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Call for submissions – Application A1233

2'-FL from new GM source for infant formula

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Friesland Campina Ingredients, seeking to permit the sale and use of 2'-fucosyllactose (2'-FL) derived from a new genetically modified *Escherichia coli* (E.coli) strain as a nutritive substance in infant formula products. A draft regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website and see [information for submitters](#).

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 31 January 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

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Supporting document

The following document¹ which informed the assessment of this application is available on the FSANZ website:

Supporting document¹ Food technology and safety assessment – Application A1233. 2'-FL from new GM source for infant formula.

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application by Friesland Campina Ingredients (the Applicant) to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of 2'-fucosyllactose ²(2'-FL) derived from a genetically modified *Escherichia coli* (*E.coli*) strain as a nutritive substance in infant formula products (IFP), i.e. infant formula, follow-on formula and infant formula products for special

² Also known as 2'-O-fucosyllactose

dietary use. The application also requested an amendment to Schedule 3 of the Code to reference or include a specification published by the European Union for this 2'-FL.

The Code already permits the addition of 2'-FL as a nutritive substance to IFP. However, this permission does not apply to the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* which has a different genetically modified source organism and specifications. The application therefore seeks to amend Schedule 26 to permit this alternative genetically modified source organism (*E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* strain E997) for the production of 2'-FL by fermentation under the brand name 'Aequival® 2'-FL'.

2'-FL derived from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is chemically and structurally identical to 2'-FL isolated from human milk. Stability studies demonstrate that the final product is suited for food uses. The Applicant proposed specifications based on those already in force in the European Union (EU) since 2019 (2019 EU specifications) and submitted data that demonstrates the final product is within these specifications.

FSANZ found no safety concerns with the microbe assessed. *E. coli* K-12 has a long history of use to produce recombinant proteins and does not pose a risk to humans. Analyses of the gene donors and the genetically modified production strain also confirmed there are no safety concerns.

FSANZ previously found no safety concerns associated with the addition of 2'-FL to IFP at concentrations within the range of naturally occurring levels in human milk. Newly available information did not change this conclusion. In addition, 2'-FL is unlikely to pose allergen concerns because the protein content of the 2'-FL product is below the limit of quantitation.

FSANZ's previous assessments also found no evidence of a nutritional concern at concentrations typically observed in human milk. No new information was provided that would indicate a need to change these conclusions.

The evidence for a beneficial role of 2'-FL in the normal growth and development of infants will be reassessed in a review to be completed by March 2026.

FSANZ concludes that direct and indirect benefits from accepting the application most likely outweigh the associated costs. After assessing the application, and for the reasons stated in this report, FSANZ has prepared a draft variation to the Code to permit the voluntary addition of 2'-FL derived from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to IFP. If approved, the draft variation would provide a permission for 2'-FL from *E. coli* K12 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* without specifying the strain. This approach will provide greater flexibility in terms of strain improvement and is consistent with current permissions in the Code. That permission would be subject to relevant requirements and conditions in Code, which include the following:

- Aequival® 2'-FL may be added alone or in combination with lacto-N-neotetraose up to a maximum level of 2.4 g/L in powder or liquid form
- maintain existing prohibition for the use of 2'-FL with galacto-oligosaccharide and inulin-type fructans
- maintain existing prohibition for the use of the words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO', or any word or words or abbreviations having the same or similar effect
- grant exclusive use permission for 15 months, linked to the brand name 'Aequival® 2'-FL'

- set a specification for 2'-FL derived from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* (this specification is consistent with the 2019 EU specifications).

1 Introduction

1.1 The Applicant

On 1 June 2021, Friesland Campina Ingredients (the Applicant) applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of 2'-fucosyllactose (2'-FL)³ derived from a genetically modified *Escherichia coli* (*E.coli*) strain as a nutritive substance in Infant Formula Products (IFP)⁴.

Friesland Campina supplies consumer products, products for the professional market, ingredients and semi-finished products for manufacturers of infant nutrition, the food industry and the pharmaceutical sector.

1.2 The application

The application seeks to amend Schedule 26 of the Code to provide permission for the sale and use of 2'-FL from *E. coli* K-12 strain E997 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* as a nutritive substance in IFP; and amend Schedule 3 of the Code to reference or include a specification published by the European Union (EU). The relevant specifications for 2'-FL from *E. coli* K-12 are set out in the first column of the table in the annex to the Commission Implementing Regulation (EU) 2019/388⁵.

Schedule S29—5 already contains a permission for the addition of 2'-FL as a nutritive substance to IFP. However, Schedule 26 of the Code does not currently list the Applicant's genetically modified organism (*E. coli* K-12 strain containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*) as a permitted source organism for the production of 2'-FL by fermentation.

1.3 The current standards

1.3.1 Australia and New Zealand Food Standards Code

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1.1 Permitted use

Paragraphs 1.1.1—10(5)(c) and (6)(g) of Standard 1.1.1 require that, unless expressly permitted, a food for sale must not be a *food produced using gene technology*, or have as an ingredient or component a *food produced using gene technology*.

2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is *food produced using gene technology* (section 1.1.2—2) as it is derived from an organism modified using gene technology (i.e. derived from genetically modified (GM) *E.coli* strains). If approved, express permission for the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*

³ also referred to as 2'-O-fucosyllactose

⁴ 'Infant formula products' refers to infant formula, follow-on formula and infant formula products for special dietary use.

⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019R0388&from=EN#ntr5-L_2019070EN.01002101-E0005

is required in accordance with Standard 1.5.2 (i.e. if it is listed in Schedule 26 and complies with any corresponding conditions).

In addition, paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance* (section 1.1.2—12). 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is *used as a nutritive substance* because its addition to food is intended to achieve specific nutritional purposes. 2'-FL is permitted to be *used as a nutritive substance* in accordance with Standard 2.9.1 (i.e. if it is listed in the table to section S29—5; and is in a permitted form at up to the maximum amount per 100 kJ specified in that table). Section S29—5 permits the use of 2'-FL as a nutritive substance in accordance with Standard 1.5.2 (i.e. if it is listed in the table to section S26—3; and complies with any corresponding conditions listed in that Schedule).

1.3.1.2 Identity and purity

Section 1.1.1—15 requires that a substance that is *used as a nutritive substance* must comply with any relevant identity and purity specification set out in Schedule 3. The application provided a proposed specification for the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* for this purpose.

1.3.1.3 Infant formula products

The composition of infant formula is regulated in Standard 2.9.1 and Schedule 29. This standard (and associated schedule) sets out specific compositional and labelling requirements for the following IFP:

- infant formula (for infants aged 0 to <12 months)
- follow-on formula (for infants aged from 6 to <12 months)
- infant formula products for special dietary use (for infants aged 0 to <12 months)

1.3.1.4 Labelling requirements

Paragraph 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food. In addition to specific labelling requirements in Standards 2.9.1 and 2.9.3 (Division 4), the following general labelling requirements also apply.

Standard 1.2.4 generally requires food products to be labelled with a statement of ingredients.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food. Paragraph 1.2.7—4(b) states a nutrition content claim or health claim must not be made about an IFP.

Standard 1.2.8 generally requires food products to be labelled with nutrition information. This Standard does not apply to IFP (specific nutrition labelling requirements are set out in Standard 2.9.1).

Section 1.5.2—4 sets out labelling requirements for foods for sale that consist of, or have as an ingredient, food that is a *genetically modified food*. A *genetically modified food* is defined in subsection 1.5.2—4(5) as a *food produced using gene technology* that contains novel DNA or novel protein; or is listed in section S26—3 as subject to the condition that its

labelling must comply with section 1.5.2—4.

Standard 2.9.1 sets out the specific requirements for declaring nutrition information and includes provisions for prohibited representations on IFP labels.

1.3.1.5 Current oligosaccharide permissions and restrictions

The ingredient under assessment is a non-digestible oligosaccharide. This section summarises the current permissions and restrictions in the Code relating to oligosaccharides.

The Code currently regulates the addition of galacto-oligosaccharides (GOS) and inulin-type fructans (ITF) (both are defined in subsection 1.1.2—2) to IFP (see section 2.9.1—7). GOS and ITF are also permitted in general foods by their specific exclusion from the definition of *used as a nutritive substance* in section 1.1.2—12 and general provisions in section 1.1.1—10. ITF includes substances such as fructo-oligosaccharides (FOS), short-chain FOS (scFOS), oligofructose and inulin (FSANZ 2013). Unlike 2'-FL, ITF are not present in human milk and GOS is found only in trace amounts (FSANZ 2008).

For IFP, section 2.9.1—7 sets out restrictions on the addition of ITF and GOS to IFP. Subsection 2.9.1—7(1) permits the addition of ITF alone (up to 110 mg/100 kJ), GOS alone (up to 290 mg/100 kJ), or ITF and GOS combined (up to 290 mg/100 kJ, with no more than 110 mg/kJ of ITF). These amounts were converted to the respective mg/100 kJ units for Code purposes from 8 g/L of GOS (alone or combined with ITF) and 3 g/L of ITF. Subsection 2.9.1—7(2) prohibits the use of ITF and/or GOS in IFP with 2'-FL either alone; or in combination with lacto-N-neotetraose (LNnT).

1.3.2 Regulation in other countries

1.3.2.1 2'-FL

2'-FL produced by microbial fermentation and by chemical synthesis is permitted for use in IFP equivalent products and many other foods in at least 37 overseas countries at a range of levels. Table 1 outlines some international permissions for 2'-FL alone. When permitted for use with LNnT, these levels are reduced.

Table 1: International permissions for use of 2'-FL in infant formula*

Country	Max. use level (g/L)
United States	2.4
Canada [#]	1.2
Singapore	1.2
European Union (EU)	1.2
Israel	2.0
Korea	2.0
Philippines	1.2

Notes to table:

*Infant formula categories vary between countries

[#] Permission as novel food with support for use in infant formula

Labelling permissions and restrictions differ across countries. Some specify the terminology that must be used for the ingredients on labels while others do not. Some countries permit claims on IFP while other countries do not.

The current Codex Alimentarius Standards for Infant Formula and Formulas for Special

Medical Purposes Intended for Infants ([Codex Standard 72-1981](#)) and for Follow-up Formula⁶ ([Codex Standard 156-1987](#)) do not contain specific provisions for 2'-FL. However, the standards contain provisions for 'optional ingredients' which would apply to the addition of substances such as 2'-FL. FSANZ notes that the Follow-up Formula Standard is currently under review⁷.

1.3.2.2 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*

2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* has received European Union novel food approval.

The Novel Foods Unit (Ministry for Medical Care, Netherlands) has determined that the 2'-FL produced through fermentation with *E. coli* K-12 strain E997 by Friesland Campina is substantially equivalent to a synthetic 2'-FL previously authorised in the European Union (EFSA 2015)⁸.

In the USA, the Food and Drug Administration (FDA) has responded with 'no questions' to the Applicant's self-assessment that 2'-FL produced using *E. coli* K-12 strain E997 is Generally Recognized As Safe (GRAS).⁹

1.3.3 Specifications in the EU

The Commission Implementing Decision (EU) 2017/2201 authorised the use of 2'-FL produced with *E. coli* strain BL21 as a novel food ingredient. Commission Implementing Regulation (EU) 2019/388 of 11 March 2019 authorised a change of the specifications for 2'-FL produced with *E. coli* K-12, the same source that is the subject of this application. The new specifications are provided in a table in the annex of the regulation. Separate specifications for 2'-FL produced with *E. coli* strain BL21 are set out in the same annex.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Food technology and safety assessment

The Code already permits 2'-FL from a different source organism for addition to IFP. The maximum permitted level is 96 mg/100 kJ, equivalent to 2.4 g/L. The purpose of the present assessment is therefore to assess the safety of 2'-FL produced using *E. coli* K-12 containing

⁶ 'Follow-up Formula' is currently defined by Codex as a *food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children* (12-36 months).

⁷ Currently under review by CCNFSDU. For further information, search on the [Codex Alimentarius website](#).

⁸ Commission Implementing Regulation (EU) 2017/2470 [EUR-Lex - 32017R2470 - EN - EUR-Lex \(europa.eu\)](#)

⁹ GRAS Notice (GRN) No. 735 <https://www.fda.gov/media/115365/download>

the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is chemically and structurally identical to the naturally occurring substance isolated from human milk. Stability studies conducted by the Applicant demonstrated that the final product is suited for the intended food uses. The Applicant has proposed specifications for Schedule 3 of the Code, based on those established in the EU. Multi-batch analyses showed that the final product is consistently within the proposed specifications, with impurities and/or contaminants resulting from the fermentation process either minor or absent.

E. coli K-12 has a long history of use for the production of recombinant proteins and does not pose a risk to humans. Analyses of the gene donors also confirmed there were no safety concerns. Characterisation of the production strain confirmed the expression plasmid carrying the α -1,2-fucosyltransferase gene was both genetically stable and fully functional.

FSANZ has previously determined that there are no safety concerns associated with the addition of 2'-FL to IFP at concentrations up to 2.4 g/L, which is within the range of naturally occurring levels in human milk from the majority of women (0.6 – 7.8 g/L). Newly available information relating to previously assessed studies of 2'-FL produced by the Applicant and another manufacturer did not indicate a reason to change this conclusion.

2'-FL was not genotoxic *in vitro* or *in vivo*. No adverse effects were observed in multiple subchronic oral toxicity studies in neonatal rats at doses up to 5000 mg/kg bw/day, or in juvenile and adult rats at doses > 7000 mg/kg bw/day. Three-week studies with neonatal piglets administered formula containing 2'-FL at concentrations up to 4 g/L also found no adverse effects. In human studies, infant formula supplemented with 2'-FL was well tolerated with no significant increases in adverse events. 2'-FL was also well tolerated in studies with children and adults. The proposed specification does not raise any safety concerns.

2'-FL is unlikely to pose an allergenicity concern because the protein content of the 2'-FL product is below the limit of quantitation.

FSANZ's previous assessments of 2'-FL found no evidence of a nutritional concern at concentrations typically observed in human milk. No new information was provided that would indicate a need to change these conclusions. The evidence for a beneficial role of 2'-FL in the normal growth and development of infants will be reassessed in a review to be completed by March 2026.

3 Risk management

Breastfeeding is the recommended way to feed infants. As infants are a vulnerable population group, a safe and nutritious substitute is necessary when breastfeeding is not possible. Before a change in the composition of IFP is permitted, there must be evidence that the change would not pose a risk to the health and safety of consumers of these products, in this case, infants.

3.1 Proposed regulatory approval

The *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology'. FSANZ is proposing to list *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* in the table to subsection S26—3(4).

If the draft variation is approved, the express permission for *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* would provide the permission for its presence in food for sale as a food produced using gene technology.

Application A1233 requested an amendment to the Code to provide a permission for 2'-FL from *E. coli* K12 strain E997 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*. Such a permission, if granted, would be specific to strain E997 only. This in turn would mean a new application would be required each and every time a permission in the Code for 2'-FL derived from any different or new strain was required.

For this reason, the draft variation prepared by FSANZ instead provides a permission for 2'-FL from *E. coli* K12 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* but without specifying the strain. This approach will provide greater flexibility in terms of strain improvement and avoid the need for new applications to be lodged to provide permissions for new strains. The approach is also consistent with current permissions in the Code.

Given 2'-FL from *E. coli* K12 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is proposed to be permitted as a *food produced using gene technology*, and noting the Applicant has not requested any changes to current permissions in the Code for 2'-FL, FSANZ considers that, if the draft variation is approved, 2'-FL from *E. coli* K12 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* would meet requirements under Standard 2.9.1 and Schedule 29 to be used as a *substance used for a nutritive purpose* at the permitted level of 96 mg/100 kJ in IFP. Also, if the draft variation is approved, this 2'-FL would have to comply with the specification outlined in the draft variation in Attachment A.

3.2 Exclusivity

An Applicant may request exclusive permission to use and sell a food (including a substance) for a certain period of time to recognise the investment made in developing the food or ingredient or nutritive substance and the need to achieve return on this investment, thereby supporting innovation. The Applicant has requested an exclusive use permission for their specific brand of 2'-FL on the basis that they have invested significantly in the technology development and safety studies.

FSANZ decided to provide the Applicant with a 15 month exclusive use permission for the 2'-FL produced by fermentation and sourced from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, commencing on the date of gazettal of the approved draft variation.

This means that, during that 15 month period, the permission for this 2'-FL would apply exclusively to this substance under the brand 'Aequival® 2'-FL' in accordance with the Code.

Once the 15 month period ends, the exclusive use permission would revert to a general permission, meaning that the permission would apply to all brands of 2'-FL produced by fermentation and sourced from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, in accordance with the Code.

An exclusive use permission in the Code does not, and cannot, prevent approval of second or subsequent applications either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken.

3.2 The five year review for 2'-FL and LNnT in Infant Formula Products.

FSANZ acknowledges Food Ministers agreed to permit 2'-FL alone or in combination with Lacto-N-neotetraose (LNnT) under the condition that a five year review (dated from gazettal, Friday 26 March 2021¹⁰) of the initial permission (see Application A1155 - 2'-FL and Lacto-N-neotetraose (LNnT) in infant formula and other products) be undertaken by FSANZ.

3.3 Labelling

3.3.1 Statement of ingredients

Standard 1.2.4 requires food for sale to be labelled with a statement of ingredients unless exempt. The label on a package of IFP must contain a statement of ingredients. Should manufacturers choose to add the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* alone or combined with LNnT to IFP, then this substance must be declared in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require ingredients to be identified using a name by which they are commonly known, or a name that describes its true nature, or a generic ingredient name if one is specified in Schedule 10 *Generic names of ingredients and conditions for their use*.

Noting the existing prohibited representations in paragraphs 2.9.1—24(1)(ca) and (cb) (refer to section 3.2.3 of this report below), these existing ingredient naming requirements would apply to 2'-FL, enabling industry to have flexibility in how they declare this ingredient (for example, using the scientific name '2'-fucosyllactose').

3.3.2 Mandatory nutrition information

Section 2.9.1—21 regulates the declaration of nutrition information in a nutrition information statement (NIS) on the label of IFP. The NIS is a single statement and may be in the form of a table, as indicated in section S29—10 *Guidelines for Infant Formula Products*.

Subparagraph 2.9.1—21(1)(a)(iii) requires the average amount of any substance used as a nutritive substance permitted by the standard to be declared in the NIS. The specific 2'-FL in this application would need to be declared in the NIS when it is voluntarily added to a IFP.

3.3.3 Prohibited representations

Paragraph 2.9.1—24(1)(ca) prohibits the use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect. In addition, paragraph 2.9.1—24(1)(cb) prohibits the use of the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect. The words and abbreviations in these provisions cannot be used anywhere on the label of a package of IFP. The 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* would be subject to these provisions regarding prohibited representations.

¹⁰Amendment No. 198, No. FSC 139, <https://www.foodstandards.gov.au/code/changes/gazette/Pages/Amendment-No.198---26-March-2021.aspx>

3.3.4 Voluntary representations

Paragraph 1.2.7—4(b) of Standard 1.2.7 states that a nutrition content or health claim must not be made about an IFP. Paragraph 2.9.1—24(1)(f) of Standard 2.9.1 also prohibits a reference to the presence of a nutrient or substance that may be used as a nutritive substance, except for a reference in: a statement relating to lactose under subsection 2.9.1—14(6), a statement of ingredients, or in the NIS. These existing prohibitions for nutrition content and health claims for IFP would apply to 2'-FL.

3.3.5 Labelling as 'genetically modified'

As discussed in Supporting Document 1, the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is highly unlikely to contain novel protein or DNA due to the purification step used in the production of this oligosaccharide. It is therefore highly unlikely that novel protein or novel DNA will be present in an IFP that contains this 2'-FL as an ingredient. However, where novel protein or novel DNA is present, the requirement to label 2'-FL as 'genetically modified' would apply in accordance with section 1.5.2—4 of Standard 1.5.2.

3.4 Risk management conclusion

Having considered and weighed all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines and current permissions for 2'-FL in the Code, FSANZ is proposing to approve a draft variation to the Code to permit the voluntary addition of 2'-FL from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to IFP.

If the draft variation is approved, the addition of 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to IFP will be subject to relevant requirements and conditions in the Code, which include the following:

- It may be added alone or in combination with LNnT up to a maximum level of 2.4 g/L for 2'-FL, as consumed.
- The existing prohibition for the use of 2'-FL with GOS and ITF would apply to IFP that contain the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.
- The existing prohibition for the use of the words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO' or any word or words or abbreviations having the same or similar effect, will apply to IFP that contain the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.
- An exclusive permission to use 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* will apply for a period of 15 months, linked to the Applicant's brand name 'Aequival® 2'-FL', commencing on the date of gazettal of the approved draft variation.
- Schedule 3 of the Code will set a specific specification based on the current EU specification for 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, with which this 2'-FL must comply.

The draft variation reflecting this option is at Attachment A. The draft explanatory statement for the variation is in Attachment B.

The draft variation is based on and reflects the draft variation recently approved by FSANZ as a result of another 2'-FL related application (i.e., Application A1190 – 2'-FL in infant

formula and other products). That approved draft variation has recently been approved by the FSANZ and provides a permission to add 2'-FL from a different source organism to infant formula, and sets a new specification for that 2'-FL. The Food Ministers Meeting has yet to consider the A1190 approved draft variation. It will do so after the release of this Call for Submissions. The assessment and draft variation prepared by for this application A1233 is therefore subject to the Food Ministers Meeting endorsement of the A1190 approved draft variation.

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received on this call for submissions.

The Applicant and individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

4.2 World Trade Organization (WTO)

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

There are relevant overseas standards and amending the Code to permit the voluntary addition of 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to IFP as proposed is unlikely to have a significant effect on international trade as this substance is already permitted in similar products in some countries overseas. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

5 FSANZ Act assessment requirements

5.1 Section 29

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for permitting genetically modified foods (OBPR correspondence dated 24 November 2010, reference 12065) and for

the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers permitting the genetically modified source organism, *E. coli* K-12, for the production of 2'-FL by fermentation. FSANZ is of the view that no other realistic food regulatory measures exist, however information received during public consultation may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of permitting the new genetically modified source organism, *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, for the production of 2'-FL, a beneficial human milk oligosaccharide, for addition to IFP.

Due to the voluntary nature of the permission, industry will use the *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* as the source organism for the production of 2'-FL where they believe a net benefit exists for them. This 2'-FL is a nutritive substance and it is already available to industry from a different source. It may benefit industry to have this additional way of sourcing 2'-FL for addition to IFP, especially where it saves on costs. This would increase competition in the manufacturing processes. A potentially greater supply and lower cost of 2'-FL from this proposed permission could also help IFP exporters that want to use 2'-FL in their products to compete internationally. Costs of producing and purchasing IFP might then reduce and availability might increase, potentially benefitting both industry and consumers.

Industry may pass some of the cost savings to consumers where it is cheaper to source 2'-FL from genetically modified *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

Permitting this additional source organism for the production of 2'-FL may result in a small but likely inconsequential cost to government in terms of compliance monitoring for an additional source micro-organism.

This application will align Australian and New Zealand with the USA and the European Union, which both permit the addition of 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to food products.

Permitting further sources of 2'-FL (beyond current permissions) could encourage product innovation that could be enabled by greater supply and lower price of 2'-FL, and offer potential export opportunities for Australia and New Zealand. That is because overseas producers of IFP can access multiple brands of 2'-FL than are currently permitted in Australia and New Zealand. Permitting this application would improve harmonisation with international regulations by allowing additional sources of 2'-FL onto the market.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting genetically modified *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, as the microbial source for the production of 2'-FL as a nutritive food substance most likely outweigh the associated costs.

5.1.2 Other measures

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

5.1.2.1 Any relevant New Zealand standards

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

5.1.2.2 Any other relevant matters

Other relevant matters are considered below.

5.2 Subsection 18(1)

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

5.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in section 2 of this report. Previous assessments found no safety concerns associated with the addition of 2'-FL to IFP. New information provided did not change this conclusion.

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

Current labelling requirements discussed in section 3.3 would apply to the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* when added to IFP and would provide information to enable consumers to make an informed choice.

5.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 3.2.3, which aim to prevent misleading or deceptive conduct, would apply to the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* when added to IFP.

5.3 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 used the risk analysis framework and considered the best available evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the 2'-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

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

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. 2'-FL is permitted in IFP equivalent products; and several other foods across various countries around the world. Permissions are for use alone or in combination with LNnT; including at a range of levels and with country-specific labelling requirements.

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

The proposed permission would support an internationally competitive food industry in relation to the addition of 2'-FL to IFP, and is consistent with existing permissions in the Code for 2'-FL.

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

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting¹¹**

As part of A1233, FSANZ has had regard to both high order and specific policy principles in the following Ministerial Policy Guidelines for the Regulation of Infant Formula Products.

- Regulation of Infant Formula Products
- Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods

FSANZ considers that through the proposed permission for 2'-FL to be added to Infant Formula Products, policy guidelines have been met.

6 Draft variation

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

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

7 References

ESFA 2015 Safety of 2'-O-fucosyllactose as a novel food ingredient pursuant to Regulation (EC) No 258/97 *EFSA Journal* 13(7) 4184

FSANZ (2008) Proposal P306, Final Assessment Report, Addition of Inulin/FOS & GOS to

¹¹ Formerly known as the Australia and New Zealand Ministerial Forum on Food Regulation

Food. Food Standards Australia New Zealand.

FSANZ (2013) Application A1055, Approval Report, Short Chain Fructo-oligosaccharides.
Food Standards Australia New Zealand.

Attachments

- A. [Draft variation to the Australia New Zealand Food Standards Code](#)
- B. [Draft Explanatory Statement](#)

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



Food Standards (Application A1233 – 2'FL from a new GM source for infant formula) Variation

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]

[Delegate's name and position]

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 (Application A1233 – 2'-FL from new GM source for infant formula) 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

Schedule 3—Identity and Purity

[1] Subsection S3—2(2) (table item dealing with the substance 2'-fucosyllactose sourced from *Escherichia coli* K-12)

Repeal the item, substitute:

2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori* section S3—40

[2] Subsection S3—2(2) (table)

Insert:

2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* section S3—46

[3] Section S3—40 (heading)

Repeal the heading, substitute:

S3—40 Specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*

[4] Section S3—40 (the phrase “For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12”)

Omit the phrase, substitute:

“For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*”

[5] After section S3—45

Insert:

S3—46 Specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*

For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, the specifications are the following:

- (a) chemical name—alpha-L-fucopyranosyl-(1→2)-beta-D-galactopyranosyl-(1→4)-D-glucopyranose;
- (b) chemical formula—C₁₈H₃₂O₁₅;
- (c) molecular weight—488.44 g/mol;
- (d) CAS number—41263-94-9;
- (e) description— white to off-white powder
- (f) 2'-FL—not less than 83%;
- (g) D-lactose—not more than 10.0%;

- (h) L-fucose—not more than 2.0%;
- (i) difucosyl-D-lactose—not more than 5.0 %;
- (j) 2'-fucosyl-D-lactulose—not more than 1.5 %;
- (k) sum of saccharides (2'-FL, D-lactose, L-fucose, difucosyl-D-lactose, 2'-fucosyl-D-lactulose)—not less than 90%;
- (l) pH (20°C, 5% solution)—3.0-7.5;
- (m) water—not more than 9.0%;
- (n) ash, sulphated—not more than 2.0%;
- (o) acetic acid—not more than 1.0%;
- (p) residual proteins—not more than 0.01%;
- (q) microbiological:
 - (i) aerobic mesophilic bacteria total count—not more than 3,000 cfu/g;
 - (ii) yeasts—not more than 100 cfu/g;
 - (iii) moulds—not more than 100 cfu/g;
 - (iv) endotoxins—not more than 10 EU/mg.

Schedule 26—Food produced using gene technology

[6] Subsection S26—3(7) (table item 1)

Repeal the item, substitute:

- | | | |
|-----------------------------------|--|---|
| <p>1 2'-fucosyllactose</p> | <p>(a) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i></p> | <ol style="list-style-type: none"> 1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare. 3. For the purposes of condition 2 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date. |
| | <p>(b) <i>Escherichia coli</i> BL21 containing the gene for alpha-1,2-fucosyltransferase from <i>Escherichia coli</i> O126</p> | <ol style="list-style-type: none"> 1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand CHR. HANSEN™ 2'-FL. 3. For the purposes of condition 2 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1190 – 2'-FL in infant formula and other products) Variation</i> and ending 15 months after that date. |

(c) *Escherichia coli* K-12
containing the gene alpha-
1,2-fucosyltransferase from
Bacteroides vulgatus

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand Aequival® 2'FL.
3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1233 – 2'-FL from new GM source for infant formula) Variation* and ending 15 months after that date.

Attachment B – Draft Explanatory Statement

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 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted application A1233 which sought to permit the sale and use of 2'-fucosyllactose (2'-FL) derived from a genetically modified *Escherichia coli* (*E.coli*) strain as a nutritive substance in infant formula products; which includes amending the Code to reference or include a specification published by the European Union (EU). The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

2. Purpose

The Authority has prepared a draft variation to the Code to:

- amend Schedule 26 to permit the addition of 2'-FL sourced from *E. coli* K-12 containing the gene alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* (without specifying the strain 'E997') in infant formula products subject to certain conditions, including an exclusive use period of 15 months for the Applicant's brand of 2'-FL (Aequival® 2'-FL); and
- insert prescribed specifications for this 2'-FL into Schedule 3.

The draft variation includes consequential amendments to the Code as a result of the above amendments.

3. Documents incorporated by reference

The draft variation prepared by the Authority does not incorporate any documents by reference.

However, the draft variation will vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3.

Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include:

- Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2019)
- United States Pharmacopeial Convention (2020)
- Food Chemicals Codex (edition)
- Commission Regulation (EU) No 231/2012

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1233 will include one round of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption, permitting the voluntary use of genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065), and the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

5. 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 94 of the FSANZ Act.

6. Variation

Items [1] to [5] will amend Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as nutritive substances, to comply with any relevant identity and purity specifications listed in Schedule 3. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

The amendments made by Items [1] to [5] will set – for the purposes of section 1.1.1—15 of the Code - a specifications for 2'-FL sourced from *Escherichia coli* K12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

Item [1] will amend the table to subsection S3—2(2) by replacing the current entry in that table for 2'-FL sourced from *Escherichia coli* K-12 with a new more detailed description of this substance. The new description states '2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*'. The purpose of this amendment – and the amendments made by items [2] to [4] below - is to draw a clear distinction between the existing specification for that 2'-FL and the specification that will be added to Schedule 3 by item [5] below. That is, the new specification for 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*).

Item [2] will amend the table to subsection S3—2(2) by inserting in alphabetical order a new entry for '2'-fucosyllactose powder from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*' and a corresponding reference to new section S3—46 (see item [5] below)

Item [3] will amend the heading to section S3—40. It will replace the current heading with a more detailed heading that refers to 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*.

Item [4] will amend section S3—40 by omitting the first sentence in that section and replacing it with 'For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*, the specifications are the following'.

Item [5] will add section S3—46 to Schedule 3 in numerical order. The new section will list a

specification for 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

Item [6] will amend Schedule 26 of the Code.

Schedule 26 relates to food produced using gene technology. 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* is a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is derived from an organism modified using gene technology.

Paragraph 1.5.2—3(a) permits a food for sale to consist of, or have as an ingredient, a food produced using gene technology if the food produced using gene technology (other than a processing aid or food additive) is listed in Schedule 26 and complies with any corresponding conditions in that Schedule.

The table to subsection S26—3(7) lists food produced using gene technology of microbial origin. Item [6] will amend item [1] of that table to provide a permission for the use of 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

In order to add the new permission to the table, item [6] will repeal and then restate the entire entry in the table for 2'-FL but with the new source permission included in the restated entry as sub-item (c) in column 2, and its associated conditions of use set out in column 3. These conditions of use are as follows:

1. the substance may only be added to infant formula;
2. during the exclusive use period, the substance may only be sold under the brand Aequival® 2'FL; and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (Application A1233 – 2'-FL from new GM source for infant formula) Variation* and ending 15 months after that date.

Condition 2 will mean that 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* may only be sold under the brand 'Aequival® 2'FL' during the exclusive use period. 'Exclusive use period' will be defined in condition 3 as the period commencing upon gazettal of the draft variation and ending 15 months after that date

Once this period ends, the permission will revert to a general permission, meaning that the proposed permission will then permit the sale of 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to be sold under any brand.

The proposed amendments made by item [6] will not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology.