 of the Code.[11]

In considering the types of foods developed to date using genome editing and cisgenesis (without inserting novel DNA), FSANZ noted most of the traits being introduced into plants and animals are ones that already exist in conventional counterparts and have a long history of safe use in the food supply.

Submitter feedback

Some submitters interpreted statements in the 2nd CFS report as meaning FSANZ intended to capture excluded NBT foods with altered characteristics as novel foods and raised concerns about this approach. Submitters found the distinction between conventional food and novel food to be unclear and requested further clarity on the threshold for when an NBT food with altered characteristics would be a novel food, including scenarios where NBTs had

[10] Food from from an organism that does not contain novel DNA in its genome (could be food from a genome edited organism or food from a cisgenic organism), or food from the parts of a grafted plant that do not contain novel DNA or novel protein.

[11] 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.

been used to achieve biofortification. There were also concerns that the absence of a definition for 'altered characteristics' could create a regulatory gap, potentially allowing foods with off target/unintended changes resulting in altered characteristics to enter the food supply without first being assessed.

FSANZ response

The intent of excluding certain NBT foods from the scope of the new GM food definition is to recognise their equivalence to conventional foods, both in terms of their food characteristics and their low risk.

In relation to altered characteristics, FSANZ notes the objective for any type of genetic modification, whether it be via conventional breeding, GM techniques or NBTs, is to introduce a desirable trait into the organism, and therefore alter its characteristics (e.g. make an animal disease resistant, or a crop drought tolerant). In some cases, it will be a derived food product, rather than the organism itself, that has the altered characteristic (e.g. soybean oil with increased oleic acid content).

FSANZ determines whether a GM food has an altered characteristic and is subject to GM labelling during an assessment of an application. This determination is based on criteria developed by FSANZ (discussed in section 4.1, see also box 1) and is not based on definitions in the Code. FSANZ considers such criteria are not relevant for determining if a food is novel, as defined in the Code. Moreover, FSANZ does not consider a definition for 'altered characteristic' is needed, or that the absence of such a definition may lead to a regulatory gap in relation to altered characteristics arising from unintended or off-target changes.

FSANZ's safety assessment (SD1) considered the issue of unintended or off-target changes in detail and noted these can occur with all methods of genetic modification, including conventional breeding. All breeding programs, irrespective of whether they use conventional methods, GM techniques, NBTs, or a combination of methods, will routinely undertake screening and selection processes to eliminate unintended/undesirable outcomes. GM techniques and NBTs are also no more likely to produce unintended outcomes than conventional methods. An unintended change to the characteristic of a food does not necessarily mean that change represents a health or safety concern (hazard). Whether a potential hazard exists will depend on the nature of the altered characteristic, not the fact the change itself was unintended.

Furthermore, the presence of an altered characteristic in a food, whether that has occurred through conventional breeding or the use of a NBT, does not automatically make that food a novel food for Code purposes. However, before marketing such food (whether a conventional food or a NBT food), it is the responsibility of a food business to exercise appropriate due diligence to ensure the food complies with the Code. Like GM foods, novel foods are prohibited from sale unless expressly permitted and listed in the Code.

In relation to the distinction between conventional food and novel food, and the threshold for when a NBT food with altered characteristics would be a novel food, it is not a one-size-fits-all situation. In determining whether a food is a novel food, foods in question need to be considered on a case-by-case basis and take account of a range of factors to firstly determine if they are a "non-traditional food", and if so, if a safety assessment by FSANZ would be warranted. It is rarely as simple as just determining whether a threshold has been exceeded (see Box 2).

Box 2. High oleic acid soybean oil

High oleic acid is an example of a trait that occurs naturally in some types of oils but has also been introduced into soybean through conventional breeding, older GM techniques and, more recently, through genome editing. Standard soybean oil typically contains about 22% oleic acid, compared to modified soybean varieties which have oleic acid levels ranging from 70-84%.

While the high oleic acid trait in modified soybean varieties would be considered an altered characteristic compared to standard soybean varieties, FSANZ considers it unlikely high oleic soybean oil (whatever the method used to introduce the trait) would be considered a novel food because:

- the levels of oleic acid in the modified soybean varieties are consistent with natural levels in other commonly consumed oils e.g., olive oil (75%), macadamia oil (80%) and avocado oil (65%)
- soybean itself and soybean oil has a long history of safe human consumption in Australia and New Zealand
- the modified soybean oils are intended to be used in a similar way to other vegetable oils with a similar fatty acid profile
- there are no toxicity concerns with the levels of oleic acid in modified soybean varieties.

Information and resources are available on the FSANZ website to assist food businesses to determine if a particular food they wish to bring to market requires pre-market assessment as a novel food.[12] Food businesses may also submit an enquiry to the Advisory Committee on Novel Foods (ACNF), although there is no legal obligation to do so.

A guidance tool has been developed to assist the ACNF in reaching its view. Examples of completed guidance tools are available from the FSANZ website.[13] Once the ACNF completes its assessment of a food, it provides a recommendation about whether the food is a novel food for the purposes of the Code. These recommendations are provided to help a food business make their own decision on whether they should submit an application to FSANZ for a novel food approval.[14]

Following approval of the P1055 draft variations, the guidance tool will be reviewed to determine if any changes or additional information is required to assist the ACNF to make recommendations should an enquiry be received for a NBT food. Should the guidance tool be updated, it will be made available online.

3.2.2 Foods and ingredients derived using precision fermentation

In the 2nd CFS, FSANZ indicated the existing regulatory approach to precision fermentation products would continue. That is, unless subject to a specific exemption, precision fermentation products would continue to be captured as GM foods and, if approved, subject to GM labelling requirements, consistent with current policy.

Submitter feedback

A number of submitters from food industry, biotechnology and research sectors raised concerns about continuing to regulate precision fermentation products as GM foods. They argued treating precision fermentation products as GM foods, even though they do not

[12] Novel foods – https://www.foodstandards.gov.au/business/novel
[13] ACNF – https://www.foodstandards.gov.au/business/novel/novelcommittee
[14] The ACNF recommendations are not legal advice and are not legally binding, nor do they represent advice, recommendations, or decisions by FSANZ on whether a food is or is not a novel food.

contain novel DNA in the final product, is inconsistent with FSANZ's outcomes-based approach and how such products are regulated internationally.

It was suggested FSANZ consider excluding precision fermentation products from GM food regulations where they are demonstrated to be substantially equivalent to conventional foods with a history of safe use. Where such products are not substantially equivalent to conventional foods, it was suggested FSANZ consider developing either a specific food standard to regulate such products or alternatively regulate them under Standard 1.5.1 – Novel foods. There was also support for prioritising Proposal P1024 – Revision of the regulation of nutritive substances and novel foods, to provide clarity for the precision fermentation sector.

FSANZ response

FSANZ has carefully considered the issues raised and acknowledges the increasing interest in, and importance of, the growing precision fermentation sector, and the need for regulatory clarity in relation to how such products will be regulated into the future. The issues raised, however, relate to the overarching regulatory and policy approach to GM foods, including labelling, which are all matters that are out of scope of P1055.

FSANZ remains open to further discussion with the sector and other interested stakeholders to explore possible future avenues for considering the issues raised above.

Decision

FSANZ re-affirms that, unless an explicit exemption applies, precision fermentation products derived from microorganisms that contain novel DNA in their genome will be regulated as GM foods under the new definition.

3.2.3 Processed food ingredients

In the 1st CFS, FSANZ explored the use of product-based exclusion criteria to exclude processed food ingredients[15] from the new GM food definition. The exclusion criteria were: (i) the ingredient is identical in composition to an equivalent conventionally derived ingredient and (ii) the absence of novel DNA and novel protein in the food for sale.

Following further assessment for the 2nd CFS, FSANZ determined it would be technically challenging to develop clear and objective criteria that could be uniformly applied across a 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. It was concluded it would not be practically possible to provide for such exclusions under the outcomes-based approach. As a result, FSANZ proposed that processed food ingredients derived from organisms that contain novel DNA in their genome would continue to be regulated as GM food.

Submitter feedback

Certain stakeholders expressed disappointment this exclusion was not retained under the proposed new outcomes-based definition for GM food. Some submissions highlighted that regulating processed ingredients as GM foods under the Code does not align with an outcomes-based approach. It was also questioned whether processed ingredients could be regulated under other parts of the Code where appropriate (e.g. as novel foods).

[15] Examples of processed food ingredients include sugar, starches, protein concentrates, amino acids, gelatine products, fats and oils.

FSANZ response

After careful consideration of submissions to the 1st CFS, FSANZ concluded that the exclusion of processed ingredients would be technically complex and challenging to apply across a wide range of products.

FSANZ also notes that, as with other product-based criteria which were proposed in the 1st CFS, many submitters raised concerns about the significant burden on product developers to demonstrate compliance, requiring them to generate large data sets for excluded products. For example, in the case of a processed ingredient, to demonstrate it is "identical in composition to an equivalent conventionally derived ingredient".

Following further assessment post the 2nd CFS and having regard to the diversity of processed products that could potentially be subject to such an exclusion, FSANZ has determined it would be more appropriate for any such exclusions to be considered on a case-by-case basis[16] via an application to FSANZ where specific evidence can be provided in support of such an exclusion.

Decision

FSANZ reaffirms its decision at 2nd CFS that processed food ingredients derived from organisms that contain novel DNA will continue to be regulated as GM foods under the Code.

3.3 Substances added to foods

FSANZ proposed to explicitly exempt food additives, processing aids and nutritive substances from the GM food definition. The rationale for the exemption was that such substances are already appropriately regulated under other parts of the Code and subject to pre-market safety assessment. FSANZ also noted other countries typically do not distinguish between GM and non-GM derived food additives and processing aids in their regulations.

Submitter feedback

No substantive issues were raised by submitters in relation to the proposed exemption of processing aids and food additives.

In relation to nutritive substances, while some submitters were supportive of the exemption because this would be consistent with EU regulations, other submitters raised some concerns. Industry submitters were concerned about the potential for inconsistent regulatory outcomes for precision fermentation products, with some products designated as nutritive substances being exempt from GM requirements and others not.

Some jurisdictions also noted while there is historical evidence that processing aids and food additives as a category of substances do not contain GM material and therefore do not trigger GM labelling requirements, the same level of historical evidence does not exist for nutritive substances as a category. They were concerned an exemption for nutritive substances would incentivise industry to claim precision fermentation products as nutritive substances to avoid GM labelling.

FSANZ response

[16] This could be for a specific product category (e.g. sugars or oils) or a specific type of ingredient within a product category (e.g. refined sugar from sugarcane).

FSANZ has carefully considered submitter comments relating to nutritive substances and agrees it is difficult to consider exempting nutritive substances without also having regard to the regulation of precision fermentation products as a whole.

As noted above, the precision fermentation sector is growing rapidly. A recent FAO report highlighted the sector is heavily focussed on producing a diverse array of substances for addition to foods for a variety of purposes (FAO 2025). The full spectrum of products under development however is currently uncertain. It is also not clear how many and what types of substances would be intended for addition to food for a nutritive purpose, or what their level of purity would be, particularly for proteins.

Given these uncertainties, FSANZ has concluded it would be difficult to consider nutritive substances separately from the regulation of precision fermentation products as a whole which, as discussed above in subsection 3.2.2, is out of scope of this proposal.

Decision

FSANZ has decided to maintain the status quo for nutritive substances by amending the draft GM food definition at 2nd CFS to remove the proposed exemption.

Nutritive substances derived from organisms or cells that contain novel DNA will continue to be regulated as GM foods, in addition to being regulated according to their purpose as a nutritive substance. Approved GM derived nutritive substances will also continue to be listed in Schedule 26 and be subject to GM labelling requirements.

Given no substantive issues were raised in relation to the exemption of food additives and processing aids from the GM food definition, FSANZ has decided to maintain the proposed exemption for these substances.

3.4 Definitions

FSANZ asked for feedback on the clarity of the new definitions for ‘genetically modified food’ and ‘novel DNA’ and whether these new definitions produce the intended regulatory outcomes.

3.4.1 New definition for ‘genetically modified food’

The draft variation repealed the definitions for ‘food produced using gene technology’ and ‘gene technology’ set out in subsection 1.1.2—2(3) of the Code and replaced them with a new definition for ‘genetically modified food’. The new definition includes a primary definition, a list of exempted foods and substances and a definition for ‘null segregant’.

Submitter feedback

The key issue raised by submitters in relation to the GM food definition was the proposed exemption for nutritive substances. The remainder of the feedback was focussed on some of the wording used in the definition, with alternative wording being provided e.g. for null segregant. Two additional exemptions were also suggested. These were for (a) foods derived from an organism or cells without novel DNA but with altered characteristics and (b) substances that are substantially equivalent to those derived from conventional sources. There were also requests to define specific terms, such as ‘derived from’ or ‘cell culture’.

FSANZ response

Except for the issues raised in relation to nutritive substances (which FSANZ has responded

to in section 3.3 above), the remaining comments on the GM food definition were relatively minor in nature, and do not indicate any substantive issues related to clarity or the intended regulatory outcomes. FSANZ has responded to these minor issues in Appendix 1. FSANZ notes additional information relating to the intent of the new definition is provided in the explanatory statement for the draft variation (Attachment B). FSANZ also intends to work with the jurisdictions to develop guidance material to support greater understanding of the new definition, including how it should be interpreted and applied (see section 5 and Appendix 2).

Decision

Based on the feedback received, FSANZ is satisfied the definition for genetically modified food is clear and produces the intended regulatory outcomes. FSANZ has therefore approved the new definition for 'genetically modified food' as amended since the 2nd CFS to remove the exemption for nutritive substances.

The new definition for 'genetically modified food' as approved by FSANZ is set out in Box 3. Table 2 below summarises the intended regulatory outcomes for different types of foods and substances.[17]

Box 3. New definition for 'genetically modified food'

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

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

[17] This table is an update to Table 3 of the 2nd CFS report.

Table 2. Intended regulatory outcomes

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 its genome	**GM food** unless subject to exemption
Food from a null segregant	**Not a GM food** (exempt)
Substances used as a food additive (FA) or processing aid (PA) from an organism or cells that contain novel DNA in its genome	**Not GM food** (exempt) FA and PA are subject to pre-market regulation under other parts of the Code
Substances used as a nutritive substance (NS) from an organism or cells that contain novel DNA in its genome	**GM food** NS are also subject to pre-market regulation under other parts of the Code
Precision fermentation product from a microorganism that contains novel DNA in its genome	**GM food** unless subject to exemption. May be subject to pre-market regulation under other parts of the Code
Food from a genome edited organism that contains novel DNA in its genome	**GM food** unless subject to exemption
Food from a genome edited organism that does not contain novel DNA in its genome	**Not a GM food** May be subject to regulation under other parts of the Code
Food from conventionally bred organisms	**Not a GM food** May be subject to regulation under other parts of the Code
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 under other parts of the Code
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

3.4.2 New definition for ‘novel DNA’

FSANZ proposed a new definition for ‘novel DNA’ (see Box 4), with the intent to capture food from both transgenic and intragenic organisms, while excluding food from cisgenic

organisms. The definition also 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.

Inserted DNA and exclusions

Submitter feedback

Submitters sought clarity on whether insertions and modifications from conventional breeding methods would be captured by the novel DNA definition e.g. mutagenesis, natural mutation and self-cloning. Submitters also questioned how the use of homology directed repair templates or altering existing DNA sequences through non-homologous end joining would be treated by the definition. It was also unclear to submitters if any DNA insertion would be captured as novel or if the inserted DNA needed to be a functional genetic unit i.e. promotor, coding region and terminator.

It was also suggested that the definition exclude non-coding DNA that modulates gene expression. The rationale given was that it does not create novel proteins and resembles breeding outcomes.

FSANZ response

FSANZ has considered the issues raised and acknowledges the outcomes-based approach represents a paradigm shift away from the previous process-based understanding of what constitutes a GM food. It will take time for businesses and enforcement agencies to become familiar with the new approach and definitions, including how they relate to specific technologies.

Under the new approach, it is the outcome in the genome that is the focus, not the technique or process used to achieve it. In the case of the new GM food definition, it is the presence of novel DNA that is the outcome of interest. It is irrelevant if the inserted DNA is a functional genetic unit, part of a genetic unit, coding or non-coding DNA, small or large. The fact that DNA has been inserted does not automatically make it novel DNA. Only certain types of inserted DNA will be novel, as set out by paragraph (b) of the definition.

The novel DNA definition has been drafted to exclude the types of genome changes introduced using longstanding conventional methods, as well as similar genome changes that can be achieved using genome editing. Classical mutagenesis, natural mutation and techniques such as self-cloning[18], which all are used to modify the endogenous genome, would not introduce novel DNA, as defined under the new definition. Also, the phrase "a person has inserted" in paragraph (a) is intended to make it clear that genome changes which are naturally occurring are not novel DNA.

To assist food businesses to determine if a particular food they wish to bring to market is a GM food and requires pre-market assessment, information relating to the intent of the new definition is provided in the explanatory statement to the draft variation (Attachment B). FSANZ also intends to develop guidance material to support greater understanding of the new definition, including how it should be interpreted and applied (see section 5 and Attachment 2).

With respect to an exclusion or exemption for non-coding DNA, while FSANZ acknowledges

[18] A self-cloned microorganism is one that has been modified to contain several copies of a gene that is already present in its genome.

the rationale provided, this proposal does not seek to change the regulatory approach to GM foods currently captured and listed in Schedule 26. If inserted non-coding DNA belongs to one of the types of novel DNA described in paragraph (b), it will be novel DNA for Code purposes.

Draft variation

The definition for novel DNA, as proposed at 2nd CFS, is provided in Box 4. Submitter feedback on the novel DNA definition far exceed that received for the primary GM food definition.

Box 4. Definition of novel DNA at 2nd CFS

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

Submitter feedback on paragraph (a)

Many submitters did not agree with the use of the term 'a person' in paragraph (a). They noted it would exclude the insertion of DNA via automated processes, it focuses on the 'process' and not the 'outcome' and does not reflect the writing style of any other standards. Submitters also commented that the term 'inserted' is ambiguous and lacks clarity. They suggest including terms such as 'exogenous DNA' and 'stable'.

FSANZ response

FSANZ has considered the feedback regarding 'a person has inserted' and has decided to retain the term. FSANZ considers it covers situations where DNA has been inserted by automated means, as 'a person' would still be involved in directing the process. Despite the use of 'a person has inserted' FSANZ does not consider this detracts from the outcomes focus of the definition. FSANZ also notes that removing 'a person has inserted' would risk capturing DNA insertions that have occurred naturally, which is not FSANZ's intent. The clarity of the definition is more important than whether the writing style has been used in other standards.

FSANZ also amended the explanatory statement (Attachment B) to clarify that the insertion of 'novel DNA' using automated processes would be captured by the definition.

FSANZ has explored whether the inclusion of 'exogenous' and 'stable' in the novel DNA definition would add clarity and considers the terms are more likely to add complexity and introduce ambiguity, and in any case are redundant. The common meaning of 'exogenous' is DNA that originates outside the target organism. However, this makes the definition unclear with respect to cisgenic DNA. In relation to adding the word 'stable', in FSANZ's view this is not needed as inserted DNA will be stably integrated in the genome or maintained episomally to create commercially viable food production organisms or cells.

Submitter feedback on paragraph (b) – 'previously been'

Feedback on the 'novel DNA' definition primarily centred around paragraph (b). Submitters felt the phrases 'has not previously been' in (b)(i) and 'has previously been' in (b)(ii) are unclear and unenforceable. It was suggested to replace these phrases with '*cannot be*' or '*could not have*' in *(b)(i)* and '*can be*' or '*could have*' in *(b)(ii)*. Other suggestions for new terms, alternative text or an entirely new definition for novel DNA were provided.

FSANZ response

For paragraph (b), FSANZ acknowledges submitter concerns around the clarity and enforceability of the phrases 'has not previously been' and 'has previously been'. Improving clarity about what foods are captured for pre-market approval is a primary objective in revising the definitions. In light of this feedback, FSANZ further considered paragraph (b) of the novel DNA definition and agrees that 'can be' is clearer and less onerous to justify scientifically. It also removes the temporal aspect of 'previously been' and shifts the focus to what can be done.

The term 'can be' was also discussed with jurisdictions when FSANZ undertook targeted consultation following the 2nd CFS. The feedback received was that the term 'can be' is simpler and clearer for enforcement purposes and likely also for compliance purposes. Based on this feedback, FSANZ has decided to replace the term 'has previously been' with 'can be'.

In considering the clarity of paragraph (b), FSANZ recognised that repetition of language in (b)(i) and (b)(ii) added a layer of complexity to the definition, making it harder for the reader to understand. The repetition relates to the wording:

> *'from a species that [can be] crossed or hybridised with the species of the organism, cell or cells'.*

To reduce complexity and improve readability, FSANZ decided to substitute 'crossable species' for the wording above, which has now been used in a new definition for 'crossable species' (see Table 3).

Submitter feedback on paragraph (b) – food from organisms modified using intragenesis

Several submitters who generally supported the proposed outcomes-based approach raised concerns and made very specific suggestions about FSANZ's approach to intragenesis. Their comments reflect a need for greater clarity on the difference between cisgenesis and intragenesis. Many submitters argued that intragenesis should also be excluded from the 'novel DNA definition' for several reasons, including that it is better aligned with FSANZ's outcomes-based regulatory approach and to prevent inadvertent capture of conventional breeding outcomes. Supplemental scientific information was also provided to FSANZ as evidence to demonstrate that intragenesis occurs naturally and has been a key driver of natural genetic variation.

Response

FSANZ acknowledges the technical distinction between cisgenesis and intragenesis is not always clear and that some overlap exists. For both techniques, the DNA originates from the same or a crossable species. In cisgenesis, the DNA is transferred in its native configuration, whereas in intragenesis, new DNA combinations are created by *in vitro* rearrangement of functional genetic elements prior to insertion. Intragenesis can therefore result in different outcomes:

Outcome 1 – A gene's regulatory components are changed (still using DNA from the same or a crossable species) but the coding region remains unchanged. This may be done to change the level or location of gene expression.

Outcome 2 – A gene's coding region is rearranged. For example, to shuffle exons or introns or other distinct elements between different genes or to create inverted repeats to express double-stranded RNA species that are used for RNA interference.

The recombination of genes occurs in nature e.g. intragenic recombination and the creation of chimeric genes via retroposition[19] in plants (Okagaki et al 2018; Wang et al 2006) and has been used in conventional breeding. However, the shuffling of coding regions to produce protein variants or the design of inverted repeats to express interfering RNAs (outcome 2) is highly specific and unlikely to be produced using conventional breeding methods.

Such new protein variants or novel RNA species can be said to have a presumption of greater risk because they do not have a history of safe use in food. FSANZ considers these types of outcomes similar to the types of modifications found in products listed in Schedule 26. As highlighted in section 1.5, Proposal P1055 is not intended to change the overall policy intent or regulatory approach to GM foods. As such, providing an exclusion for intragenesis is out of scope of this proposal.

However, FSANZ acknowledges there are nuances to intragenesis and the final outcome achieved. For example, a developer may use cis-DNA, which only includes a coding region, to replace the coding region of another gene. The outcome is a coding region with different regulatory components. Here, the outcome observed will look like intragenesis but the process used is cisgenesis.

Following consideration of these issues and further assessment, FSANZ considers sufficient justification exists to capture outcome 2 as novel DNA, but not outcome 1. FSANZ has therefore revised the wording of subparagraph b(ii) to focus specifically on whether the coding region was rearranged or recombined prior to insertion (see Table 3), as this is more relevant to risk and consistent with the types of intragenic products already listed in Schedule 26.

Submitter feedback on paragraph (b) – other terms

Submitters suggested adding the term 'coding sequence' in reference to novel DNA and replacing 'species' with 'gene pool', as the latter captures the total range of cross-compatible germplasm available to a breeder.

Response

Similar to the suggestion from submitters to exclude or exempt non-coding DNA from the definition, limiting the novel DNA definition to 'coding sequences' goes beyond the original policy intent of Standard 1.5.2.

FSANZ considered the term 'gene pool', but decided 'species' is a more commonly understood term. Further, it would be more straightforward for compliance and enforcement purposes to determine which species are crossable, as opposed to the total range of cross-compatible germplasm.

[19] Retroposition is the process where messenger RNA is transcribed back into DNA and subsequently inserted into a new genomic location.

Submitter feedback on paragraph (b) – what is not considered novel DNA

Some submitters raised concerns regarding the regulatory status of what is not considered novel DNA, including:

- left and right border sequences from the *Agrobacterium*-mediated transformation process
- the genomic location of any inserted DNA
- codon optimisation
- small insertions and deletions from genome editing.

They suggested that FSANZ specify explicitly in the 'novel DNA' definition which DNA sequences are not considered novel DNA. Others preferred clarifying information in a guidance document.

Response

FSANZ has considered whether there is a need to add explicit exemptions for DNA sequences that are not considered novel DNA. FSANZ acknowledges submitter concerns that the left and right border sequences from *Agrobacterium*-mediated transformation process would be considered 'DNA from a species that is not a crossable species'. FSANZ considers such sequences are a by-product of the DNA insertion process and are unimportant to safety.

To make it clear for compliance and enforcement purposes that left and right border sequences from *Agrobacterium*-mediated transformation are not novel DNA for Code purposes, FSANZ considers an explicit exemption necessary. FSANZ has therefore revised the definition for novel DNA accordingly (see Table 3) and included additional clarifying information in the explanatory statement.

For the genomic location of any inserted DNA, or codon optimisation, FSANZ considers the novel DNA definition is clear that these types of events or genome changes do not come within the meaning of 'novel DNA':

- **Genomic location** – paragraph (a) and (b) of the novel DNA definition does not reference genomic location and hence the location of the inserted DNA is not a relevant consideration is determining whether inserted DNA is novel DNA.
- **Codon optimisation** – in the case of a cisgene (i.e. DNA from a crossable species), so long as it does not meet paragraph (b), it is not relevant if the sequence of the DNA was codon optimised prior to insertion.

While explicit exemptions are not required, clarifying information has been included in the explanatory statement.

Regarding small insertions and deletions from genome editing, it would be challenging to define 'small insertions' and may lead to inconsistent and/or perverse outcomes if limits are set. Further, when considering the new definition of novel DNA, the size of the insertion is irrelevant. The most relevant question is whether the inserted DNA is from a species that is not a crossable species i.e. paragraph (b)(i).

Deletions do not come within the meaning of 'novel DNA' (see paragraph (1)(a)).

Decision – Draft variation

FSANZ has decided to make minor technical and structural changes to the novel DNA definition to improve clarity and readability. To give effect to these changes, the draft

variations to Standard 1.1.2 – Definitions used throughout the Code, Standard 1.5.2 – Food produced using gene technology, and Schedule 26 – Food produced using gene technology, as well as the explanatory statement, were changed at approval. The 2nd CFS version of the novel DNA definition and the final definition are provided in Table 3 for comparison purposes. See also Attachment A.

Table 3. Novel DNA definition at 2nd CFS and at approval.

2nd CFS version	Final version
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	(1) 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 one of the following: (i) DNA from a species that is not a crossable species; (ii) DNA that (A) is from a crossable species; and (B) contains a coding region that was rearranged or recombined prior to the insertion referred to in paragraph (1)(a); (iii) DNA that is not from an existing species. (2) In this section, ***crossable species*** means a species of organism, cell or cells that can be crossed or hybridised with the species of organism, cell or cells referred to in paragraph (1)(a). (3) Despite subsections (1) and (2), novel DNA does not include flanking left and right border sequences arising from *Agrobacterium*-mediated transformation.

3.4.3 Consequential changes to the Code

In addition to the 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 are to Standard 1.1.2 – Definitions used throughout the Code, as discussed in sections 3.4.1 and 3.4.2 above. However, several other standards and schedules require amendment because of the changes to Standard 1.1.2. At the 2nd CFS, these were:

- 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

As discussed in section 3.3, FSANZ has decided to maintain the status quo for nutritive substances and not proceed with the proposed exemption. Several consequential changes to Standard 2.9.1 – Infant formula products and Schedule 29 – Special purpose foods were proposed at 2nd CFS because of the new definition for GM food, which included the proposed exemption for nutritive substances.

Apart from omitting reference to "*food produced using gene technology" in subparagraph 2.9.1—49(1)(c)(i) and substituting with "*genetically modified food", FSANZ has decided to reject the remainder of the consequential changes to Standard 2.9.1 and Schedule 29 as these all relate to the proposed exemption for nutritive substances.

Since the 2nd CFS, FSANZ became aware a further consequential change to the Code was required in Standard 1.3.3 – Processing aids. This change was necessary to give effect to the exclusion of processing aids from the GM food definition. FSANZ has included this consequential change in the approved draft variation and explanatory statement.

Many of the consequential changes are minor in nature and did not receive any substantive comments at the 2nd CFS. They do not require further discussion here but are set out in *Attachment A – Approved draft variations to the Australia New Zealand Food Standards Code*.

More notable changes are discussed below, except for those relating to the labelling requirements for GM food, which are discussed in section 4. The full list of standards and schedules changed at approval is provided in section 1.6.

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

Schedule 26 – additional definitions

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 subsection S26—2(2)

At the 2nd CFS, FSANZ considered whether to retain a specific definition for 'conventional breeding' once a new GM food definition was adopted. It was decided that an explicit definition for 'conventional breeding' would not serve any useful purpose in terms of the implementation or interpretation of the new definition for 'genetically modified food'. FSANZ also noted it would need to be revised to be retained.

In response to this decision, a single comment was received highlighting how the 'line' definition refers to conventional breeding and hence the latter definition should be retained. FSANZ also notes that other submitters sought clarity on whether genome changes from conventional breeding would be captured by the new 'novel DNA' definition.

While the 'line' definition refers to 'conventional breeding' (Box 5), FSANZ does not consider this reference sufficient to warrant a new definition. The meaning of 'conventional breeding' is commonly understood and its use in the Code is only in relation to 'line'. A clear dichotomy between GM and conventional food no longer exists and thus defining conventional breeding

would add complexity (see section 3.4.1 in the 2nd CFS document). In terms of clarity and the implementation of the new regulatory approach to GM food, FSANZ is satisfied the removal of the definition for 'conventional breeding' has little to no impact.

Including a revised definition for 'conventional breeding' also will not increase clarity for the 'novel DNA' definition. FSANZ is satisfied the 'novel DNA' definition makes it clear a food that is not a GM food will either be a conventional food or equivalent to a conventional food i.e. a NBT is used to introduce the types of genetic modifications made using conventional methods. Further, FSANZ has updated Table 3 to clarify conventional foods are not GM foods and intends to work with jurisdictions to develop guidance material to support greater understanding of the new definition, including how it should be interpreted and applied (see section 5).

Definition for line and transformation event under subsection S26—2(2)

FSANZ made minor changes to the definition for 'line' at the 2nd CFS to make it applicable to animals and revised the definition of 'transformation event' to remove reference to 'gene technology' (see Box 5).

Box 5. Definition of line and transformation event at 2nd CFS

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

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

One submitter raised several issues relating to the 'line' definition stating it was ambiguous in relation to null segregants and that the term 'transformation event', which is used in the 'line' definition, is superfluous. It was suggested 'transformation event' be replaced with 'a unique novel DNA' and part (b)(iii) of the definition be reworded to be outcomes-based.

The definition for 'line' is intended to be read in conjunction with the table to subsection S26—3(4) of the Code, 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).

In relation to the definition for 'line' being ambiguous in relation to null segregants, FSANZ notes that, by definition, a null segregant does not contain a transformation event or events i.e. it does not contain novel DNA. Therefore, for the purposes of the 'line' definition, a null segregant is equivalent to an animal or plant derived through conventional breeding. If a null segregant is crossed with a conventional plant or animal ('does not contain a transformation event'), the progeny will not contain novel DNA and therefore do not come within the definition for 'line'. Alternatively, if a null segregant is crossed with an approved GM plant or animal line 'that contains a transformation event', any progeny that have inherited the novel DNA will come under the existing permission in place in Schedule 26.

FSANZ has considered the term 'a unique novel DNA' and acknowledges it would simplify

subsection S26—2(2) by removing the need for a 'transformation event' definition. In the end, it was decided to retain 'transformation event' as it is a term routinely used in the context of genetic modification and thus a term that is commonly understood.

Regarding paragraph (b)(iii) of the 'line' definition, FSANZ has decided to maintain the use of the term 'conventional breeding'. While process-based, paragraph (b)(iii) of the definition makes it clear that animal and plant lines that are produced using only conventional breeding do not come within the meaning of 'line'.

While considering the clarity of the 'line' definition, FSANZ recognised the structure is complex, particularly for the text in subparagraph (b). To improve readability, FSANZ has decided to restructure the 'line' definition, while preserving all the elements and wording of the definition at the 2nd CFS (see Attachment 2).

Amendments to the tables to section S26—3

To give effect to the decision to reject all but one of the draft consequential variations to Standard 2.9.1 – Infant formula products and Schedule 29 – Special purpose foods, the human-identical milk oligosaccharide entries in the tables to section S26—3 will remain.

4 Labelling

Proposal P1055 does not change the existing approach to the labelling of GM foods. Approved GM foods remain subject to mandatory labelling with a 'product-based' approach (see section 2.1.2).

The revised definition of 'genetically modified food' will have an impact on the labelling outcomes for a small number of foods, as explained below. However, FSANZ considers these will have minimal practical impact for consumers, given these foods are unlikely to be labelled as 'genetically modified' under existing Code requirements.

FSANZ has also clarified some labelling requirements to ensure GM labelling applies according to the existing labelling policy e.g. when a GM food is an ingredient of a compound ingredient.

4.1 Approach and intent

FSANZ responded to submitter comments to the 1st CFS regarding the implications for GM labelling of the then preferred approach to amending the definitions. FSANZ considered this approach aligns with existing product-based labelling, ensuring regulatory clarity and maintaining the policy intent for GM labelling set by food ministers (see section 4.1.2 in the 2nd CFS for the discussion on this issue).

FSANZ proposed changes to clarify current labelling provisions to ensure they continue to capture the existing intent for product-based labelling. Some proposed changes were consequential to the revised outcomes-based approach (see sections 4.2.1 and 4.2.2 in the 2nd CFS).

Submitter feedback

Most submitters to the 2nd CFS opposed the revised outcomes-based approach for pre-market assessment because it would exclude certain foods from being labelled 'genetically modified', thus limiting consumers' ability to make informed choices. They considered GM labelling is essential to satisfy consumer demand, ensure transparency, uphold trust in the

food supply and maintain the social licence of gene technology.

Concerns were raised about the inconsistency and potential erosion of consumer trust if food additives, processing aids and nutritive substances (which are subject to GM labelling requirements under the existing standards) were excluded from GM labelling. Some consumers also highlighted the importance of process-based labelling to enable informed choice. Refer to Appendix 1 for specific submitter comments.

FSANZ response

FSANZ understands many submitter comments stem from a perception the number of foods labelled as 'genetically modified' will decrease, rather than any change in the GM labelling approach itself.

FSANZ's assessment indicates the outcomes-based definitional approach for pre-market assessment will result in similar labelling outcomes to those under existing Code requirements. Table 4 below provides a comparative illustration of labelling outcomes based on existing Code requirements and under the P1055 variation. In the table, cells shaded green indicate the food or substance would be GM labelled, while cells shaded blue indicate where GM labelling would not apply.

As shown in Table 4, under existing Code requirements, substances used as food additives or processing aids from an organism or cells containing novel DNA would not require GM labelling if the novel DNA or novel protein from these substances is absent in the food for sale. This outcome reflects the labelling exemption for these substances in paragraph 1.5.2—4(1)(b) of the Code. GM labelling would apply if novel DNA or novel protein is present from these substances in the food for sale, however, this is typically not the case as these substances are often highly refined. In practice, this means the same labelling outcomes would typically result from both the existing Code requirements and the P1055 variation. However, FSANZ cannot exclude the possibility that on rare occasions novel DNA or novel protein from these substances may be present in the food for sale. Should this occur, GM labelling would not be required under the outcome-based definitional approach.

The table also shows two cells (shaded green) where 'food from a genome edited organism that does not contain novel DNA in its genome' and 'food derived from the part of a grafted plant that does not contain novel DNA or novel protein' may have required GM labelling for an altered characteristic if they were captured under the existing Code requirements.[20] However, it is uncertain if these foods would be captured for pre-market assessment under the existing Code provisions, and this uncertainty is one reason for clarifying requirements under P1055.[21] In addition, the changes introduced by these two NBTs would be consistent with those from conventional breeding (section 2.3.4 in the 2nd CFS), making GM labelling for these foods unlikely even if captured. As a result, the real-world labelling outcomes for these NBTs under the current Code are highly likely to be the same as under the P1055 variation. FSANZ therefore considers the exclusion of these NBT foods from the definition of GM foods would have minimal practical impact for consumers in terms of labelling.

For detailed responses to specific submitter comments, refer to Appendix 1.

[20] FSANZ's criteria for determining if a GM food has an altered characteristic for labelling purposes are provided on our webpage: https://www.foodstandards.gov.au/consumer/gmfood/labelling

[21] For background on this issue, see section 2.1.2 in the final report of the Review of food derived using new breeding techniques: https://www.foodstandards.gov.au/consumer/gmfood/Review-of-new-breeding-technologies

Table 4. Comparison of labelling outcomes based on existing Code requirements and under the P1055 variation

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

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

4.2 Clarifications and consequential changes to labelling provisions

FSANZ noted in the 2nd CFS that although the labelling approach has not changed, current labelling provisions were clarified to ensure they continued to capture the existing intent for product-based labelling. Some changes were consequential to the revised approach. Based on the assessment and consideration of submitter comments to the 2nd CFS, FSANZ has maintained these amendments, which are described below.

4.2.1 Specific clarifications

Item 20 of the approved draft variation to Standard 1.5.2 clarifies the following:

- A food for sale that contains a GM food will 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)).
- Labelling requirements apply where the GM food is listed as an approved GM food (paragraph 1.5.2—4(1)(a)).
- 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)).
- If a GM food is subject to the labelling requirements, these requirements will apply to a GM food ingredient of a compound ingredient. An example of a GM food ingredient of a compound ingredient has been included (subsection 1.5.2—4(4)).

Item 13 of the approved draft variation clarifies that information relating to GM food will 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)).

4.2.2 Amendments consequential to the revised approach

As noted in section 3.4 of this report, the new definitions for 'genetically modified food', 'novel DNA' and 'novel protein' are also relevant for labelling purposes. The new definition for 'genetically modified food' explicitly excludes substances used as a processing aid or used as a food additive. Therefore, the following current labelling exemptions in paragraph 1.5.2—4(1)(b) and (c) are redundant and will be removed:

- 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[22] 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 in paragraph 1.5.2—4(1)(a) also will 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

[22] **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).

condition that its labelling must comply with section 1.5.2—4 of the Code. Paragraph 1.5.2—4(1)(b) of the approved draft variation achieves the same effect i.e. a GM food will 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 Development of guidance material

FSANZ asked submitters at the 2nd CFS whether additional clarifying information would be helpful to accompany the proposed new definitions and, if so, what type of information would be most useful. At the time, FSANZ had not decided whether guidance material would be developed, and if developed, what form that would take.

Submitter feedback

There was considerable support among submitters for guidance material. Feedback was received across all stakeholder groups and highlighted the desire for more information about food produced using gene technologies, NBTs and the new definitions in the Code. Many submitters also made suggestions about the type of information required and how such information could be communicated e.g. infographics, decision trees, illustrative examples. Submitters also supported education material specifically for consumers, in addition to industry and jurisdictional guidance to support compliance and enforcement.

FSANZ response

FSANZ appreciates the valuable suggestions from submitters about what information would be most helpful and how best to convey it. FSANZ notes a significant amount of explanatory information and education material related to gene technology and NBTs is already available in FSANZ reports and webpages[23,24], however acknowledges existing material may require updating and further detail and explanation may be required in relation to specific technical aspects of the new definition and how it should be interpreted and applied.

Suggestions on the type of information and ideas for how to communicate this information has either been collated in Appendix 2 of this report or FSANZ has had regard to them in section 3.4 or Appendix 1.

Decision

Based on feedback received, FSANZ has decided additional clarifying information in the form of industry and jurisdictional guidance is warranted. Development of this guidance will consider the suggestions and ideas collated in Appendix 2, with work undertaken in consultation with jurisdictions and endorsed by Implementation Sub-committee for Food Regulation (ISFR). FSANZ also expects to consult with other relevant stakeholders during the development of the guidance material. Work will commence once food ministers endorse the draft food regulatory measure approved by FSANZ.

In terms of information for consumers, FSANZ intends to update content on its website where appropriate. Appendix 1 lists relevant webpages where such content already exists.

[23] New breeding techniques – https://www.foodstandards.gov.au/consumer/gmfood/new-breeding-techniques-nbts
[24] Education materials on GM foods and NBTs – https://www.foodstandards.gov.au/consumer/gmfood/Education-materials-on-GM-foods-and-NBTs

6 Other relevant matters

6.1 Potential impacts on the organic sector

Submitter feedback

The organic sector, including certified organic operators, expressed concerns at the 2nd CFS about the impact the draft variations would have on Australian and New Zealand organic systems. Their concerns centred on three key areas: supply chain integrity, verification challenges, and access to export markets.

Submitters from this sector were concerned about an increased risk of contamination of the organic supply chain with NBTs, leading to potential loss of organic certification for producers and a reduction in consumer trust in organic labelling. Submitters also raised concerns that operators will face difficulty verifying organic and non-GM ingredients in the absence of disclosure requirements for NBT foods. Many submitters believed GM labelling is critical to confirming the organic status of products, and the absence of labelling for NBT products would lead to restricted sourcing options for ingredients and increased costs for operators.

Some submitters from this sector expressed concern the proposed regulatory approach to NBT foods would be incompatible with the regulatory frameworks of key organic export markets and would lead to a loss of market access to those regions with strict non-GM regulations. Further concerns were raised about the potential impact on the reputation of the Australian and New Zealand organic industries and how this could affect export opportunities.

In contrast, other submitters highlighted the robust segregation systems the organic sector currently employs and noted there are well-established coexistence strategies in place for GM, organic and conventional agriculture in Australia. These submitters also pointed to the existing ability of global supply chains to segregate produce based on a wide range of criteria, including organic and GM.

FSANZ response

FSANZ has carefully considered the feedback received from submissions and from follow up discussions with peak organic industry and certifying bodies in Australia and New Zealand. These discussions assisted FSANZ to gain a deeper understanding of this industry and further assess whether and how it may be impacted by the proposed definitional changes. FSANZ notes that many of the concerns and issues raised by this sector are outside of FSANZ's regulatory remit and are not within its statutory functions to address.

Further discussions with the sector indicate certified organic operators already maintain strong traceability and segregation mechanisms to meet organic certifier audit requirements and ensure compliance with relevant organic standards. Importantly, FSANZ was able to confirm that GM labelling and analytical testing for the presence of GM material is not used in the organic certification process. Instead, organic operators rely on certified organic inputs or conventional inputs in conjunction with product information or affidavits from suppliers to confirm the absence of GM material, as well as other residue contamination. Additionally, many organic ingredients and seeds are imported.

It is FSANZ's assessment that many of the coexistence challenges raised by the organic sector

will not be created by the proposed definitional change but rather represent existing industry challenges, including those related to the global shift towards the adoption of NBTs and the fact the industry is heavily reliant on the importation of certified organic ingredients. FSANZ also notes the concerns being raised by the New Zealand organic sector may also reflect industry uncertainty about the proposed change to the regulatory environment for GMOs in New Zealand (refer to section 6.2 below).

FSANZ's consultation confirmed that, despite these challenges, the industry already effectively manages the coexistence of different production systems. FSANZ also notes GM and NBT foods already coexist with organic foods in countries which have clarified their regulatory approach to NBTs and that these countries have been a source of imported products for some organic operators. For example, FSANZ is aware some organic operators in New Zealand source certified organic products from Argentina, which adopted separate regulations for NBTs in 2015.

In addition, broader industry-led frameworks have been created for managing market segregation. For example, Grain Trade Australia has developed the Market Choice Framework for GM Crops[25] and the Grain Industry Stewardship Framework for New Technologies[26]. These frameworks demonstrate the capability of industry to manage the introduction of new technologies while maintaining market integrity across different production systems.

FSANZ has therefore concluded the proposed amendments to the Code are unlikely to significantly impact the Australian and New Zealand organic sector, which already has robust systems in place to effectively manage system challenges related to the widespread and global adoption of NBTs. The full analysis can be found in the DRIS (SD4).

6.2 Alignment of domestic regulations

Throughout FSANZ's work on NBTs, stakeholders have consistently expressed the desire for alignment of domestic regulations related to gene technology. The focus is usually on alignment between the definitions in the Code for GM food and the definitions for GM Organisms (GMOs) in the Gene Technology Act 2000 (GT Act) and its regulations. Alignment with New Zealand regulations would also be a relevant consideration given Standard 1.5.2 applies in both countries.

Submitter feedback

The feedback received at the 2nd CFS is nuanced. While the need for greater domestic alignment is a recurrent issue raised by some submitters, others have predicted greater alignment will occur because of proposed Code changes while at the same time noting complete alignment may not be necessary due to different objectives and risks to be managed. Another consideration is the ongoing work of the New Zealand Government to update regulations for the use of gene technologies and proposed amendments to Australia's GT Act.

Some submitters requested more detailed consideration of the potential risks of non-alignment between the Code and the Australian GT regulations e.g. ingredients being defined as GM under the Code but not by the OGTR, or vice versa. Other submitters requested FSANZ consider the level of oversight between OGTR and FSANZ for precision fermentation products

[25] https://www.graintrade.org.au/sites/default/files/Delivering%20Market%20Choice%20with%20GM%20Crops.pdf
[26] https://www.graintrade.org.au/sites/default/files/Publications/Technology%20Framework%20V2-Web.pdf

and genome-edited foods without novel DNA in its genome.

FSANZ response

In the 2nd CFS, FSANZ stated that greater regulatory alignment will occur over time as relevant domestic regulations related to gene technology are progressively reformed. Since the 2nd CFS, the New Zealand Government has released the Gene Technology Bill 2024 and policy decision documents[27], while in Australia the final draft of the Gene Technology Amendment Bill is being prepared for consideration and approval by Commonwealth, State and Territory gene technology ministers, before its introduction into the Federal Parliament.[28]

While full alignment between the Australian GT Act/Regulations and Standard 1.5.2 would appear to be a sound objective, this must be weighed against the different intent and objectives of the GT Act in comparison to Standard 1.5.2 and other relevant provisions of the Code and the Australian and New Zealand food laws which incorporate and apply the Code. FSANZ notes the GT Act's objective to protect the health and safety of people and the environment, and to regulate certain dealings with GMOs, is both broader in scope (in terms of the risks to be managed) and reach than Standard 1.5.2 when applied as part of Australian and New Zealand food laws.

It is FSANZ's assessment that full alignment of the Code with other regulatory frameworks for gene technology would result in the regulation for GM foods being disproportionate to the risks and objectives it is intended to address.

The scope of risks to be managed under Standard 1.5.2 as applied by Australian and New Zealand food laws is restricted to the safety for human consumption of GM food and is significantly narrower than those managed under the GT Act. FSANZ notes, however, that the amendments to the Code will bring the Code's GM food regulations into closer alignment with the Australian GT Regulations, which already exclude null segregant organisms and a certain type of genome editing. Closer alignment with New Zealand gene technology regulations would also be anticipated should the Gene Technology Bill 2024 and accompanying regulations be passed.

In relation to precision fermentation, FSANZ has not identified any alignment issues and expects current regulatory approaches to be maintained.

In terms of potential risks arising from non-alignment, FSANZ is satisfied there are no gaps from a safety perspective as the exempted or excluded food products have been determined to not warrant a safety assessment as they are equivalent in risk to conventional food.

FSANZ therefore maintains its conclusion at 2nd CFS that increased regulatory alignment of domestic regulations will occur over time.

[27] Ministry of Business, Innovation & Employment webpage on gene technology regulation – https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation

[28] The Department of Health and Aged Care webpage on proposed amendments to the GT Act 2000 – https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200

6.3 International harmonisation and trade

FSANZ provided a comprehensive update on the international situation at 2nd CFS. This update showed more and more countries are adopting, or in the process of considering, regulatory approaches to NBTs that recognise their equivalence to conventional breeding. This growing global trend is expected to facilitate international trade in NBT products.

Submitter feedback

Many submitters supported FSANZ's proposed approach. The shift from a process-based to a outcomes-based approach is seen as beneficial for aligning Australia and New Zealand's regulatory framework with other trading economies. For example, the exemption of processing aids from the GM food definition aligns with frameworks in Europe and the United States, which they consider promotes an efficient and competitive food industry.

While complete harmonisation with international regulations is unlikely, submitters support efforts to harmonise, as it will help Australian producers engage with global markets, address climate change and health challenges, and avoid increasing costs and complexity in the global food system.

Other submitters advocated retaining the old definitions and approach until European regulations are finalised.

FSANZ response

FSANZ's approach to revising the definitions is consistent with the emerging global picture. The food industry may benefit from greater international harmonisation and reduced barriers to trade. This is explored further in the DRIS (see SD4). An overview of regulatory approaches around the world is provided in SD5, including updated information on developments that have occurred since the 2nd CFS.

In relation to legislation in the European Union, FSANZ notes the timeline for its finalisation is unclear, nor is it clear what benefit (if any) there would be for Australia and New Zealand if P1055 were delayed, particularly given this would further prolong negative impacts on the food and agriculture sectors.

FSANZ's overall approach at approval remains unchanged and aligns with regulatory approaches that have been adopted, or are being considered, by other countries around the world.

7 Risk communication

7.1 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. Public submissions were called to assist consideration of the proposal (see section 2.2.3).

Subscribers and interested parties were notified about the 1st and 2nd CFS via the FSANZ Notification Circular, media release, FSANZ's digital 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. Similarly, a webinar on 2 September 2024 supported the release of the 2nd CFS.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. The FSANZ Board had regard to all submissions made during the call for submission periods. All comments are valued and contribute to the rigour of our assessment.

7.2 World Trade Organization (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 being considered, by other countries around the world, there may be differences with some countries.

To enable other WTO members to comment on the proposed amendments, a notification was 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 notification coincided with the 2nd CFS.

No comments were received from WTO members.

8 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:

8.1 Section 59

8.1.1 Consideration of costs and benefits

In assessing the proposal, FSANZ had regard to (as required by paragraph 59(a) of the FSANZ Act) whether the costs that would arise from the proposal outweigh the direct and indirect benefits. FSANZ also met impact analysis requirements applying to national standards setting bodies.[29]

[29] The Office of Impact Analysis *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies* – https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national

A DRIS has been prepared (see SD4) and contains FSANZ's analysis of:

- the costs and benefits, as required by the FSANZ Act
- broader impact analysis questions to meet impact analysis requirements.

The Office of Impact Analysis has assessed the quality of the regulatory impact analysis in the Decision RIS as compliant with impact analysis guidelines, containing an adequate level of analysis that is commensurate with the significance of the impacts.

The DRIS analyses two options to address the identified problems:

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

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

The most significant impacts of option 2 are:

- clarifying what foods and ingredients are GM for Code purposes
  - Protecting public health and safety by closing regulatory gaps that make it unclear when an NBT food is required to undergo pre-market approval.
  - Benefitting food developers by being clear on when an NBT food is required to be submitted to FSANZ for pre-market approval.
  - Providing government agencies with an enforceable definition.
  - Perceived decrease in informed choice for some consumers because of some NBT foods not being subject to mandatory GM labelling and certain GM foods (e.g. food additives and processing aids) no longer being subject to mandatory GM labelling under the new definition for GM food (despite these foods being highly unlikely to be labelled GM under existing Code requirements).

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

For the full analysis, refer to the DRIS at SD4.

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

8.1.2 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 because of the proposal.

8.1.3 Any relevant New Zealand standards

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

8.1.4 Any other relevant matters

Other relevant matters are considered below.

8.2 Subsection 18(1)

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

8.2.1 Protection of public health and safety

The 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.

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

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

8.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues to date.

8.3 Subsection 18(2) considerations

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 section 2.2.1), the scientific assessment that was undertaken for the 1st CFS (see section 2.2.2), additional information obtained from submitters to the 1st and 2nd CFS (see section 2.2.3), and information obtained from consumer research (see SD3).

FSANZ has used this information to inform decisions regarding the proposed amendments set out in the draft variations (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 6.3 and SD5). FSANZ's approach aligns internationally with regulatory approaches that have been adopted, or are being considered, 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 has made a notification under the TBT and SPS agreements (section 7.2).

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

FSANZ has not identified any issues to date.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

There is no policy guideline for GM food *per se* as the standard pre-dated the development of explicit policy guidelines. The 2014 Ministerial Policy Guideline Labelling of foods produced or processed using new technologies[30] is relevant to NBTs. FSANZ considers the intent of this policy guideline is consistent with existing GM labelling policy for informed consumer choice based on the food 'product' for sale. Accordingly, an NBT food that is a 'GM food' will be subject to the same labelling requirements that currently apply to GM food.

9 Implementation

At the 2nd CFS, FSANZ proposed there be no transition period and the standard 12-month stock in trade provisions contained in section 1.1.1—9 of the Code will apply. This was because the proposed variations are:

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

No comments were received from submitters to indicate this would present any issues to food manufacturers or enforcement agencies. As such, FSANZ has decided that the approved draft variations should commence on gazettal.

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

10 References

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Appendix 1: FSANZ response to issues raised in submissions to the 2nd CFS

1 Submitters to the 2nd CFS

Submitter	Abbreviation
AgResearch Limited	AgResearch
Agrifood Innovation Institute	AFII
Agrownomics	Agronomics
All G Foods Proprietary Limited	AGF
Animal Medicines Australia	AMA
ARC Centre of Excellence in Plants for Space	CE-P4S
ARC Training Centre for Accelerated Future Crops Development	CFCD
Auckland GE Free Coalition	AGEFC
Australian Beverages Council Limited	ABCL
Australian Food and Grocery Council	AFGC
Australian Grape and Wine Incorporated	AGWI
Australian Institute of Food Science and Technology	AIFST
Australian Organic Limited	AOL
Australian Seed Federation	ASF
AUSVEG	AUSVEG
BASF Australia Limited	BASF
Biodynamic Research Institute	BDRI
BioGro New Zealand Limited	BGNZ
BioTech New Zealand	BTNZ
Buy Pure New Zealand	BPNZ
Cellular Agriculture Australia	CAA
Ceres Organics Limited	Ceres
Chantal Shop	CS
Children's Health Defence Australian Chapter	CHD
Commonsense Organics Limited	CSO
Cotton Australia	CA
CropLife Australia	CLA
Commonwealth Scientific and Industrial Research Organisation	CSIRO
Danisco New Zealand Limited on behalf of International Flavors and Fragrance Incorporated	Danisco/IFF
Eat Local Eat Wild	ELEW
EuropaBio	EUB
Fonterra Co-operative Group Limited	FCG
Food and Beverage Accelerator	FaBA
Food Frontier Institute Limited	FF
Foundation on Future Farming (Zukunftsstiftung Landwirtschaft)	FoFF

Submitter	Abbreviation
Friends of the Earth New Zealand	FoENZ
GE Free New Zealand	GEFNZ
GE Free Tai Tokerau	GEFTT
Gene Ethics	GE
GrainGrowers	GG
Grain Trade Australia	GTA
Healthy Food Systems Australia	HFSA
HEART Party	HEART Party
Horticulture New Zealand	HNZ
Incafe Organic Coffee	IOC
Infant Nutrition Council	INC
Institute of Health and Environmental Research Incorporated	IHER
InterGrain Proprietary Limited	IG
Kete Ora Trust	KOT
Life Sciences Network Incorporated	LSN
Lux Organics Limited	LuxO
Manu Waiata Restoration and Protection Society Secretariat	MNRPSS
Maple Street Co-op	MSCoop
Milla Saber Clothing	MSC
Miruku Limited	Miruku
Ministry for Primary Industries (New Zealand)	MPI
National Farmers Federation	NFF
Natural Grocers (USA)	NG
Natural Sugars New Zealand	NSNZ
Nestlé	Nestle
New South Wales Food Authority	NSWFA
New Zealand Beverage Council	NZBC
New Zealand Food and Grocery Council	NZFGC
New Zealand Health Trust	NZHT
New Zealand Outdoors and Freedom Party	NZOFP
Noumi Limited	Noumi
Novozymes Australia Proprietary Limited	Novozymes
OGM Dangers	OGMD
Organic Consumers Association of Australia Incorporated	OCAA
Organic Dairy and Pastoral Group	ODPG
Organic Farm New Zealand	OFNZ
Organic Industries of Australia Limited	OIA
Organic and Regenerative Investment Co-operative	ORICoop
Organics Aotearoa New Zealand	OANZ
Organic Winegrowers New Zealand	OWNZ
Permaculture International College	PIC

Submitter	Abbreviation
Physicians and Scientists for Global Responsibility	PSGR
Queensland Health	QLDH
Santos Organics	SO
Seniors' Voice, Otamatea	SVO
Soil and Health Association of New Zealand	S&H
South Australian Department for Health and Wellbeing	SA Health
Southern Organic Group	SOG
SPS International Incorporated	SPSII
Takahiwai Māori Committee	TMC
Te Pūtahitanga o Te Waipounamu	TPoTW
Te Waka Kai Ora	TWKO
T&G Global Limited	T&G
Thames Organic Shop	TOS
The Australasian Association and Register of Practicing Nutritionists	AARPN
The New Zealand Institute for Plant and Food Research Limited	PFR
The Non-GMO Project	NonGMO Project
The Organic Food Chain Proprietary Limited	OFC
University of Adelaide Institutional Biosafety Committee (late comment)	IBC-UniAdelaide
Victorian Departments of Health and Energy, Environment and Climate Action	The Victorian Departments
Voices for Freedom	VFF
Waiheke Herbs	WH
Watershed Landcare Incorporated	WL
WePlanet Australia	WPA
World of Wellness International	WoW
World Council for Health Australia	WCH

2 Approach proposed at 2nd CFS

2.1 An outcomes-based approach

Viewpoint	Raised by	FSANZ response
Regulatory approach		
Raised one or more of the following concerns about the approach and definition: • lack of government oversight on exempted NBT foods • lack of transparency in processes involving food development • proposed definition is in favour of industry over public • proposed approach is not reflective of the science • increased risk of misinterpretation by producers and suppliers.	Campaigns; Private Individuals; OFNZ; IOC; PIC; LuxO; ODPG; ELEW; MNRPSS; NZHT; WoW; OGMD; SO; AOL; AGEFC; GEFNZ; GEFTT; ORICoop; GE; PSGR; TWKO; KOT; FoENZ; S&H; SOG; OIA; HFSA; OANZ; NonGMO Project; CSO; BPNZ; NZOFP; HEART Party; IHER; CHD; SVO; BGNZ	Noted These concerns were addressed in the 2nd CFS.[31] FSANZ notes no new information, including scientific evidence, was provided that would cause FSANZ to alter its previous safety assessment or conclusions, or the proposed regulatory approach to exclude certain NBT foods from regulatory capture as GM food. NBT foods that are excluded from the new definition for GM food are equivalent to conventional food and therefore do not require pre-market safety assessment by FSANZ. In relation to feedback from submitters on the clarity of new definitions, FSANZ has made further changes in response. Refer to section 3.4 of this report. FSANZ also will be preparing guidance material to assist with interpretation. Refer to section 5 of this report.
It would be clearer to exempt broadly understood and accepted technologies (e.g. SDN-1) from the GM food definition, rather than the proposed approach based on the presence of novel DNA.	NSWFA	After careful consideration of submissions, FSANZ decided to maintain an outcomes-based approach as it best addresses the proposal objectives. Please refer to section 3.1 of this report. An approach which provides exemptions for specific technologies is likely to become outdated and does not accommodate techniques that may emerge in the future.

[31] P1055 2nd CFS – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Viewpoint	Raised by	FSANZ response
The presence of 'novel DNA' in and of itself does not pose a risk.	Miruku; CAA; AgResearch	FSANZ agrees that novel DNA in and of itself does not present a hazard. However, it provides a clear and objective measure to determine if a food is a GM food for Code purposes. For further information, please refer to section 3.1 of this report.
Disagreed with the approach of using the presence of novel DNA as the basis for the definition of GM food and noted that this will result in the exclusion of many NBTs from the definition. Expressed the view that the definition does not adequately address the full range of changes to foods that occur as a result of genetic technologies and their associated risks, and that it does not clearly differentiate between conventional breeding and NBTs.	OANZ; BPNZ; Ceres; GEFNZ; GEFTT; OANZ; AGEFC; S&H; FoENZ; Private individual JA	As stated above, the rationale for using 'novel DNA' as the basis for the GM food definition is that it provides a clear and objective measure for determining if a food is or is not a GM food. It is not the purpose of the novel DNA definition to differentiate between conventional breeding and NBTs. Rather, its purpose is to differentiate between NBT foods that are equivalent to conventional foods, and NBT foods that are not. This approach is based on FSANZ's safety assessment[32] for P1055, which found that excluded foods can be considered equivalent in risk to conventional foods.
Animals produced using NBTs should be considered separately from plants and microorganisms in the GM food definition, noting that countries that have excluded certain organisms produced via NBTs from the scope of GM regulations have only done so for plants.	FCG	After careful consideration of the submission, FSANZ view is that a separate regulatory approach for animals producing using NBTs is not warranted. It should also be noted that the current definitions for 'food produced using gene technology' and 'gene technology' also apply to plants, animals and microorganisms. The safety assessment for this proposal also considered plants, animals and microorganisms. FSANZ is not aware of any new scientific information or scientific rationale that would suggest a need to consider animals produced using NBTs separately. The fact that some countries have chosen to focus on plants first is not a compelling reason for FSANZ to adopt the same approach.

[32] 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

Viewpoint	Raised by	FSANZ response
Definition of novel DNA		
Changes caused by genetic technologies may be difficult to distinguish from those that occur naturally, which could lead to problems with the definition for the following reasons: • novel DNA may be very difficult, if not impossible, to detect • it may be difficult to determine whether or not the newly discovered DNA sequence in the genome is novel.	MPI; PFR	Noted. The revised definition for novel DNA (see section 3.4.2 of this report) is intended to provide clear and objective criteria for determining whether inserted DNA is novel. FSANZ notes: • Novel DNA is defined to exclude the types of genetic modifications introduced naturally or through conventional breeding. If a NBT is used to introduce the types of genetic modifications made through conventional methods, these modifications will not meet the definition of novel DNA. • Discovered DNA sequences can be easily compared against genomic sequences (e.g. open access databases) to determine if it is derived from an existing, crossable species.
The '*novel DNA*' definition should exclude 'low risk' DNA sequences, including: • DNA sequences from previously reviewed and approved traits • DNA sequences that are already present in food and have a history of safe use • DNA sequences from viruses that infect the host • inverted repeat sequences from endogenous genes used to downregulate endogenous genes using RNAi.	SPSII	After careful consideration of the submission, FSANZ notes such exclusions fall outside the scope of P1055. The core intent of P1055 is to update the definition for GM food to address the emergence of NBTs. It is not the intent to review the overall regulatory approach to GM foods. Food derived from organisms containing novel DNA will continue to be captured for pre-market assessment.
The '*novel DNA*' definition overlooks potential use of RNA and reverse-transcriptase for transformation, which could encourage developers to exploit this gap to avoid GM requirements, despite no current technology existing.	MPI	FSANZ notes the novel DNA definition is not based on a specific technique or technology. Novel DNA is either present or absent. If the use of RNA and reverse transcriptase for transformation results in the insertion of novel DNA into the genome of the organism from which the food is derived, the food will be considered GM food for Code purposes.

Viewpoint	Raised by	FSANZ response
The '*novel DNA*' definition will shift the field of food research to focus on cisgenesis to avoid food safety oversight.	AgResearch	FSANZ notes that all foods, whether they are captured for pre-market assessment or not, are required to comply with relevant food standards and be safe and suitable before they may be sold.
FSANZ should implement a maximum base pair change threshold (similar to the EU's proposed 20 base pair limit) for determining what constitutes conventional breeding.	Fonterra; AFGC; NZFGC; INC	FSANZ has carefully considered this suggestion but does not consider it necessary to define a maximum base pair change threshold. The size of an insert is irrelevant to determining whether a sequence is novel DNA. The only relevant question is whether the inserted DNA is from a species that is not a crossable species.

2.2 Excluding low-risk foods from the GM food definition

Viewpoint	Raised by	FSANZ Response
Safety and risks of NBT foods		
Raised general safety concerns about NBTs, including lack of history of safe use, off-target effects, changes that differ from what can be achieved via conventional breeding, allergic and toxicity reactions, horizontal gene transfer, adverse health effects and environmental impacts. Emphasised that all NBT foods must undergo rigorous animal feeding trials, ongoing monitoring and provide peer-reviewed scientific evidence to confirm their safety.	Campaigns; Private individuals; AGEFC; GE; GEFNZ; IHER; GEFNZ; GEFTT; OIA; IOC; S&H; CHD; PSGR; AOL; HFSA; KOT; Agrownomics; TWKO; CSO; OGMD; FoENZ; HEART Party	Noted. FSANZ comprehensively addressed the need for pre-market safety assessment of NBT foods in both the 1st CFS and 2nd CFS, and concluded such assessment is not needed if the NBT food is equivalent in its characteristics to conventional food FSANZ notes no new information, including scientific evidence, was provided that would cause FSANZ to alter its previous safety assessment or conclusions, or the proposed regulatory approach to exclude certain NBT foods from regulatory capture as GM food.
FSANZ has not conducted a thorough risk assessment or methodological reviews of NBT foods and instead uses a flawed safety assessment to disregard the uncertainties and precautions associated with gene editing.	PSGR	FSANZ does not agree. The safety assessment considered a wide range of genetic changes (both natural and induced, intended and unintended) that have occurred or have been introduced to conventional foods as a

Viewpoint	Raised by	FSANZ Response
		suitable benchmark to evaluate the safety of NBT foods. In considering this issue, it is important to note that: • making comparisons to conventional foods for establishing safety is a well-accepted concept that is routinely applied to GM foods and has been widely adopted by regulatory agencies around the world • no plausible safety issues have been identified for any GM food assessed over the last 25 years.
These submitters advocate for the precautionary principle for NBT foods as scaling up NBTs increases the risks to human, animal and environment.	Campaigns; Private Individuals; CSO; TWKO; S&H; CHD; PSGR; OANZ	Noted. FSANZ notes no new information, including scientific evidence, was provided that would cause FSANZ to alter its previous safety assessment or conclusions, or the proposed regulatory approach to exclude certain NBT foods from regulatory capture as GM food.
Equivalence of certain NBT products and conventional foods		
These submitters stated the equivalence of certain NBT foods to conventional foods may be applicable to 'safety', but it ignores the public health protection aspect of the FSANZ Act. As such, actual public health outcomes and the epidemic of chronic disease related to food have been completely ignored in FSANZ's safety analysis.	HEART Party; Private Individuals; PSGR	FSANZ does not agree. An excluded NBT food will be equivalent to its conventional counterpart in terms of its product characteristics and risk profile. Therefore, it will be subject to the same regulation and public health consideration as conventional counterpart foods.

Viewpoint	Raised by	FSANZ Response
These submitters refute FSANZ's 'equivalence' claim between certain NBT and conventional food, citing lack of long-term independent studies. Some submitters seek further clarity on characteristics that determine 'equivalence' and a definition for 'equivalence'.	Campaigns; Private Individuals; AGEFC; GEFNZ; GEFTT; GE; IHER; CSO; PSGR; HFSA; Agrownomics; FoENZ; OIA; AOL; TWKO; S&H; VFF; WCH	Noted. The issue of equivalence was addressed in the safety assessment (Supporting Document 1) which compared the types of genetic changes that are introduced using conventional breeding methods to those that can be introduced using NBTs. FSANZ's assessment was that NBTs can be used to introduce the same types of genetic changes as conventional breeding. When that occurs, the NBT food will be equivalent to conventional food in its product characteristics and risk.
General safety concerns about GM foods		
Submitters raised general safety concerns about GM foods, including lack of history of safe use, off-target effects, allergic and toxicity reactions, and reduced nutritional value compared to conventional food. They also highlighted potential adverse health and environmental impacts, arguing that the risks of genetically modified food production significantly outweigh any perceived benefits. Some submitters provided papers and articles as evidence for the safety issues concerning GM foods. GEFNZ objects to FSANZ's dismissal of these papers on FSANZ website,[33] arguing that it is the responsibility of FSANZ to provide studies and data on GM food safety for submitters' comment.	Campaigns; Private Individuals; Ceres; GEFNZ; GEFTT; AGEFC; GE; WoW; PSGR; IHER; TWKO; CSO; IOC; S&H; VFF; WCH; FoENZ	Noted. These concerns were addressed in the 2nd CFS. FSANZ notes no new information, including scientific evidence, was provided that would cause FSANZ to alter its previous safety assessment or conclusions, or the proposed regulatory approach to exclude certain NBT foods from regulatory capture as GM food. The purpose of P1055 was not to re-evaluate the safety of GM foods which now have a history of safe use over several decades. The regulatory approach to GM foods remains unchanged and these foods will continue to require pre-market safety assessment by FSANZ.
Safety of cell cultured food or precision fermentation products		
Support rigorous and precautionary assessment of all materials and processes used in cell cultured foods and precision fermentation products.	Campaigns; Private individuals; CHD; HFSA	Noted. All cell-cultured foods and precision fermentation products require

[33] Response to a feeding study in rats by Zdziarski et al – https://www.foodstandards.gov.au/consumer/gmfood/Response-to-a-feeding-study-in-rats-by-Zdziarski-et-al

Viewpoint	Raised by	FSANZ Response
		pre-market safety assessment by FSANZ before they can be sold in Australia and New Zealand. These assessments consider the production process and inputs relevant to safety.
Issues related to ultra processed foods (UPFs)		
Most NBT and GM foods are ultra processed foods (UPFs), and P1055 expands them, causing adverse health outcomes. The food supply should be protected from unlabelled ingredients and FSANZ should focus on preventive health policies. The information on FSANZ's website on UPFs is inadequate [GE].	Campaigns; Private individuals; ORICoop; GE; HFSA; GEFNZ; GEFTT; S&H;CHD; HEART Party; OANZ; IHER; WL	Noted. Issues relating to UPFs in the food supply are not relevant to consideration of this proposal.

2.3 Specific food categories

Viewpoint	Raised by	FSANZ response
Food with altered characteristics and the novel food standard		
Interpreted the intent of the proposed approach as being to capture NBT foods with no novel DNA but with altered characteristic/s as novel foods. Raised a number of concerns with this approach.	NSWFA; FCG	Please see subsection 3.2.1 of this report which addresses these issues.
Foods and ingredients derived using precision fermentation		
A number of concerns were raised about the approach to foods and ingredients derived using precision fermentation. Submitters also made several suggestions for how the approach should be revised.	AFGC; FF; AIFST; ABCL; NZBC; AGF; CAA; Noumi; Nestle; FaBA; FCG; NSWFA	Please see subsection 3.2.2 of this report which addresses issues relating to precision fermentation.

Sought clarity on the following issues relating to precision fermentation products: • status of partial proteins (dipeptides/tripeptides) • proposed status of proteins derived from plant molecular farming • process for approving improved production strains – whether a new application is required even when the product is the same.	CAA	If the partial proteins from precision fermentation and proteins from plant molecular farming are the result of the insertion of novel DNA into the production organism they will be regulated as GM food. Whether a new application is required for the same product from an improved production strain will need to be considered on a case-by-case basis, taking into account the scope of the original permission in the Code. FSANZ notes this is outside the scope of Proposal P1055.
Increasingly, genes inserted into a host for precision fermentation are likely to be synthesised to match that from the conventional source organism, or representative of a class of microorganisms rather than a specific organism, therefore identifying the donor as a specific organism could be misleading.	CAA; Noumi	Noted. The way in which approved products of precision fermentation are listed in the Code is not within the scope of P1055.
Processed food ingredients		
Several issues relating to the status of processed food ingredients under the proposed approach were raised.	CLA; BASF; AFII; AIFST; ASF; LSN; FaBA	Please see section 3.2.3 of this report which addresses the issue relating to processed food ingredients.
Language to specify that processed food ingredients and precision fermentation products should be assessed "regardless of the presence or absence of novel DNA in the final food" should be added to make the regulatory intent more explicit.	Danisco/IFF	Noted. As set out in subsections 3.2.2 and 3.2.3 of this report, and in 'Table 2 – Intended regulatory outcomes at approval', foods from an organism or cells that contains novel DNA in its genome will be regulated as GM food unless subject to an exemption.

2.4 Exemptions from the new GM food definition

Viewpoint	Raised by	FSANZ response
Substances added to foods: processing aids, food additives and nutritive substances		
Explicit reference to the exemption of flavourings as food additives would improve clarity for manufacturers and enforcement agencies.	INC	Noted. Section 1.1.2—2 in the Code states that a 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'. Therefore, FSANZ considers an explicit exemption for flavourings as food additives unnecessary.
Expressed support for the exclusion of processing aids and food additives from the GM food definition but seek further justification for exclusion of nutritive substances, arguing that nutritive substances that contain novel DNA/protein should be subject to GM labelling for informed consumer choice.	NSWFA; INC; MPI	After careful consideration of the submissions at 2nd CFS, FSANZ decided to revise the definition for 'genetically modified food' to remove the exemption for nutritive substances. Please refer to sections 3.3 and 3.4.1 of this report.
Sought clarification on the following issues relating to the exclusion of processing aids, food additives and nutritive substances: • Questioned if the GM element of these foods be assessed, noting that these substances are already subject to pre-market assessment under different parts of the Code. • Questioned if an approved PA, FA or NS produced from a microbial source different from that already listed, require a new application / pre-market assessment.	NSWFA	FSANZ notes that the assessment of these substances will continue to consider the method of production, including any genetic modification of the production organism. Whether a new application is required in the event the same substance is produced from a different microbial source would need to be determined on a case-by-case basis, taking into account the scope of the original permission in the Code. FSANZ notes this issue is beyond the scope of Proposal P1055. As stated above in this table, nutritive substances are no longer subject to an explicit exemption under the new definition for GM food. Please refer to subsections 3.3 and 3.4.1 of this report.

Viewpoint	Raised by	FSANZ response
Excluding nutritive substances while continuing to approve them by host/donor in Schedule 29 appears to be a duplicative process, and it would be more efficient to provide a generic approval based on specifications in Schedule 3. This would also align with the approach taken in the EU.	Noumi; CAA	Noted. As stated above in this table, nutritive substances are no longer subject to an explicit exemption under the new definition for GM food. Please refer to subsections 3.3 and 3.4.1 of this report. FSANZ notes the way in which nutritive substances are approved and listed in the Code as nutritive substances, is beyond the scope of P1055.
Food from null segregant organisms		
Expressed support for the exclusion of food derived from null segregants from the GM food definition, noting that it aligns with the recent exemption by the New Zealand Environmental Protection Authority (NZEPA). One submitter (MPI) emphasised that businesses should be required to provide proof of the absence of novel genetic material.	BASF; CFCD; AFGC; AMA; ASF; AFII; SA Health; MPI	Noted. In addition to the exemption of null segregants under the Hazardous Substances and New Organisms (HSNO) Act in New Zealand and the Australian Gene Technology Regulations, the exemption of null segregants from GM regulations is consistent with other countries around the world. In relation to proof of absence of novel DNA, Australian and New Zealand food laws require those who trade in food to ensure their food complies with relevant Code requirements, including requirements that will relate to the new GM food definition.
Opposed the exclusion of food derived from null segregants from the GM food definition, on the basis that null segregants have been derived from gene technology.	OGMD; CHD; PSGR; OANZ; BPNZ; WoW; Ceres	Noted. The rationale for excluding null segregants is explained in more detail in section 2.3.5 of the 2nd CFS report. Their exclusion is supported by FSANZ's safety assessment and is consistent with approaches around the world.
Sought clarity on whether the null segregant definition is aligned with the OGTR's definition for null segregants.	AIFST	FSANZ notes there is no explicit definition for null segregants under the *Gene Technology Regulations 2001*. However, FSANZ notes the regulatory intent under the GT Regulations and the

Viewpoint	Raised by	FSANZ response
		Code are aligned. [34]
Food from grafted plants		
Stated that the exemption of the part of the plant used as food would require demonstration that no migration of novel DNA/protein occurs across the graft junction.	MPI	Noted. Australian and New Zealand food laws require those who trade in food to ensure their food complies with relevant Code requirements, including requirements that will relate to the new GM food definition.
Requested clarity on the following points in relation to food derived from grafted plants: • the basis for the change in language between the 1st CFS (which referred to 'novel characteristics' as the basis for capture of food from grafted plants) and the 2nd CFS (which refers to 'novel protein' and 'novel DNA' as the basis for capture) • the reason that the presence of novel DNA / novel protein in food derived from grafted plants would trigger pre-market assessment as GM food, while the presence of other novel substances, including RNA, would not.	NSWFA	The change in language is due to the revised approach at the 2nd CFS which now focuses on the outcome in the genome (presence of novel DNA). This is in contrast to the approach at the 1st CFS which focused on product characteristics. Further details, including why 'novel protein' is referenced and the possible presence of other novel substances, is described in section 2.3.5 of the 2nd CFS report.
Requested further clarification as to whether the reference to grafted plants in Table 3 of the 2nd CFS document relates to: • a non-GMO scion grafted onto a GMO rootstock • a GMO scion grafted onto a non-GM rootstock • a GMO rootstock with a different GMO plant grafted onto it.	GEFNZ; GEFTT	The GM food definition exemption only applies to food derived from part of a grafted plant that does not contain novel DNA or novel protein. That could be the scion or it could be the rootstock. If the food is produced from the grafted scion, and that scion does not contain novel DNA or novel protein, then the food will not be a GM food.

[34] Overview of changes to the Gene Technology Regulations 2001 – https://www.ogtr.gov.au/resources/publications/overview-status-organisms-modified-using-gene-editing-and-other-new-technologies

Viewpoint	Raised by	FSANZ response
Substances used in cell culture		
Expressed general support for the exclusion of substances used in microbial and plant cell cultures from the GM food definition, but raised one or more of the following issues: • the exclusion should apply only to microbial and plant cell cultures and not to mammalian cell cultures as they carry a different risk profile • the exclusion should only apply where the food has been refined from the media – assessment may be required where spent media is used as a novel food or ingredient • further clarity is required on the pre-market assessment process for precision fermentation products used as production inputs in cell cultures • substances used in cell cultures other than in cell-cultured food (e.g. substances added to microbial fermentation) should also be excluded from the GM food definition.	AFGC; NZFGC; INC; FCG; NSWFA	Noted. The exemption applies to "a substance used to support the growth and viability of cells during cell culture" which could be animal, plant or microbial cells. In relation to mammalian cell cultures, these will undergo assessment as cell-cultured foods (please refer to application A1269).[35] The assessment of a cell-cultured food includes consideration of the cell culture process including any media inputs. FSANZ notes the explicit exemption only applies to the GM food definition. It does not exempt such substances from consideration under other parts of the Code such as those that relate to novel foods, food additives or processing aids.

3 Definitions

3.1 Definition for genetically modified food

Viewpoint	Raised by	FSANZ response
(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		

[35] Cultured Quail as a Novel Food (A1269) - https://www.foodstandards.gov.au/food-standards-code/applications/A1269-Cultured-Quail-as-a-Novel-Food

Viewpoint	Raised by	FSANZ response
(iv) derived from cells that contain novel DNA; and		
Suggested the following definition for GM food: *Food derived from organisms that have had their cell's function modified using gene technology or have had their cells existence made possible using Genetic modifications*.	WoW	Noted. The proposed alternative definition for GM food is process-based which is at odds with the outcomes-based approach FSANZ has decided to adopt for the reasons stated in this report. Please refer to section 3.1 of this report for further discussion.
(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.		
What is a GM food (a) and what is not (b) is not clearly separated in the current drafting. This may lead to ambiguity in what needs pre-market safety assessment and approval. Suggestions: • change "(b) does not include any of the following: (…)" to "(b) is not any of the following"; or • remove "and" from point (a) "(iv) derived from cells that contain novel DNA; and".	EuropaBio	Noted. FSANZ does not agree the provision could or would be interpreted by a court in the manner suggested by the submitter, noting that none of the jurisdictions responsible for enforcement raised this as an issue. However, to avoid any possible confusion, FSANZ amended the provision.
Suggest that FSANZ include an additional exemption in *1.1.2—16(b)* for foods which are chemically indistinguishable from conventional foods, but which have been derived from organisms containing novel DNA. Options proposed: *(vi) food that* *(A) does not contain novel DNA or novel protein; and* (B) *does not have an altered characteristic as a result*	LSN; AGF; Noumi	Noted. FSANZ's approach to the GM food definition is based on the presence of novel DNA in the genome of the organism from which a food is derived, rather than the characteristics of the food. Please refer to section 3.1 of this report, as well as sections 2.3.2 and 2.3.3 of the 2nd CFS, for further discussion of the rationale for the approach.

Viewpoint	Raised by	FSANZ response
of novel DNA. (LSN) *(vi) Substances intended for general use in formulated foods that do not contain novel DNA or novel protein and are substantially equivalent* to the same ingredient derived from conventional sources.(AGF; Noumi)*		FSANZ agrees that product characteristics determine the hazard profile of foods, including GM foods. In the 1st CFS, FSANZ considered excluding processed food ingredients from the new GM food definition. However, after further assessment, FSANZ found it technically challenging to create clear, objective criteria applicable across diverse products without risking inconsistent regulatory outcomes. Consequently, FSANZ concluded that such exclusions would not be feasible under the outcomes-based approach. Please refer to section 3.2.3 of this report for further discussion.
These submitters proposed a number of alternate definitions for '*null segregant*', to clarify whether the process by which novel DNA is removed from an organism is relevant to whether an organism is considered a null segregant: *A null segregant means*: • *An organism that no longer contains novel DNA as a result of breeding or deletion of insertions. (AIFST; CAA)* • *'Null segregants are the offspring of GMOs that do not inherit the GM component'. (ASF; AFII)*	AIFST; CAA; ASF; AFII	Noted. The explicit exemption for food from null segregants was included in the GM food definition to remove any doubt regarding the regulatory status of food from null segregants. However, even without the explicit exemption, food derived from organisms which do not contain novel DNA (irrespective of whether they meet the definition for a null segregant) will not be GM food. The process by which novel DNA is no longer present is irrelevant to whether an organism is considered to meet the definition of null segregant.
The following parts of the definitions contradict each other: ***genetically modified food** means:* *(a) a food that is:* *(ii) derived from an organism that contains novel DNA; or* *(iv) derived from cells that contain novel DNA.* *A **null segregant** means an organism, cell or cells that:* *(a) is descended from an organism, cell or cells that contain novel DNA*	GEFNZ; GEFTT	The full definition for null segregant is: *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) <u>does not contain novel DNA</u>* The inclusion of part (b) ensures there is no contradiction between the GM food definition and the definition for null segregant.

Viewpoint	Raised by	FSANZ response
Suggests the following additional underlined text to the drafting: *(vi) food <u>that is a null segregant or</u> derived from a null segregant.*	QLDH	Noted. FSANZ considers this addition unnecessary. As noted above, the explicit exemption for null segregant was included to remove any doubt about the regulatory status of this category of products. Whether a food is a null segregant, or derived from a null segregant is moot. The only relevant consideration is whether the organism or cells from which the food is derived contains novel DNA.

3.2 Definition for novel DNA

Viewpoint	Raised by	FSANZ Response
In this Code, novel DNA means DNA that (a) a person has inserted into the genome of an organism, cell or cells; and		
The proposed definition for 'novel DNA' lacks clarity and will not fully achieve the intended regulatory outcome. The specific issues raised are discussed in detail in section 3.4.2 of this report.	Miruku; T&G; Nestle; PFR; AgResearch; LSN; CFCD; CE-P4S; BASF; CAA; SPSII; CLA; CA; CSIRO; Danisco/IFF; FCG; ASF; AFII; MPI; NSWFA; The Victorian Departments; AUSVEG; GTA; EUB; AFGC; AIFST; Private individual GM	After careful consideration of the submissions, FSANZ has revised the definition for 'novel DNA'. FSANZ has addressed the issues raised in subsection 3.4.2 of this report.

Viewpoint	Raised by	FSANZ Response
The term '*novel DNA*' may cause confusion given the: • existing 'novel food' category in the Code • use of 'novelty' as a regulatory trigger in other jurisdictions e.g. Canada.	CAA; Miruku	Noted Please refer to subsection 2.3.3 of the 2nd CFS report for FSANZ's rationale for using the term 'novel DNA'. FSANZ also notes: • the term 'novel DNA' is already used in the Code as part of the GM labelling requirements in Standard 1.5.2 • the context of the novel DNA definition within Standard 1.5.2 is distinct and should avoid confusion with the use of the word 'novel' in other contexts in the Code and elsewhere.
These submitters do not agree with the use of the term '*a person*'.	BDRI; NSNZ; MPI; NSWFA; SA Health; GEFNZ; GEFTT; PFR; CAA; AIFST	Noted. Please refer to subsection 3.4.2 of this report which discusses the use of the term 'a person' in the novel DNA definition.
FSANZ should consider amending 1.1.2—17(a) with the following underlined text, to clarify that natural processes, such as the insertion of mobile genetic elements, are not within the scope of the definitions: *a person has inserted, <u>using gene technology,</u> into the genome of an organism, cell or cells.*	CSIRO	Noted. FSANZ considers the phrase "a person has inserted" clearly indicates the genetic modification was not a natural occurrence. The Explanatory Statement (Attachment B) further clarifies that foods in which the insertion of 'novel DNA' has occurred through a natural process, without any intervention by a person, are not captured and regulated as GM food by the Code.
The term '*inserted*' is ambiguous and lacks clarity. The addition of the term 'exogenous' is suggested to add specificity: *In this Code, novel DNA means <u>exogenous</u> DNA that…*	AgResearch; LSN; AFGC; AIFST; Private individual GM	Please refer to subsection 3.4.2 of this report which discusses the term 'inserted' and the suggestion to include 'exogenous' in novel DNA definition.
(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.		

Viewpoint	Raised by	FSANZ Response
The phrases '*has not previously been*' in *(b)(i)* and '*has previously been*' in *(b)(ii)* are unclear and unenforceable. Some submitters suggest replacing the wording with '*cannot be*' or '*could not have*' in *(b)(i)* and '*can be*' or '*could have*' in *(b)(ii)*.	SA Health; MPI; CSIRO; NSWFA; FCG; CFCD; CE-P4S;The Victorian Departments; NZFGC; SPSII; CLA; AMA; INC; ASF; AFII; BTNZ	After careful consideration of submissions and further assessment, FSANZ revised the novel DNA definition – please refer to subsection 3.4.2 of this report.
SPSII suggested adding the following <u>underlined text</u> to the definition: *(b)(ii) …. where the sequence or arrangement of the inserted DNA was changed prior to its insertion <u>and the edit does not result in a product with a history of safe use in food</u>; or*	SPSII	FSANZ acknowledges the suggested revisions and additions to the definition for 'novel DNA'. Please refer to subsection 3.4.2 of this report for FSANZ's detailed response.

Proposed the following alternate definitions for '*novel DNA*':
• *'**Novel DNA** means 'coding sequences that generate novel proteins in the host that do not have a history of safe use in food'.*
• *'**Novel DNA** means DNA in the form of coding sequences that have been stably inserted into the genome and are:*
  ○ *from genetic sources outside of an organism's cross-compatible gene pool; or*
  ○ *could not have been introduced using conventional breeding methods, or could not have occurred in nature; or*
  ○ *not from an existing species'.*
	SPSII; CLA; the Victorian departments; CA; AMA; ASF; AFII; BTNZ; BASF	

Foods derived from organisms modified using intragenesis should not be captured as GM food for one or more of the following reasons: • outcomes identical to those obtained via intragenesis occur naturally and through conventional breeding; • excluding intragenesis from the 'novel DNA' definition would provide greater alignment with existing standards in other countries (e.g. Canada) and is better aligned with an	AMA; SPSII; CLA; BTNZ; The Victorian Departments; FF; BASF; GG; ASF; AFII; CA	

Viewpoint	Raised by	FSANZ Response
outcomes-based regulatory approach; • there is a risk that the proposed definition will inadvertently capture conventional breeding outcomes.		
Requested clarity on the types of modifications that would be considered cisgenesis and intragenesis. Provided an example whereby an unmodified maize promoter sequence was inserted into the maize genome either (1) upstream of a gene or (2) to replace the endogenous promotor of a gene and sought to confirm whether these and similar examples would be considered cisgenesis.	CLA; BTNZ	
Defining 'novel DNA' based on how it was added to an organism prevents it from adequately reflecting the risk of potential outcomes. For example, when a promoter is inserted before an existing gene (cisgenesis), it can result in vastly increased protein concentrations that avoid assessment. Meanwhile, the introduction of novel DNA (transgenesis) requires full assessment even when a product is expressed at very low concentrations.	AgResearch	Noted. The types of products that will be excluded under the new definition will be equivalent to conventional food in terms of risk. FSANZ notes such differences in protein expression profiles are also seen in conventional foods, which have a long history of safe use.
Suggested the definition for novel DNA should be amended to explicitly exclude food produced by cisgenesis.	AFGC; AIFST	Noted, however FSANZ considers a specific exemption is not required. One of the advantages of basing the GM food definition on the presence of novel DNA is that the definition does not hinge on any specific technique or technology. Cisgenesis does not transfer novel DNA between organisms.
Suggested adding/replacing the following words to improve the clarity of the 'novel DNA' definition: • adding 'stable' in reference to 'inserted DNA'; • adding 'coding sequence' in reference to 'novel DNA'; • replacing 'species' with 'gene pool' as it captures the total range of cross-compatible germplasm available to a	CLA; AMA; BTNZ; The Victorian Departments; ASF; AFII	Noted. FSANZ has addressed these suggestions in subsection 3.4.2 of this report. FSANZ considers the definition for 'novel DNA', as revised following

Viewpoint	Raised by	FSANZ Response
breeder		the 2nd CFS, is clear and will achieve the intended regulatory outcomes. Additional information to assist with the interpretation of the definitions will be provided through guidance – refer to section 5 of this report.
Raised concerns regarding the regulatory status of the following: • left and right border sequences from the *Agrobacterium*-mediated transformation process; • the genomic location of any inserted DNA; • codon optimisation; • small insertions and deletions from genome editing. Some submitters requested that FSANZ specify explicitly in the '*novel DNA*' definition which DNA sequences are <u>not</u> considered novel DNA. Others preferred clarifying information in the guidance document. PFR suggested the following text addition to 1.1.2—17: *(c) unless otherwise exempted by the Guidance Documents as being a secondary consequence of the primary change and producing only negligible additional risk.*	AFGC; T&G; PFR; CAA; CFCD, CE-P4S	Noted. FSANZ has addressed these concerns in subsection 3.4.2 of this report and refers submitters to the revised definition for 'novel DNA' in Attachment A and the explanatory statement in Attachment B. Considering the revision to the novel DNA definition and explanatory statement, as well as additional information in subsection 3.4.2, the additional text suggested by PFR is not required.
Suggested adding the following criterion to the novel DNA definition to exclude low risk foods based on their risk equivalence to conventional foods: *<u>(iv) are inaccessible through conventional methods</u>.*	LSN	After careful consideration of the submission, FSANZ views is the novel DNA definition, as revised following the 2nd CFS, is clear and objective. FSANZ notes it would be a significant challenge for compliance and enforcement purposes to determine what DNA insertions 'are inaccessible through conventional methods', as this is very subjective.

3.3 Other definitions

Viewpoint	Raised by	FSANZ Response
Novel protein		
Suggested adding the following underlined words to the 'novel protein' definition to clarify that it is a GM product and not a novel food: *Novel protein means a protein encoded or produced by novel DNA.*	INC; NZFGC	FSANZ acknowledges this suggestion but considers the additional text is unnecessary as the drafting clearly states that novel protein is encoded by novel DNA. The definition for 'novel protein' should be read alongside the definition for 'novel DNA'.
The definition of '*novel protein*' is limited to protein encoded by novel DNA. For example, when CRISPR is used to introduce double-strand breaks into protein coding regions, a large number of protein sequences not achievable by traditional mutagenic methods may be produced as a result of recombination, with risk profiles for the resultant foods that may differ from conventional foods.	MPI; NSNZ	FSANZ notes that classical mutagenesis induces random double-strand breaks, and can result in a wide range of mutations, many of which remain uncharacterised. However, food derived using classical mutagenesis methods has a long history of safe human consumption. Please refer to FSANZ's safety assessment for discussion about unintended changes and the range of mutations that can be introduced using classical mutagenesis (Supporting Document 1). FSANZ is satisfied the range of mutations introduced through genome editing pose no greater risk than those introduced through conventional breeding methods or that occur in nature.
Consequential changes		
The term 'protein engineered' should be retained in Schedules 3 and 18, as it provides additional specificity to the identity of the permitted substances and recognises that engineered variants are structurally and functionally distinct from wild type proteins.	NSWFA	FSANZ acknowledges the removal of the 'protein engineered' term potentially broadens the scope of the permissions in Schedule 3 and 18. FSANZ notes however that this change does not present a safety concern and is consistent with how enzyme permissions are typically granted in the Code. The 'protein engineered' term was used for the purpose of GM labelling to indicate the novel protein (the enzyme) has an amino acid sequence that is *not* found in nature, as this is relevant for the labelling of processing aids, where a separate definition for 'novel protein' applies. As processing aids have been specifically excluded from the GM food definition, labelling requirements for GM food no longer apply to processing aids. Consequently, the term 'protein engineered' no

Viewpoint	Raised by	FSANZ Response
		longer serves a purpose in the Code. Please refer to section 4.1, and Table 4 of this report for further information relating to labelling aspects.
Schedule 26		
The term 'substance' in the table for subsection ***S26–3(7) – Genetically modified food of microbial origin*** should be replaced with 'food' to align with the table heading and reduce ambiguity.	NSWFA	FSANZ notes the suggestion but does not agree the change is necessary. Products that are currently listed in subsection *S26–3(7) – Genetically modified food of microbial origin* are referred to in the Code as 'substances'. FSANZ has therefore decided to retain this term.
Line, transformation event and conventional breeding		
Several issues and suggestions were raised in relation to the definitions for '***line***' and '***transformation event***'. Refer to subsection 3.4.3.	NSWFA	FSANZ acknowledges the feedback from this submitter. Please refer to subsection 3.4.3 of this report which discusses the definitions for 'line' and 'transformation event'.
Others		
1(a)(iii) contains incorrect English: ***genetically modified food*** *means:* *(a) a food that is:* *(iii) cells that contain novel DNA.* Suggested (*iii*) be altered to *comprised of cells that contain novel DNA* Suggested adding the following underlined text: ***genetically modified food*** *means:* *(a) a food that is:* *(iv) derived from or produced using cells that contain novel DNA.*	INC	FSANZ has given priority to the clarity of the definition over grammatical accuracy. The meaning of '*comprised of*' includes 'contains'. This would change the meaning of the sentence and add a layer of complexity to the definition. FSANZ considers the addition of the term *'produced using*' is redundant. The term '*derived from'* covers situations where food is produced using cells that contain novel DNA.

Viewpoint	Raised by	FSANZ Response
Paragraph 1.5.2—4(1)(a) of the draft variation at 2nd CFS states labelling requirements will apply where the GM food is listed as an approved GM food. However, paragraph 1.5.2—4(1(b) states that GM labelling would not apply if the GM food ingredient does not contain novel DNA or novel protein. This approach appears to be contradictory and sends confusing messages to product developers, food manufacturers and consumers.	BASF	FSANZ considers there is no contradiction. Subsection 1.5.2—4(1) of the variation is to be read in its entirety and has the same effect as the existing paragraphs 1.5.2—4(1)(a) and (b) of the Code. A food may be classified as a 'genetically modified food', but it would be exempt from labelling if the food for sale containing that GM food does not contain novel DNA, novel protein or altered characteristics (for example, a highly refined GM food).

4 Labelling

Viewpoint	Raised by	FSANZ Response
Consequences of new definitions of 'genetically modified food' and 'novel DNA'		
Opposed the revised definitional approach because excluded foods would not be labelled as 'genetically modified' and consumers would lose the ability to make informed choices. These submitters stated GM labelling is necessary for the following reasons: • consumers have a right to know if food, including NBT food, has been genetically modified and therefore avoid these foods • there is clear consumer demand for this information • it would maintain trust in the food supply • it would be simpler and cheaper to have blanket labelling of GM ingredients in foods • GM labelling has been an integral part of the 'social licence' of gene technology over the last 20 years. Several submitters noted concerns that the proposed approach represents a sweeping change for food production and reduction in consumer choice.	Campaigns; Private individuals; GEFNZ; GEFTT; PSGR, AGEFC, KOT; ORICoop; Agrownomics; NZHT; CS; CSO; SO; S&H; IHER; GE; VFF; WCH; OANZ; ODPG; OFNZ; ELEW; AARPN; MSC; WH; SVO; BGNZ; TOS; WL	FSANZ has maintained the product-based approach for GM labelling, reflecting the policy set by food ministers in 2000 and reaffirmed in 2011. This approach is based on providing meaningful information for informed consumer choice and ensuring consumer trust (see section 4.1.2 in the 2nd CFS). FSANZ considers the revised definitional approach will have minimal practical impact on consumer choice. NBT foods excluded from the definition of 'genetically modified food' would likewise not be labelled under the existing Code requirements (see section 4.1, including Table 4 of this report). FSANZ disagrees that blanket labelling of GM ingredients would be simpler and cheaper. Requiring food suppliers to maintain sufficiently detailed records to determine whether an ingredient had undergone genetic modification, regardless of the presence of novel DNA or novel protein, is an unnecessary cost that was not supported by a cost analysis commissioned by food ministers. In response to the comment relating to the 2020 Ministerial Policy

Viewpoint	Raised by	FSANZ Response
Three submitters stated the proposed changes directly contravene the 2020 *Ministerial Policy Guideline on food labelling to support consumers to make informed healthy food choices* [36], which states the physical product should include information to provide consumers the opportunity to identify foods that contribute to healthy dietary patterns.		Guideline on food labelling to support consumers to make informed healthy food choices, FSANZ considers that this Policy Guideline does not directly apply because this proposal deals with the definition, clarification of what foods require pre-market safety assessment and approval as GM foods, not their contribution to diets.
Considered that hypothetical but unsubstantiated future benefits to consumers is unethically being used to trade-off the clear demand for consumer choice, with labelling dismissed and deemed out of scope before this stage of the consultation.	AGEFC	The existing product-based labelling approach for GM food was ruled out of scope when Proposal P1055 was prepared (see section 1.6.2 of the 1st CFS). The clarifications and consequential amendments proposed at 2nd CFS preserve the policy intent of the existing GM labelling approach and have been maintained (see section 4.2 in this report, and sections 4.1 and 4.2 in the 2nd CFS).
Expressed concern about the effect on GM labelling of excluding food additives, processing aids and nutritive substances from the proposed definition of 'genetically modified food': They stated: • it would mean GM labelling does not apply when novel DNA or novel protein is present, which may be significant to consumers who wish to make choices based on that criteria • it may create inconsistency in GM labelling requirements and cause stakeholder confusion as to what triggers the labelling requirement • industry determines the purpose of the food or substance addition to avoid the GM labelling requirement (e.g. added to food as a nutritive substance instead of as an ingredient), which may erode consumer trust • Food Ministers reaffirmed the existing labelling approach	NSWFA; MPI	Under the existing Code, food additives and processing aids are exempt from GM labelling if they do not contain novel DNA or novel protein, which is usually the case. The exclusion of these substances from the definition of 'genetically modified food' therefore will have minimal practical impact on GM labelling (see section 4.1, including Table 4 of this report). This approach is consistent with other international regulators who also do not distinguish between GM and non-GM food additives and processing aids (see section 2.3.5 in the 2nd CFS). FSANZ has revised its approach since the 2nd CFS and will not exempt nutritive substances from the 'genetically modified food' definition (see section 3.3 of this report). As such, GM labelling will continue to apply to nutritive substances if novel DNA, novel protein, or altered characteristics from those substances are present in the food for sale.

[36] Ministerial Policy Guideline on food labelling to support consumers to make informed healthy food choices - https://www.foodregulation.gov.au/resources/publications/policy-guideline-food-labelling-support-consumers-make-informed-healthy-choices

Viewpoint	Raised by	FSANZ Response
in 2011 for GM labelling of foods or ingredients that have altered characteristics or contain detectable novel DNA or protein (see Recommendation 29 of the report 'Labelling Logic: Review of Food Labelling Law and Policy').[37]		The purpose of adding an ingredient or additive has always been a decision for industry. FSANZ notes that food additives and processing aids will remain subject to a pre-market safety assessment and approval, regardless of their GM status.
Recommended FSANZ undertakes further assessment regarding the labelling implications of these substances being excluded from the definition of 'genetically modified food'. One submitter noted there is some industry appetite to inform consumers when novel DNA or novel protein from these excluded substances is present in the food for sale.	NSWFA; NZFGC	FSANZ does not consider that further assessment of labelling implications is necessary. The proposed outcomes-based definitional approach for pre-market assessment will achieve similar labelling outcomes as the current product-based labelling approach (see Table 4 in section 4.1 of this report). Manufacturers will still be required to declare the presence of novel DNA or novel protein from an approved GM nutritive substance in the food for sale. However, food additives and processing aids will no longer meet the definition as a GM food in the Code and the mandatory statement 'genetically modified' will not apply. As noted in the row above, under the existing Code, food additives and processing aids are exempt from GM labelling if they do not contain novel DNA or novel protein, which is usually the case. The exclusion of these substances from the definition of 'genetically modified food' therefore will have minimal 'real world' impact on GM labelling (see section 4.1, including Table 4 of this report).
Considered labelling should apply when novel DNA or novel protein is present in a food for sale to meet the obligation to ensure consumer choice. Alternatively, these submitters suggested GM labelling should apply if these foods are excluded from a GM pre-market assessment.	MPI; INC	Food for sale containing novel DNA or novel protein from an approved GM food must comply with mandatory GM labelling requirements, consistent with the existing regulatory approach. FSANZ considers it is inappropriate to apply GM labelling requirements to foods excluded from the definition of 'genetically modified food' and thus not subject to a GM pre-market assessment.
Considered the proposed amendments to the labelling	NZFGC; ABCL;	FSANZ disagrees with submitter comments that the GM labelling

[37] Labelling Logic: Review of Food Labelling Law and Policy - https://webarchive.nla.gov.au/awa/20170215181007/http://foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic

Viewpoint	Raised by	FSANZ Response
provisions represented a change to the GM labelling approach, which contrasts with FSANZ's statement that the GM labelling approach has not changed.	NZBC; GEFTT	approach has changed. The proposed consequential amendments to the labelling provisions are to remove labelling exemptions made redundant by the proposed definitions for 'genetically modified food' and 'novel DNA' (see subsection 4.2 in this report).
Commented that, under the proposed approach, GM labelling would not apply to NBT food with an altered characteristic if that NBT food was not considered a GM food. Although industry may choose to voluntarily label or advertise altered characteristics, this information would not be guaranteed for consumers. The submitter noted this effect of the revised approach for the definitions may be inconsistent with Food Ministers' reaffirmation of the existing labelling approach, where GM labelling relating to the altered characteristic applies regardless of the presence of novel DNA or novel protein. The submitter commented that Food Ministers reaffirmed the existing labelling approach in 2011 in response to Recommendation 29 of the report 'Labelling Logic: Review of Food Labelling Law and Policy'.	NSWFA	FSANZ notes that certain NBTs are excluded from the new GM food definition because they are no different to conventional food i.e., they do not contain novel DNA. They will also not contain novel protein and most of the introduced traits already exist in conventional counterparts (see section 3.2.1 of this report). Under the existing GM labelling policy, FSANZ would not consider these introduced traits as altered characteristics for labelling purposes. Furthermore, FSANZ notes that not all GM food (which includes NBT food if they were to be captured under the current Code) would have an altered characteristic for labelling purposes (see section 4.1 of this report). The revised definitions remove the current Code ambiguity about whether those NBT foods are captured for pre-market assessment as a GM food. GM labelling requirements do not apply to food that is not captured as a GM food. However, a new trait in a food, whether that has occurred through conventional breeding or the use of a NBT, may trigger that food to undergo a pre-market assessment via a different pathway (see section 3.2.1 of this report). FSANZ would then consider whether other labelling measures are warranted. As noted by the submitter, industry may voluntarily provide information about the desirable trait, and nutrition content and health claim requirements may be relevant.
Noted the potential for significant risks and uncertainties arising from NBTs and considered such food products should be clearly labelled to ensure public health is not compromised.	IOC; GEFNZ; GE	FSANZ's safety assessment has not identified any safety concerns associated with food produced using NBTs that are excluded from the definition of 'genetically modified food', which is consistent with the conclusions of other overseas regulators. Excluded NBT foods are considered to be as safe as conventional food.

Viewpoint	Raised by	FSANZ Response
Process-based labelling		
Opposed the existing product-based labelling approach for the following reasons: • it undermines the priority order objective in the FSANZ Act to provide adequate information to consumers to inform choice • most consumers want to know if food is made with gene technology, anywhere in the production of the food.	HFSA; AGEFC; HEART Party	See response above regarding food ministers' consideration of the policy position for GM food labelling. Furthermore, the outcomes-based definitional approach for pre-market assessment will result in similar labelling outcomes to the current product-based labelling approach (see Table 4 in subsection 4.1 of this report).
Believed that genome-edited foods should continue to be labelled, regardless of whether they contain novel DNA. One submitter stated the current process-based labelling approach must be maintained and applied consistently to all GM foods, irrespective of the presence of novel DNA.	Campaign 3; AOL	Labelling genome-edited food as 'genetically modified' when novel DNA or novel protein is absent would represent a change to the existing 'product-based' approach for GM labelling, which is not changing under the proposed amendments. A change to a 'process-based' approach for GM labelling would require a change in Ministerial policy, which is out of scope of Proposal P1055 (see sections 1.5 and 4 of the 2nd CFS; subsection 1.6.2 in the 1st CFS).
Sought process-based labelling for the following reasons: • it is important information to enable informed choices based on ethical and cultural values • its absence undermines their company's business model of being able to supply clearly labelled foods and products.	Private individuals; AOL, S&H; GEFNZ; AGEFC; CSO; GEFTT	See response above relating to informed choice. FSANZ has responded to issues relating to GM labelling and food represented as organic in subsection 6.1 of this report.
Others		
Requested foods be clearly labelled as 'GMO free'.	Private individual	The Code does not regulate claims such as 'GMO free', non-GM', or 'non-GMO'. FSANZ notes these voluntary representations are subject to fair trade legislation in Australia and New Zealand. Refer to FSANZ's webpage on this issue.[38]
Expressed concern regarding the absence of labelling for a broad range of foods including 'mock milk', 'synthetic seafood',	Private individuals	FSANZ notes that issues relating to the naming of milk and seafood analogues are not within the scope of Proposal P1055. General food

[38] Genetically modified (GM) food labelling - https://www.foodstandards.gov.au/consumer/gmfood/labelling

Viewpoint	Raised by	FSANZ Response
food additives (including colours and flavourings) and processing aids.		identification requirements in the Code would apply, which require that foods must be labelled with an accurate name or description that indicates the true nature of the food. For information about these generic labelling requirements, see our webpage about truth in labelling.[39] The Code mandates that food additives, including colours and flavourings, must be listed in the statement of ingredients on the label of packaged food, regardless of whether they are GM foods. For information about these generic labelling requirements, see our webpage about the labelling of food additives.[40] Under existing Code requirements, non-GM processing aids are typically exempt from labelling unless they contain a listed food allergen that must be declared and is present in the food for sale (see subparagraph 1.2.3—6(2)(a)(ii)).

[39] Truth in labelling – https://www.foodstandards.gov.au/consumer/labelling/truth
[40] Food additive labelling – https://www.foodstandards.gov.au/consumer/labelling/Labelling-of-food-additives

5 Guidance material and non-regulatory measures

Viewpoint	Raised by	FSANZ Response
Consumer guidance		
These submitters supported the development of consumer guidance materials. Some of the submitters provided the following suggestions: • plain English education material • frequently asked questions (FAQs) addressing common questions about the safety and benefits of GM/NBT foods, GM labelling requirements and the proposed regulatory changes • explanation of the proposed exemptions from the GM food definition • definitions for scientific terminologies & methodologies in simple language • general description of pre-market safety assessment; • figure illustrating the relationship between GM organisms, GM foods and GM labelling • examples of how NBTs and conventional breeding techniques might overlap.	NSWFA; MPI; AFGC; MSCO; SA Health; QLDH; OriCoop	FSANZ notes that a significant amount of plain English explanatory information and consumer education material related to gene technology and NBTs is already available in FSANZ reports and webpages.[41,42] Additionally, a general description of the pre-market safety assessment and labelling requirement of GM foods can also be found on the FSANZ website.[43,44] FSANZ will update the content of FSANZ webpages with clarifying information where appropriate once P1055 is finalised.

[41] General information about GM foods – https://www.foodstandards.gov.au/consumer/gmfood/gmoverview
[42] Education materials on GM foods and NBTs – https://www.foodstandards.gov.au/consumer/gmfood/Education-materials-on-GM-foods-and-NBTs
[43] Safety assessment of GM foods – https://www.foodstandards.gov.au/consumer/gmfood/safety
[44] Genetically modified (GM food labelling – https://www.foodstandards.gov.au/consumer/gmfood/labelling

Viewpoint	Raised by	FSANZ Response
These submitters noted FSANZ's consumer research indicates that consumers desire more information about food produced using gene technologies. They suggested FSANZ coordinate information from universities and scientific agencies to demonstrate government and scientific support for NBTs. CSIRO offered support in providing case studies and information about specific foods for consumer information. NSWFA suggested FSANZ and OGTR should collaborate to clarify the proposed amendments to the Food Standards Code and how these relate to the proposed amendments to the Gene Technology Act. NSWFA suggested including infographics to explain the regulatory remit of FSANZ and the OGTR.	CSIRO, NZFGC; INC; AFII NSWFA	
Jurisdictional and industry guidance		
These submitters supported the development of guidance material for industry and jurisdictions and provided specific suggestions for the format and content, which are included in Appendix 2. They also suggested scenarios and examples to help contextualize the definitions, which are included in Appendix 2.	BPNZ; OANZ; NSWFA; SA Health; MSCoop; NSNZ; ORICoop; SPSII; Miruku; T&G; Nestle; CLA; BASF; Noumi; Danisco/IFF; IG; NZFGC; AIFST; PFR; CSIRO; AgResearch; CFCD; CE-P4S; FaBA; MPI; QLDH; VicDoH & VicDJPR; FCG; AGWI; AFGC; FF; GG; ABCL; NZBC; CAA;	Noted. FSANZ will work collaboratively with the jurisdictions through the Implementation Sub-committee for Food Regulation (ISFR) to develop guidance material. Please refer to section 5 of this report.

Viewpoint	Raised by	FSANZ Response
	Noumi; GE; AMA; INC; BTNZ; BPNZ; AGEFC; Private individual GM; IBC-UniAdelaide (late comment)	
Requested clarity on labelling requirements, including comparing current GM labelling requirements with those required under the new framework.	NSWFA; AFGC	FSANZ notes that the focus of the guidance material will be on the new definitions (not the labelling requirements). Consequential changes for labelling are clearly set out under section 4.2 of this report.
Emphasised the need for updating the FSANZ Application Handbook to clarify pre-market approval requirements, urging for amendments to be completed before implementation.	Nestle; NZFGC; MPI; FCG; INC	Noted. FSANZ has commenced work on updating the Application Handbook. We note that Proposal P1055 and the updates to the Application Handbook are separate matters. Therefore, the updates to the Application Handbook will proceed on its own timeline, independent of Proposal P1055, and is subject to available resources.
Requested clarity on how foods that developers have concluded are not GM foods under the new definition would be assessed for compliance, and raised a number of questions which are included in Appendix 2.	BASF; BDRI; GEFNZ; GEFTT; Private individuals MW, GM	Noted. FSANZ will work collaboratively with jurisdictions through ISFR to develop guidance to assist with compliance. Please refer to section 5 of this report.
Guidance material – other considerations		
These submitters recommended that guidance material be made available before the new definitions are implemented, tailored to stakeholder needs, publicly consulted, and regularly reviewed in line with technology development.	Miruku; T&G; PFR; BTNZ; NSNZ; CAA; NZFGC; BASF; FCG; FF; NSWFA; FaBA	Noted. Guidance materials will need to be developed in consultation with and endorsed by jurisdictions through ISFR. Work on developing the guidance materials can commence once the Food Ministers Meeting has made a decision to endorse the draft food regulatory measure approved by FSANZ.
Existing material on GM foods on the FSANZ website needs	ABCL; NZBC	Noted.

Viewpoint	Raised by	FSANZ Response
updating. The information on the FSANZ website on GM foods is influenced by industry and lacks sufficient scientific evidence.	Private individual SV	Information on GM foods on FSANZ's website[45] will be updated following proposal P1055's approval. FSANZ operates independently and within the parameters defined in the Act. FSANZ's information on GM foods is developed using the best available scientific evidence including peer-reviewed scientific literature and publications to develop information on GM foods and is aligned with international regulators and science-based organisations.
MPI agrees with FSANZ that an advisory committee is unnecessary under the revised definitions. NSWFA suggests that the existing Advisory Committee on Novel Foods (ACNF) could serve as industry liaison for determining if an excluded NBT food is a novel food, noting the ACNF may require additional guidance to fulfil this function.	MPI; NSWFA	Noted. Please refer to subsection 3.2.1 of this report for further information about the ACNF and its role in making recommendations on when excluded NBT foods would be novel foods.

6 Consideration of costs and benefits

Viewpoint	Raised by	FSANZ Response
Stated that no impact analysis on the changes suggested can be found.	Campaigns	FSANZ is required by section 59 of the FSANZ Act to have regard to whether the costs that would arise from a proposed measure outweigh their benefits. FSANZ must also meet the requirements of the *Regulatory Impact Analysis Guide for Ministers' Meeting and National Standards Setting Bodies* of the Office of Impact Analysis. FSANZ provided a consideration of costs and benefits at the 2nd CFS for stakeholder consideration, indicating a Decision Regulation Impact Statement (DRIS) would be prepared at the approval stage. For the final impact analysis, please refer to the DRIS FSANZ has

[45] Information on GM Foods - https://www.foodstandards.gov.au/consumer/gmfood

Viewpoint	Raised by	FSANZ Response
		prepared.
Submitters made several critiques regarding the consideration of costs and benefits (SD 5). These included: • the lack of comprehensive and meaningful impact analysis, and particularly regarding the shift to the proposed outcomes-based approach • no referenced, peer-reviewed published research has been undertaken as to the impact of the proposed changes • no documented evidence being provided to support the claims and conclusions • Making no attempt to quantify the costs and benefits • Not adequately considering the impact on the organic and non-GM sector • Absence of a market analysis to segment the organic and non-GM food sector from the food industry that choose to use GM ingredients • The balance of the analysis favoured regulatory alignment over market demand for non-GMO food and is not of the public interest • FSANZ was not clear how costs were defined in the analysis • Further analysis should be consulted on.	OANZ; ORICoop; OIA; AOL; NZHT; GEFNZ; AGEFC; BDRI; BPNZ; KOT; GE; PSGR; HFSA; Private individuals JA, JW, KM; Campaigns; OGMD; VFF	FSANZ is required by section 59 of the FSANZ Act to have regard to whether the costs that would arise from a proposed measure outweigh their benefits. FSANZ must also meet the requirements of the Regulatory Impact Analysis Guide for Ministers' Meeting and National Standards Setting Bodies (the Guide) of the Office of Impact Analysis (OIA). FSANZ indicated at the 2nd CFS a DRIS would be prepared at the approval stage. FSANZ gave stakeholders an opportunity at both Call for Submissions to provide evidence or information, particularly quantifiable evidence, available to them to support the inclusion of impacts that may result from the proposed amendments. FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Please refer to subsection 5.5 of the DRIS for consideration of the impacts to organic operators. The final analysis has been assessed by the OIA. The DRIS was assessed as being compliant with the requirements of the Guide.
FSANZ did not demonstrate the extent to which GM ingredients are already present in widely consumed ultra-processed food.	OANZ; ORICoop;	FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Section 1.4 of the DRIS addresses the presence of GM food in the Australian and New Zealand food supply.
Noted the costs that some businesses may face from the proposed approach, such as: • businesses that may need to update processes, documentation, change suppliers and any promotional	AFGC; NSWFA	FSANZ notes the possible costs to businesses suggested by submitters. FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Please refer to subsection 5.4. of the DRIS for the final analysis of

Viewpoint	Raised by	FSANZ Response
information or claims around GM non-use, particularly in relation to processed ingredients that don't contain novel DNA • additional cost associated with self-determination; • additional time required for an Advisory Committee on Novel Foods enquiry • familiarisation costs with the new GM food framework arising from the definitional changes. One submitter noted it is also important to consider the possible positive and negative indirect impacts such as future workforce implications, effects on other businesses, and impacts on more traditional food industries.		impacts to food developers and manufacturers.
Suggested the proposal will affect industry and potentially drive-up costs of food to consumers because of additional efforts required by food producers to secure their supply chain.	GEFNZ; GEFTT	FSANZ understands certified organic operators adopt a variety of practices to ensure GM materials do not contaminate their operations, among other residue contaminations, and certified organic producers are unlikely to be significantly impacted by the proposed amendments. Please refer to subsection 5.5 of the DRIS.
This submitter questioned FSANZ considering competition, in the context of altering the genetics of living organisms worldwide, as a public good.	Private individual SV	Under subsection 18(2) of the FSANZ Act, FSANZ must have regard to the desirability of an efficient and internationally competitive food industry. FSANZ notes that encouraging competition is important for innovation and providing lower prices to consumers. Please refer to subsection 5.4 of the DRIS.
Highlighted the burden on the precision fermentation industry from the proposed approach. The costs associated with pre-market approval as proposed currently may be prohibitive and unnecessarily stifle further innovation, reduce choice and potentially increase costs to consumers.	AFGC; CAA	At the 2nd CFS, FSANZ was clear that foods and ingredients derived using precision fermentation 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 or processing aid.
The value of non-GMO exports to the Australian and New Zealand economies needs to be robustly quantified and that	AGEFC; PSGR	Certified organic operators and their exports are unlikely to be significantly impacted by the proposed amendments.

Viewpoint	Raised by	FSANZ Response
alignment of standards should not come at the cost of this export value. FSANZ failed to consider the economic advantage to farmers and growers that can be gained from NZ's current non-GM food production status.		Please refer to subsection 5.5 of the DRIS.
Noted the costs that some consumers might face from the proposed changes, including: • redirecting the cost of proving safety to the consumer, as there is a cost margin in purchasing foods with non-GMO or organic accreditation • less label information for consumers, regarding substances, food additives, and processing aids • escalating the cost of living. Submitters also shared their concerns regarding the consumer right to know where food comes from. Responses to these submissions can be found in the labelling table.	PSGR; CSIRO; Private individual JA	All food must be safe and suitable in order to be sold. GM food is still required to undergo pre-market safety assessment to determine whether the GM food is safe. Claims such as 'non-GMO' and 'organic' are values-based and are available for consumers to purchase foods that align with their values. Under the existing Code, food additives and processing aids are exempt from GM labelling if they do not contain novel DNA or novel protein, which is usually the case. The exclusion of these substances from the definition of 'genetically modified food' therefore will have little 'real world' impact on GM labelling (see Table 4 in subsection 4.1 of this report). The proposed approach is unlikely to negatively impact the price of food. FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Please refer to subsection 5.3 of the DRIS for the final analysis of impacts to consumers.
Commented on consumer preferences, noting that: • consumers globally are willing to pay a premium for GMO-free food • consumers discount GMOs, including gene edited food, as they want to avoid it and will now have to seek out food that specifically has a non-GMO label or that is organic. One submitter shared that consumer acceptance is likely to increase as products with health and environmental benefits	PSGR; BPNZ; Private individual GM	FSANZ notes submitter comments regarding consumer preferences. FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Please refer to subsection 5.3 of the DRIS for the final analysis of impacts to consumers.

Viewpoint	Raised by	FSANZ Response
enter the market.		
Highlighted costs to government that may be borne by the proposed approach, including: • providing advice on Code interpretation • costs arising from inconsistent implementation by jurisdictions due to lack of clear FSANZ guidance as to how to apply the new framework • burden to enforcement agencies by relying on self-regulation of developers • limiting the capacity of regulators in the absence of clear statements on expected testing and traceability methodologies, and mandatory disclosure by developers. One submitter noted that while the proposed approach is not directly responsible, the increasing number of gene-edited products entering the global food system highlights the need for enhanced genetic screening to ensure compliance with the Code which will inevitably be a cost borne by the government.	NSWFA; AEGFC; GEFNZ; Private individual GM	FSANZ notes the possible costs to government suggested by submitters. FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Please refer to subsection 5.6 of the DRIS for the final analysis of impacts to government.
Wider availability of NBT foods being beneficial for consumers is hypothetical and not proven, whereas the market demand for non-GMO food is proven. The submitter questioned why FSANZ cited the potential consumer, sustainability and climate-related benefits of NBTs.	GEFNZ	FSANZ noted at 2nd CFS in subsection 4.2 of SD2 – Cost benefit considerations that there are challenges in predicting how the changes proposed may impact in the long term. FSANZ has revised its consideration of costs and benefits in light of stakeholder feedback. Please refer to subsection 5.7 of the DRIS for the final analysis of the long-term impacts.
Increasing the variety of food available to consumers should not be considered a benefit given some of this increase will be unhealthy foods, and in turn diet-related diseases.	HFSA	FSANZ noted at 2nd CFS in subsection 4.2 of SD2 – Cost benefit considerations that there are challenges in predicting how the changes proposed may impact in the long term. While FSANZ cannot predict the types of foods that may be produced by NBTs, some examples of NBT foods being developed are given in section 2 of the DRIS.

Viewpoint	Raised by	FSANZ Response
Noted the long-term costs of monitoring and evaluating the safety and environmental impacts of NBT foods had not been considered.	OANZ; AGEFC	FSANZ considers it unnecessary that long-term monitoring of the impacts of NBT foods be undertaken in the absence of safety hazards. FSANZ notes such surveillance is also not undertaken for existing approved GM foods. There is therefore unlikely to be a cost associated with such long-term monitoring. Environmental issues are outside FSANZ's authority and expertise. Please refer to subsection 5.6 of the DRIS for the final analysis of impacts to government.

7 Organic and non-GM sector

Viewpoint	Raised by	FSANZ Response
Raised a number of concerns relating to impact on the integrity of the organic and non-GM supply chain and perceived challenges with verifying the status of organic and non-GM products. These are discussed in more detail in section 6.1 of this report. • the scope of GM labelling may be a barrier for ingredient suppliers who wish to make non-GM claims as they may be less confident that their products are not derived from NBTs. Consequently, it may be difficult for businesses to meet their certification requirements.	Campaigns; Private individuals; OFC; OWNZ; NG; AOL; ODPG; LuxO; OANZ; ORICoop; MPI; CSO; KOT; BDRI; OIA; AGEFC; GEFNZ; ELEW; BPNZ; GE; OCAA; OFNZ; S&H; NonGMO Project; KOT, GEFTT; FoFF	FSANZ has considered and addressed these issues in subsection 6.1 of this report and subsection 5.5 of the DRIS.
Raised concerns about the impacts of the proposed changes on exporters of organic and non-GM products, citing a number of issues which are described in section 6.1 of this report.	Campaigns; Private individuals; AOL; NG; ORICoop; ELEW; BDRI; OIA; AGEFC; KOT; OFC; OWNZ; ODPG; LuxO; OANZ; MPI; CSO; GEFNZ; BPNZ; GE; OCAA; OFNZ; S&H; NonGMO Project; KOT, GEFTT	

Viewpoint	Raised by	FSANZ Response
Noted that the food supply chain in Australia is well-placed to manage coexistence and market segregation concerns, and highlighted a number of points which are described in section 6.1 of this report.	CLA; ASF; GTA; GG	
Questioned how FSANZ has considered the National Organic Standard.	ORICoop; ELEW	Issues relating to the National Organic Standard and the New Zealand Organic Products Bill are matters for the Department of Agriculture, Fisheries and Forestry (DAFF) in Australia and MPI in New Zealand, respectively.
The New Zealand Government Organic Products Bill may become meaningless if pre-market safety assessments are not required.	KOT	

8 Alignment of domestic regulations

Viewpoint	Raised by	FSANZ Response
There were divergent views on the impact of the proposed *Code* changes to the Gene Technology (GT) Act, with some submitters foreseeing greater alignment and others predicting lesser alignment. Some submitters acknowledge that a complete alignment of the *Code* with other domestic regulations may not be necessary due to different food safety objectives and risks. (HNZ, MPI; SA Health) Some submitters expressed support for greater alignment between Australia and New Zealand, highlighting the ongoing work on New Zealand's GT Act and amendments to Australia's GT Act.	FCG; INC; NSWFA; HNZ; MPI; SA Health	Noted. The alignment of domestic regulations related to GM organisms and GM food is discussed in subsection 6.2 of this report.

Viewpoint	Raised by	FSANZ Response
More detailed consideration of the potential risks of non-alignment between the FSANZ and OGTR regulations is required. For example, the implications of ingredients being defined as genetically modified under the Code but not by the OGTR, or vice versa.	NSWFA; The Victorian Departments	
The proposal requires clarification on the alignment between OGTR and FSANZ, as there appears to be a grey area in relation to precision fermentation where FSANZ also focuses on the 'process' rather than the 'product'.	CAA	
The exclusion of genome-edited foods without novel DNA from the definition of GM food is at odds with previous assessments by the OGTR. The level of oversight established by the OGTR should be maintained by FSANZ.	AOL	

9 International harmonisation and trade

Viewpoint	Raised by	FSANZ Response
International harmonisation and trade		
Expressed positive views on the likely effects of P1055 on international trade and harmonisation. These are discussed in detail in section 6.3 of this report.	LSN; Danisco/IFF; AFII; NFF; INC; GTA	Please refer to subsection 6.3 of this report.
Existing legislation should be retained until EU regulations are finalised to avoid the possibility for less stringent regulations than the EU. FSANZ's definition should align with the current process-based EU definition of GMOs.	OANZ; PGSR; Private individual MF	

10 Other relevant issues

Viewpoint	Raised by	FSANZ Response
Consumer trust and sentiment		
Exempting certain NBT foods from pre-market assessment as GM foods and from GM labelling will have a negative impact on public confidence in food safety and trust in regulators / government.	Private individuals; AGEFC; GEFNZ; GEFTT; PSGR; WoW; VFR; OANZ	FSANZ notes this comment. Ensuring public confidence in the food supply is a core part of FSANZ's remit under the Act. It is difficult to know whether the proposed approach will directly impact consumer trust in the food regulatory system. The best way FSANZ can maintain confidence is to continue ensuring GM food is safe and regulated appropriately. Trust is a multi-faceted concept and FSANZ notes there are other important actors in the system that also impact consumer trust and confidence. FSANZ will continue to measure consumer trust in the annual consumer insights tracker (CIT) survey.
Consumer surveys demonstrate considerable concern among both Australian and NZ consumers regarding GM technology and GM foods despite long-term marketing attempts.	FoENZ	Research on Australian and New Zealand consumers indicates that GM foods are not a top-of-mind food safety issue for the vast majority of consumers. However, when directly asked, consumers indicate that they still have concerns about the long-term effects of using gene technology in food production. A substantial proportion of consumers surveyed appear to want more information about the use of gene technology, whether GM or NBTs, in food production. Refer to SD3 for further information.
Consumer surveys show that the public want the right to know if food is produced by gene technology, including NBTs.	GEFNZ; GEFTT; Private individual CC	Please see response above under ***4 Labelling - process-based labelling***.
Noted a potential disparity in consumer views relating to NBTs and GM in FSANZ's consumer research (2nd CFS), where NBTs are seen on a spectrum of food produced using GM but indicated regulation of NBTs was desirable. Noted a concern about whether there has been sufficient consultation and communication to achieve consumer acceptance of this change in approach. Reference to the 2024 report published on the OGTR website 'Community attitudes towards gene	NSWFA	FSANZ notes the updated OGTR research which is broadly consistent with the findings in the overall consumer research available in SD3. FSANZ notes the decrease in level of trust of government and government agencies overall found in this report. In FSANZ's annual CIT survey the majority of consumers had confidence that food sold in Australia and New Zealand is safe to eat. Further, for those who were aware of FSANZ the majority also had

Viewpoint	Raised by	FSANZ Response
technology' was provided and highlights the decline in trust in some regulators.		trust in FSANZ. The full report is available on the FSANZ website.[46] FSANZ will continue to measure consumer trust in the CIT.
Consumers actively discount GMO, including gene edited food. Australian and New Zealand families have to date, recognised that they could avoid GMOs because of stringent labelling laws. As consumers actively discount GMO food, they will now have to seek out food that specifically has a non-GMO label or that is organic.	PSGR	FSANZ notes the literature provided. As above, research on Australian and New Zealand consumers indicate that GM foods are not a top-of-mind food safety issue for the vast majority of consumers. Approved GM foods will continue to be subject to mandatory product-based GM labelling requirements to enable informed consumer choices. See section 4 of this report and above in this table for clarifications relating to GM labelling.
Expressed a lack of trust in self-assessment of the GM status of products by developers.	GE; VFF; GEFNZ; AGEFC; TWKO; S&H; Private individuals; CSO; AGEFC; ODPG	FSANZ notes this issue is not new and has been previously addressed in the 2nd CFS. Please refer to the 2nd CFS, Appendix 1, Table B (pages 61-62). It is the legal responsibility of all food businesses to ensure their food is safe and suitable, according to the Code, irrespective of whether it has undergone a pre-market safety assessment by FSANZ. This approach is not unique to GM foods; it applies to all foods across our regulatory system. This system has been in place for many years in both Australia and New Zealand and continues to operate effectively in protecting public health and safety.
Process and engagement		
Expressed one or more of the following concerns about FSANZ's engagement with stakeholders: • FSANZ insufficiently engaged with key sectors including the organic sector, natural health & beauty industry, Māori	Campaigns; Private individuals; NonGMO Project;	FSANZ engages comprehensively with stakeholders through various methods, including formal channels like public consultations and consumer survey, and informal interactions.

[46] Consumer Insights Tracker - https://www.foodstandards.gov.au/science-data/social-science

Viewpoint	Raised by	FSANZ Response
and tangata whenua stakeholders prior to the 2nd CFS • more engagement and information sharing with diverse populations should have been undertaken throughout the process, not just at key decision points	OANZ; BPNZ; AOL; OCAA; IOC; TWKO; ODPG; GEFNZ; GEFTT; BGNZ; ORICoop; ELEW; PIC	FSANZ has conducted two rounds of public consultation for P1055 and one round of public consultation during the NBT review as well commissioned several consumer surveys as part of the broader effort to engage with stakeholder and gain consumer insights to inform the regulatory approach for NBTs. Post the 2nd CFS, FSANZ has engaged extensively with various stakeholders including the organic sector. FSANZ is dedicated to maintaining open and effective communication with all relevant parties and actively encourages stakeholder engagement post this proposal.
Raised one or more concerns relating to FSANZ's consultation process: 1. Given the significant changes between the 1st and 2nd CFS, the public comment period was too short, and should have been extended. 2. The consultation has pre-determined outcomes, and the views of submitters are consistently ignored and not genuinely considered. 3. For consultations held in 2018 and 2021, FSANZ failed to disclose the balance of opinion for and against the proposals. 4. The consultation questions for the 2nd CFS were restrictive, leading, and were tailored for industry submitters.	Campaigns; Private individuals; NonGMO Project; OANZ; BPNZ; AOL; OCAA; TWKO; ODPG; GEFNZ; GEFTT; ORICoop; PGSR; WoW; CSO; AGEFC; PIC	FSANZ notes these concerns. 1. FSANZ's standard public consultation period for all proposals and applications is 6 weeks, with extensions only granted in exceptional circumstances. In this case, such circumstances did not exist. 2. Feedback from all submitters is valued and contributes to the rigor of FSANZ's assessment and regulatory approach. FSANZ has carefully considered the issues and concerns raised by submitters, however no new information, including scientific evidence, was provided that would cause FSANZ to alter its previous safety assessment or conclusions or the proposed regulatory approach to exclude certain NBT foods from regulatory capture as GM food. 3. The balance of opinions for and against the proposal, as well as the issues raised are discussed and addressed in the published consultation and approval reports. FSANZ's decisions are evidence-based. Submissions are published on our website, allowing the public to read and form their own conclusions. 4. FSANZ included questions in the 2nd CFS to gather submitter views on specific areas, with submitters having the option to provide additional feedback in the 'additional information' section.

Viewpoint	Raised by	FSANZ Response
Raised one or more of the following concerns about potential conflicts of interest and biases associated with P1055: 1. FSANZ has a pro-industry bias, and P1055 benefits biotech companies and businesses without having regard for views of the public. 2. The expert advisory panel for P1055 consists of conflicted 'experts'. 3. FSANZ Board members must declare all potential conflicts of interest and any funding /donations received from companies to ensure that its role in protecting public health and consumer rights is not compromised. 4. Requested an independent inquiry into FSANZ's relationship with industry and choice of scientific inputs for decision making. 5. Questioned where FSANZ takes its policy direction from. 6. FSANZ's consumer research excluded certain groups.	Campaigns; Private individuals; PSGR; WoW; VFF; GEFNZ; GEFTT	FSANZ notes these concerns. 1. 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 with the public. 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. 2. FSANZ does not agree. Members of the expert advisory panel for P1055 are required to identify, declare and manage all conflicts of interests relating to their role, and sign the *Conflict of Interest Deed* before being appointed as a member. 3. FSANZ Board members are required by Australian law to declare and manage conflicts of interest. Board members comply with those laws. 4. FSANZ engages with various stakeholders, including industry, through formal and informal interactions, public consultations, and advisory groups. This collaboration ensures the development of effective food safety standards. FSANZ is committed to transparency and regularly updates its stakeholder engagement activities[47] to maintain public trust and inclusivity. 5. FSANZ's policy is guided by the Food Ministers' Meeting (FMM), which includes food ministers from Australia and New Zealand. These ministers issue policy guidelines that FSANZ must consider when developing food standards.[48] The FSANZ Board oversees the organisation's operations and ensures that policies align with these guidelines.

[47] FSANZ Stakeholder engagement - https://www.foodstandards.gov.au/about-us/stakeholder-engagement
[48] Food policies - https://www.foodregulation.gov.au/about-the-system/policies

Viewpoint	Raised by	FSANZ Response
		FSANZ's role is to develop draft standards for the FMM to assess and approve. The decision-making role rests with the FMM. 6. FSANZ's consumer research included a nationally representative sample of Australians and New Zealanders. Please refer to the P1055 webpage[49] to access the full consumer survey reports.
FSANZ is not adhering to the objectives of the FSANZ Act to protect public health and provide adequate information to enable consumers to make a choice.	Private Individuals; GEFNZ; GEFTT; PSGR; VFF; OANZ; BPNZ	FSANZ does not agree. In its assessment and decision to approve the draft variation, due regard was given to the statutory objectives relating to the protection of public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices. Please refer to section 8 of this report.
Traceability and monitoring		
Robust testing and traceability for NBTs is required to: • satisfy market demands, verifying genetic status, and gathering information needed for various certifications (organic, vegan), consumer inquiries, and non-GM claims • preserve the integrity of the food system, consumer confidence and trade • maintain transparency across the supply chain.	GEFNZ; GEFTT; AGEFC; OANZ; ORICoop; BPNZ; FCG; AFGC	FSANZ has previously addressed issues relating to testing and traceability of NBT foods. Please refer to the 2nd CFS, Appendix 1, Table B (pages 63-64). FSANZ also notes that industry-led frameworks exist for managing market segregation, ensuring integrity across different production systems. There is also an opportunity for industry to develop an industry-led traceability system in the absence of government-led regulation. Please refer to section 6.1 of this report for further detail.
Comments raised relating to post-market surveillance and monitoring of NBTs: • labelling will allow for epidemiological studies to be undertaken and the speedy withdrawal of harmful products from the market • a FSANZ-funded surveillance program should be initiated post-approval to monitor the impact of NBTs and the approval decision should be reviewed after 10 years.	IHER; Private Individual KR	FSANZ has previously addressed issues relating to post-market surveillance and monitoring. Please refer to the 2nd CFS, Appendix 1 Table B (pages 50-51).

[49] P1055 webpage - https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Viewpoint	Raised by	FSANZ Response
FSANZ should consider a public register for NBT foods and ingredients, similar to the approach proposed for precision-bred organisms in England. Additionally, companies should be required to notify any foods produced from NBTs to allow traceability.	FCG; NZFGC; INC; GEFNZ; GEFTT; Private individuals	It is not part of FSANZ's statutory function to require notification or registration of foods that do not require pre-market assessment and approval under the Code. England has specific legislation that authorises the Food Standards Agency (FSA) or the Department for Environment, Food, and Rural Affairs (DEFRA) to create and maintain a register of precision-bred organisms. See the Genetic Technology (Precision Breeding) Act 2023[50] (in particular section 18). In contrast, FSANZ has no clear legislative authority to do this, nor does FSANZ have any power to compel notification, registration, and the provision of related information, all of which would be required to establish a reliable and trustworthy register. In addition, there is scope for industry to establish and maintain a register of foods for sale that have been developed using NBTs.
Indigenous perspectives, cultural and ethical impacts		
These submitters expressed one or more of the following views: • The proposal reflects a scientific and regulatory worldview that may not align with Indigenous knowledge systems, which emphasise the interconnectedness of people, land, food and spiritual wellbeing. • P1055 does not adequately recognise cultural, philosophical, spiritual and ethical beliefs, including treaty-related obligations concerning Māori cultural values, expressions, practices and food sovereignty. • The proposal may impact the management of the Indigenous verification system (Hau Parakore) and therefore not uphold traditional Māori knowledge (mātauranga Māori). • FSANZ should engage in partnership-based dialogue with	Campaigns; Private Individuals; TWKO; TMC; TPoTW; OFNZ	FSANZ notes and acknowledges these concerns. Submissions from Indigenous peoples, including Māori, Pasifika, Aboriginal and Torres Strait Islander individuals and groups, were welcome on this proposal. FSANZ recognises that there are many different worldviews, perspectives, and knowledge pertaining to the use of gene technologies and new breeding techniques in food development that can be challenging to reconcile. In considering P1055 and reaching its decision, FSANZ was required to have regard to the best available scientific evidence, existing policy related to GM foods, input from both public and targeted consultation, consumer research, international developments in the regulation of new breeding techniques, and analysis of the costs and benefits of the proposed changes. We acknowledge the P1055 proposal reflects a

[50] Gene Technology (Precision Breeding) Act - https://www.legislation.gov.uk/ukpga/2023/6/contents/enacted

Viewpoint	Raised by	FSANZ Response
mana whenua, including thorough discussion of how the proposal may affect the rights and interests of Indigenous peoples.		scientific and regulatory worldview that may not align with Indigenous knowledge systems, which emphasise the interconnectedness of people, land, food and spiritual wellbeing. We also note that many of the concerns raised with FSANZ appear to have particular relevance to the New Zealand Gene Technology Bill 2024 and the Treaty of Waitangi. Such matters are more appropriately addressed by the New Zealand Government as part of their consideration of the Gene Technology Bill. FSANZ has highlighted the issues raised with relevant New Zealand government officials and publishes all submissions to ensure transparency of issues raised during the proposal. FSANZ further notes that claims such as 'non-GMO' and 'organic' are available for consumers to purchase foods that align with their values.
Terminology		
The terms 'exclusion' and 'exemption' are used interchangeably in the 2nd CFS. This could have implications when subject to legal, as opposed to scientific, interpretation.	CLA	In the context of the GM food definition, 'exclusion' refers to foods that are not captured because they do not contain novel DNA. 'Exemptions' apply to the specific categories of foods (e.g. processing aids, food additives) which are explicitly exempt from the definition, even if they would otherwise be considered GM foods.
FSANZ should adopt the FAO definition for precision fermentation.	Novozymes; EUB	The core intent and focus of P1055 is to provide a clear and risk-proportionate regulatory framework for food from NBTs. More specific issues relating to precision fermentation and how it is defined are outside the scope of P1055 but may be addressed in future work.
The term 'New Breeding Techniques' is a misleading rebrand of GM technology and foods. The term used by the EU, 'New Genomic Techniques', is more transparent, and should be adopted in place of NBTs.	KOT; GEFNZ; GEFTT; OANZ; Private individual OM	FSANZ has used the term 'New Breeding Techniques' since 2011 in all documents and consultations relating to proposal P1055. This term is commonly used and recognised internationally.
The terminologies used are plant focused – do the definitions also encompass microorganisms?	Novozymes; EUB	The terminologies used throughout the proposal and the draft variation are inclusive of plants, animals and microorganisms.

Viewpoint	Raised by	FSANZ Response
Other		
The proposed changes could undermine the brand identity of NZ by reducing its credibility as a safe and high-quality non-GMO producer, possibly impacting the market position and economic value of NZ. Some submitters also expressed the view that, by maintaining stringent regulations on NBT foods, Australia could increase its desirability as a source of natural, non-GM foods for export.	Campaign 4; MSC; OANZ; BPNZ; Ceres; Private Individuals	FSANZ notes these concerns. GM foods are already present in the food supply in both Australia and New Zealand. The changes to the definition for GM food as a result of P1055 will only affect food for sale, by clarifying which foods are GM foods for Code purposes and regulating NBT foods in a more risk-proportionate manner. The changes under P1055 will not affect New Zealand's agricultural production policies or its regulations on GM organism cultivation. These are currently under consideration via the New Zealand Gene Technology Bill. In Australia, where approved GM organisms are already able to be cultivated and sold for food, FSANZ considers that maintaining the *status quo*, where the status of NBT foods is unclear, would not be desirable from a trade perspective.
The proposal has failed to assess the risk to biosecurity, particularly for New Zealand. If the FSANZ claim of substantial equivalence were to be incorrect, the release of NBTs could present a threat to the provenance of related native species, or to the genetic integrity of key export crops.	PSGR	Biosecurity issues are outside of FSANZ's remit and are regulated by other regulatory regimes and agencies. The changes under P1055 will not affect the regulations on GM organism cultivation and the release of NBT organisms. This is a matter for the OGTR in Australia and EPA in New Zealand. FSANZ also notes that organisms modified through unguided repair of site-directed nucleases (SDN), also known as SDN-1, have been excluded from regulation as GMOs since 2019.[51]
FSANZ should require NBT developers to have commercial insurance coverage for potential unintended consequences and should verify its assessment of NBTs having negligible	AGEFC; GEFNZ; GEFTT	Noted. This issue does not fall within the scope of P1055.

[51] Overview of the status of gene edited organisms from the OGTR – https://www.ogtr.gov.au/resources/publications/overview-status-organisms-modified-using-gene-editing-and-other-new-technologies

Viewpoint	Raised by	FSANZ Response
risk with the insurance industry before proceeding with P1055.		
Expressed various concerns about patents and NBTs/GMOs.	AGEFC; GEFNZ; GEFTT; Private individual LT; PSGR; BPNZ; Agrownomics	FSANZ has previously addressed issues related to patents and NBT/GM foods. Please refer to the 2nd CFS Appendix 1, Table B (pages 62-63).

Appendix 2: Submitter suggestions for guidance material

The following tables list feedback from submitters on what information would be helpful to accompany the new definitions (Table A) and how this information should be presented in industry and jurisdiction guidance material (Table B).

Table A. Clarifying information to consider

GM food definition	The term 'derived from' is ambiguous and requires further clarification.
	Clarification of the terms '*cells*', '*cell-culture*', '*during cell-culture*' and '*process cells*'.
Novel DNA definition	'Crossed or hybridised' – additional guidance is required for developers and breeders on determining cross-compatibility.
	Clarification of the terms '*species*' and '*existing species'*.
	Further clarification on what is not 'novel DNA' and consideration of specific techniques (e.g. gene silencing, use of repair templates) or outcomes (replacing a promotor).
	Clarification on how the new definitions will apply to vegetatively propagated crops.
Application of definitions	Detailed criteria to enable applicants to assess their products.
	Detailed compliance requirements for exempted products.

Table B. Elements to consider

	Decision trees / flow charts, including the regulatory status of specific product categories
	FAQs
	Examples
	Case studies
	Explanatory text – for all new definitions, including 'novel DNA' and 'novel protein', 'null segregant', and 'line'

Attachments

A. Approved draft variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variations to the *Australia New Zealand Food Standards Code* (2nd call for submissions)

Attachment A – Approved 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 food that:

(a) is any of the following:

(i) an organism that contains *novel DNA;

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

(iii) cells that contain novel DNA;

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

(b) is not any of the following:

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

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

(iii) a substance used to:

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

(B) process cells during cell culture;

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

(v) 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*

(1) 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 one of the following:

(i) DNA from a species that is not a crossable species;

(ii) DNA that:

(A) is from a crossable species; and

(B) contains a coding region that was rearranged or recombined prior to the insertion referred to in paragraph (1)(a);

(iii) DNA that is not from an existing species.

(2) In this section, ***crossable species*** means a species of organism, cell or cells that can be crossed or hybridized with the species of organism, cell or cells referred to in paragraph (1)(a).

(3) Despite subsections (1) and (2), novel DNA does not include flanking left and right border sequences arising from *Agrobacterium*-mediated transformation.

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] Paragraph 1.2.1—9(3)(b)

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

[11] Paragraph 1.2.1—9(3)(ba)

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

[12] 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

[13] 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 1.3.3 – Processing aids

[14] Section 1.3.3—6 (Note 2)

Repeal Note 2.

Standard 1.5.2 – Food produced using gene technology

[15] Standard title

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

[16] 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.

[17] Section 1.5.2—1

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

[18] Section 1.5.2—2 (Notes 1 to 3)

Repeal the Notes, substitute:

Note 1 Section 1.1.2—16 (Definition of ***genetically modified food***) provides as follows:

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

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

Note 2 Section 1.1.2—17 (Definition of ***novel DNA***) provides as follows:

(1) 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 one of the following:
  - (i) DNA from a species that is not a crossable species;
  - (ii) DNA that:
    - (A) is from a crossable species; and
    - (B) contains a coding region that was rearranged or recombined prior to the insertion referred to in paragraph (1)(a);
  - (iii) DNA that is not from an existing species.

(2) In this section, ***crossable species*** means a species of organism, cell or cells that can be crossed or hybridized with the species of organism, cell or cells referred to in paragraph (1)(a).

(3) Despite subsections (1) and (2), novel DNA does not include flanking left and right border sequences arising from *Agrobacterium*-mediated transformation.

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.

[19] 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.

[20] 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

[21] Subparagraph 2.9.1—49(1)(c)(i)

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

Schedule 3 – Identity and purity

[22] Subsection S3—35(2)

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

[23] Subsection S3—35(2)

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

Schedule 18 – Processing aids

[24] Subsection S18—4(2) (Note 3)

Repeal the Note.

[25] Table to subsection S18—4(5)

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

[26] Table to subsection S18—9(3)

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

[27] Table to subsection S18—9(3)

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

[28] Table to subsection S18—9(3)

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

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

Repeal the Note.

Schedule 26 – Food produced using gene technology

[30] Standard title

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

[31] 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 section 1.5.2—3.

[32] Section S26—1

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

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

Repeal the definition.

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

Repeal the definition, substitute:

line means:

(a) an animal or plant that has genetic material which includes a transformation event or events; or

(b) an animal or plant that:

(i) is descended from an animal or plant described in paragraph (a); and

(ii) is the result of conventional breeding of that animal or plant with:

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

(B) 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; and

(iii) is not an animal or plant derived solely as a result of conventional breeding.

[35] **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.

[36] **Section S26—3 (title)**

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

[37] **Subsection S26—3(1)**

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

[38] **Subsection S26—3(4) (Table heading)**

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

[39] **Subsection S26—3(7) (Table heading)**

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

Attachment B – Explanatory Statement

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 and provide new defined terms that are 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 approved a draft variation – the *Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legistlation.gov.au).

This instrument is not 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 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 purpose of the approved draft variation is to amend definitions of terms used in the Code relating to genetic technologies and provide new defined terms that are clearer and better reflect existing and emerging genetic technologies including new breeding techniques. The approved draft variation also makes other amendments to the Code required as a consequence of the changes to the definitions.

4. Documents incorporated by reference

The approved 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 included 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. The second call for submissions (including the draft variation) was issued on 30 July 2024 and ended on 10 September 2024.

Targeted consultation with an Expert Advisory Group (EAG) 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.

Targeted consultation with government representatives was undertaken from April 2020 to March 2025.

Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

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) was prepared by the Authority and has been assessed by the OIA as compliant (OBPR22-03666).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to ‘the variation’ in this section are references to the approved 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 variation 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] to [3] of the Schedule to the variation amend Standard 1.1.1 of the Code. In particular:

Item [1] amends section 1.1.1—2 by omitting the term ‘Food produced using gene technology’ (wherever that term occurs in that section), and substituting the omitted term with ‘Genetically modified food’.

Item [2] amends section 1.1.1—10 by omitting ‘*food produced using gene technology’ (wherever that term occurs in that section), and substituting the omitted term with ‘*genetically modified food’.

An asterisk placed immediately before a term in the Code means that subsection 1.1.2—2(3) of the Code defines that term or refers to a provision of the Code that defines that term. See section 1.1.1—16 of the Code.

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

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

The effect of the amendments made by **Items [1]** - **[3]** is:

- 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), as defined by the new definition 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 variation amend Standard 1.1.2 of the Code. In particular:

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

Item [4] repeals the definition for ‘food produced using gene technology’ in the subsection.

Item [5] repeals the definition for ‘gene technology’ in the subsection.

Item [6] inserts the following new entry into the subsection:

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

Item [7] repeals the entry for 'novel food' in the subsection, and substitutes 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] adds two new provisions to Standard 1.1.2 after section 1.1.2—15, each of which sets out a new definition that applies throughout the Code. The new provisions are sections 1.1.2—16 and 1.1.2—17.

Section 1.1.2—16 sets out the new definition for 'genetically modified food'.

Subsection 1.1.2—16(1) provides that a reference in the Code to 'genetically modified food' means a food that:

(a) is any of the following:
  (i) an organism that contains novel DNA;
  (ii) food derived from an organism that contains novel DNA;
  (iii) cells that contain novel DNA;
  (iv) food derived from cells that contain novel DNA; and
(b) is not any of the following:
  (i) a substance used as a food additive;
  (ii) a substance used as a processing aid;
  (iii) a substance used to:
    (A) support the growth and viability of cells during cell culture; or
    (B) process cells during cell culture;
  (iv) food that is derived from part of a grafted plant, where that part does not contain novel DNA or novel protein;
  (v) 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' is defined in subsection 1.1.2—2(3) of the Code (see **item [7]** above).

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

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

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

Paragraph 1.1.2—16(1)(b) provides that the followings foods are not a 'genetically modified food' despite paragraph 1.1.2—16(1)(a):

- Food additives and processing aids. These substances are excluded as they 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 excluded as they 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. These foods are excluded as they are equivalent to food derived through conventional breeding approaches.
- Food derived from a null segregant. These foods are excluded as they are 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 make clear that a null segregant organism, cell or cells is not a GM food for the purposes of the Code. It has never been the intent to capture and regulate food from a null segregant organism, cell or cells as GM food under the Code.

The new definition of GM food in effect reframes the Code's regulatory approach to GM food, where food is now 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 previous 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 is likely to be achievable 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'.

The new definition sets out what types of DNA are 'novel DNA' for the purposes of the new definition for GM food (see above). The new definition is also relevant for the purposes of labelling (see **item [20]** below).

Subsection 1.1.2—17(1) provides that a reference in the Code to 'novel DNA' means DNA that:

(a) a person has inserted into the genome of an organism, cell or cells; and
(b) is one of the following:
    (i) DNA from a species that is not a crossable species;
    (ii) DNA that:
        (A) is from a crossable species; and
        (B) contains a coding region that was rearranged or recombined prior to

the insertion referred to in paragraph (1)(a);

(iii) DNA that is not from an existing species.

Subsection 1.1.2—17(2) defines 'crossable species' for the purposes of section 1.1.2—17 as meaning a species of organism, cell or cells that can be crossed or hybridized with the species of organism, cell or cells referred to in paragraph 1.1.2—17(1)(a).

Subsection 1.1.2—17(3) provides that, despite subsections 1.1.2—17(1) and 1.1.2—17(2), flanking left and right border DNA sequences arising from *Agrobacterium*-mediated transformation is not novel DNA for the purposes of the Code.

Paragraph 1.1.2—17(1)(a) provides that 'novel DNA' means DNA that, among other things, 'a person has inserted into the genome of an organism, cell or cells'. The paragraph's purpose is to ensure that foods in which the insertion of 'novel DNA' has occurred through a natural process, without any intervention by a person, are not captured and regulated as GM food by the Code. The paragraph will apply to and capture the insertion of 'novel DNA' through the use of automated process, as such processes would be under the control or direction of a person.

Paragraph 1.1.2—17(1)(b) provides that only certain categories or types of DNA will be 'novel DNA' if inserted by a person into the genome of an organism, cell or cells (as required by paragraph 1.1.2—17(1)(a)). That is -

- DNA that is from a species that is unrelated (i.e., not able to be crossed or hybridised) to the species from which food is derived.
- DNA that 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 the coding region (which may encode either a protein or other expressed product such as RNA) has been rearranged or recombined prior to insertion. Such rearrangement or recombination could involve a full coding region, part of a coding region or parts of multiple coding regions;
- DNA that is not from an existing species; for example, where the sequence of the DNA cannot be attributed to an existing species. This would include DNA that has been computationally designed de novo.

The intent of paragraph 1.1.2—17(1)(b) is to limit the scope of what constitutes GM food for Code purposes to foods that are not or would unlikely be produced using conventional breeding methods.

The intent of **subsection 1.1.2—17(3)** is to make it clear that residual left and right border sequences that flank the inserted DNA as a result of using *Agrobacterium*-mediated transformation are not novel DNA for Code purposes, despite being DNA from a non-crossable species. Such DNA is non-coding and does not pose any safety concerns.

The definition of 'novel DNA' provided by section 1.1.2—17 does not refer to or rely on any of the following:

- the genomic location of any inserted DNA;
- codon optimisation of the inserted DNA that does not alter the amino acid sequence of the expressed product.

Standard 1.2.1 – Requirements to have labels or otherwise provide information

Items [9] – **[12]** of the Schedule to the variation amends Standard 1.2.1 of the Code. In

particular:

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

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

Item [11] amends paragraph 1.2.1—9(3)(ba) by omitting the term 'foods produced using gene technology', and substituting the omitted term with 'genetically modified food'.

Item [12] amends paragraph 1.2.1—15(f) by omitting the term '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 subsection 1.1.2—2(3) of the Code defines that term or refers to a provision of the Code that defines that term. See section 1.1.1—16 of the Code.

The provisions in Standard 1.2.1 amended by **items [9]** – **[12]** 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.

The effect of the amendments made by **items [9] – [12]** is to apply the labelling and information requirements in Standard 1.2.1 to GM food as defined following the amendment made by **item [8]** above.

Standard 1.2.4 – Information requirements – statement of ingredients

Item [13] of the Schedule to the variation amends 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) includes a reference to section 1.5.2—4 (see **item [20]** 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 the following to be listed (in brackets) in a statement of ingredients: an ingredient of a compound ingredient if the compound 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.

The effect of the amendment in **item [13]** is that a GM ingredient of a compound ingredient is also required to be listed in accordance with section 1.5.2—4, if the compound ingredient comprises less than 5% of the food for sale.

Standard 1.3.3 – Processing aids

Item [14] of the Schedule to the variation amends Standard 1.3.3 of the Code by repealing Note 2 to paragraph 1.3.3—6.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

The effect of the amendment in **item [14]** is to remove reference to protein engineered enzymes that are used as food processing aids. The note previously explained requirements for these enzymes in relation to food produced using gene technology, and will no longer be required given the exclusion of substances used as a processing aid from the new definition for GM food in **item [8]** above.

Standard 1.5.2 – Food produced using gene technology

Items [15] – **[20]** of the Schedule to the variation amend Standard 1.5.2 of the Code. In particular:

Item [15] amends the title of Standard 1.5.2 by omitting the term 'Food produced using gene technology' from the title and substituting the omitted term with 'Genetically modified food'.

The effect of this amendment is to rename the Standard as Standard 1.5.2 – Genetically modified food.

Item [16] amends 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 Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New Note 3 identifies the following for 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 in **items [15]** and **[16]** are consequential to amendments to definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [33]** – **[35]** below.

Item [17] amends section 1.5.2—1 by omitting the term '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 [15]** above.

Item [18] amends Notes 1 - 3 in section 1.5.2—2 by repealing those Notes and substituting them with new Notes 1 - 4.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New Note 1 sets out a copy of the definitions of GM food and 'null segregant' in 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 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 in **item [18]** are consequential to amendments to definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [33]** – **[35]** below.

Item [19] amends 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 subsection 1.1.2—2(3) of the Code defines that term or refers to a provision of the Code that defines that term. See section 1.1.2—16 of the Code.

This amendment:

- removes 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 are specifically excluded from the new definition for GM food in **item [8]** above;

- substitutes the term ‘food produced using gene technology’ with ‘genetically modified food’.

The overall effect of this amendment is 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 [20] amends 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 as a consequence of the amendments to the definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [33]** – **[35]** below.

The new definition of GM food is explained above, 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. The subsection provides that 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).

A GM food is listed in section S26—3 if and when the Authority determines during pre-market assessment of that food 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. The new subsection provides that, 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 labelling provisions in Standard 1.2.1 will require this information to appear or 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.

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 Code are not legally binding for the Code. Instead, their purpose is simply to identify or 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*'.

The aim of this amendment is to:

- simplify and clarify the current labelling provisions under the 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 are specifically excluded from the new definition for GM food 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 are redundant as a consequence of the amendments to definitions 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 1.1.2—11 and 1.1.2—13 of the Code respectively.

Standard 2.9.1 – Infant formula products

Item [21] of the Schedule to the variation amends Standard 2.9.1 of the Code by omitting ‘*foods produced using gene technology’ from subparagraph 2.9.1—49(1)(c)(i), 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.

The effect of the amendment is 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 in **items [4]** – **[8]** above.

The intent of this amendment is to ensure that labelling requirements applying to GM food apply, where relevant, to special medical purpose products for infants.

Schedule 3 – Identity and purity

Items [22] and **[23]** of the Schedule to the variation amend Schedule 3 of the Code. In particular:

Item [22] amends subsection S3—35(2) by omitting ‘protein engineered enzymes’ (wherever occurring) from the subsection, and substituting the omitted term with ‘enzymes’.

Item [23] amends subsection S3—35(2) by omitting ‘a protein engineered enzyme’ (wherever occurring) from the subsection, and substituting the omitted term with ‘an enzyme’

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

The effect of the amendments set out in **items [22]** and **[23]** is to remove references to ‘protein engineered’ from Schedule 3 as this term is redundant given the exclusion of substances used as a processing aid from the new definition for GM food 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 are specifically excluded from the GM food definition, labelling requirements for GM food would no longer apply to processing aids. Consequently, the term ‘protein engineered’ will no longer serve a purpose in the Code.

Schedule 18 – Processing aids

Items [24] – **[29]** of the Schedule to the variation amend Schedule 18 of the Code. In particular:

Item [24] amends Note 3 to subsection S18—4(2) by repealing the Note.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

Note 3 to subsection S18—4(2) relates to protein engineered variants of enzymes, which are

identified in sections 1.3.3—6 and 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 [25] amends the table to subsection S18—4(5) by omitting ‘, protein engineered variant’ (wherever occurring) from the table.

Item [26] amends the table to subsection S18—9(3) by omitting ‘, protein engineered variant,’ (wherever occurring) from the table.

Item [27] amends the table to subsection S18—9(3) by omitting ‘Protein engineered enzyme’ (wherever occurring) from the table, and substituting the omitted term with ‘Enzyme’

Item [28] amends the table to subsection S18—9(3) by omitting ‘Protein engineered enzymes’ from the table, and substituting the omitted term with ‘Enzymes’.

Item [29] amends the Note to the table to subsection S18—9(3) by repealing the Note.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or 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.

The effect of the amendments in **items [24]** – **[29]** is to remove terms in Schedule 18 which include references to ‘protein engineered’ because the term ‘protein engineered’ will become redundant given the exclusion of substances used as a processing aid from the new definition of GM food 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 are specifically excluded from the GM food definition, labelling requirements for GM food will no longer apply to processing aids. Consequently, the term ‘protein engineered’ will no longer serve a purpose in the Code.

Schedule 26 – Food produced using gene technology

Items [30] – **[39]** of the Schedule to the variation amend Schedule 26 of the Code. In particular:

Item [30] amends 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 [31] amends Note 1 to the title of Schedule 26 by repealing the Note, and substituting it with a new Note 1.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New Note 1 explains 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 section 1.5.2—3 of the Code (for an explanation of new section 1.5.2—3, see **item [19]** above).

Item [32] amends 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 in **items [30]** – **[32]** above are consequential to the amendments to definitions of terms used in the Code relating to genetic technologies in **items [4]** – **[8]** above.

The intent of the amendments in **items [30]** – [**32]** 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 will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.

Item [33] amends subsection S26—2(2) by repealing the definition for 'conventional breeding' in the subsection.

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

Item [34] amends subsection S26—2(2) by repealing the definition for 'line' in the subsection, and substituting it with a new definition for 'line'.

The new definition provides that a reference in Schedule 26 to 'line' means:

'(a) an animal or plant that has genetic material which includes a transformation event or events; or

(b) an animal or plant that:

(i) is descended from an animal or plant described in paragraph (a); and

(ii) is the result of conventional breeding of that animal or plant with:

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

(B) 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; and

(iii) is not an animal or plant derived solely as a result of conventional breeding.'

The effect of the new definition for 'line' is to broaden its scope to both plants and animals. The existing definition for 'line' refers only to plants.

Item [35] amends 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 amendment is remove reference to ‘gene technology’, and refer instead to ‘novel DNA’, to be consistent with the new definition for GM food in **item [8]** above. The term ‘gene technology’ will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.

Item [36] amends 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 [37] amends subsection S26—3(1) by omitting ‘food produced using gene technology’ from the subsection, and substituting the omitted term with ‘genetically modified food’.

Item [38] amends 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’.

Item [39] amends the heading of the table to subsection S26—3(7) by omitting ‘Food produced using gene technology’ from the heading, and substituting the omitted term with ‘Genetically modified food’.

The effect of the amendments set out in **items [36]** – [**39]** will be that these provisions refer to GM food instead of ‘food produced using gene technology’, as the latter term will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.

Attachment C – Draft variations to the Australia New Zealand Food Standards Code (2nd call for submissions)

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:

(b) 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.
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.

Column 1	***Column 2***	***Column 3***
Substance	*Source*	*Conditions of use*
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.