23 February 2024
282-24

Call for submissions – Application A1283

A1283 - 2′-FL from GM *Corynebacterium glutamicum* in infant formula products

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Advanced Protein Technologies Corp. to amend the Australia New Zealand Food Standards Code to permit the use of 2′-fucosyllactose produced from a genetically modified *Corynebacterium glutamicum* as a nutritive substance in infant formula products and has prepared a draft food regulatory measure. 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 at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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

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

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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

DEADLINE FOR SUBMISSIONS:6pm (Canberra time) 22 March 2024

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

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

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

Supporting document

The following document which informed the assessment of this application are available on the FSANZ website:

SD1 Risk and technical assessment – Application A1283

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Advanced Protein Technologies Corp. to amend the Australia New Zealand Food Standards Code (the Code) to permit 2′-fucosyllactose (2′-FL) produced from genetically modified (GM) *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* to be used as a nutritive substance in infant formula products.

The Code already permits 2′-FL from other GM sources to be used as a nutritive substance in infant formula products. However, the Code does not currently permit the use of 2′-FL produced from genetically modified *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* for that purpose.

The applicant has also requested an exclusive use permission under the brand name 'Momstamin 2′-FL' for a period of 15 months after gazettal.

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FL synthesised from the applicant's source organism to infant formula products at the proposed use levels. The applicant's 2′-FL is chemically and structurally identical to the naturally occurring substance present in human milk. It is also chemically and structurally identical to 2′-FL already assessed by FSANZ and permitted in the Code. Given this, the associated health benefits from the addition of 2′-FL to infant formula products for infants remain the same: (1) an anti-pathogenic effect; (2) immunomodulation and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

For reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit the use of 2′-FL produced from a GM source i.e. *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* as a nutritive substance in infant formula products in accordance with the Code. If approved, the draft variation would:

- amend Schedule 26 of the Code to permit the applicant's 2′-FL to be used as a nutritive substance in infant formula products subject to certain conditions, including an exclusive use period of 15 months linked to the applicant's brand name 'Momstamin 2′-FL', and
- insert a new specification for the applicant's 2′-FL into Schedule 3 of the Code, with which the applicant's 2′-FL would have to comply when used as a nutritive substance in infant formula products (or sold for such use).

FSANZ now seeks submissions on the draft variation (Attachment A).

1 Introduction

1.1 The applicant

The applicant, Advanced Protein Technologies Corp. (APTech) is a biotechnology-based company that specialises in fermentation and metabolic engineering for the manufacture of products related to food and biopharmaceutical industries. APTech manufactures a wide range of products, including human milk oligosaccharides, active pharmaceutical ingredients, and protein materials to be used for foods, pharmaceuticals, and other biotechnological purposes.

1.2 The application

On 4 September 2023, APTech applied to amend Schedule 26 of the Australia New Zealand Food Standards Code (the Code) to permit the use of 2′-fucosyllactose (2′-FL) produced from a new source organism, *Corynebacterium glutamicum* APC199 containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* as a nutritive substance in infant formula products.

1.3 The current Code requirements

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

1.3.1 Infant formula products

The composition and labelling of infant formula products are specifically regulated in Standard 2.9.1 and Schedule 29. They set out specific compositional and labelling requirements for the following infant formula products:

- 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).

1.3.2 Permitted use

1.3.2.1 Food produced using gene technology

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 from various sources is already permitted in the Code as a *food produced using gene technology of microbiological origin* for use in infant formula products, however not from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans.*

The applicant's 2′-FL is a *food produced using gene technology* (section 1.1.2—2) as it is produced from an organism modified using gene technology i.e. produced from GM *C. glutamicum.* Consequently, express permission for the applicant's 2′-FL would be required in accordance with paragraph 1.5.2—3(a) (i.e. to be listed in Schedule 26 and to comply with any corresponding conditions).

1.3.2.2 Nutritive substances

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* (as defined in section 1.1.2—12). The applicant's 2′-FL would be *used as*

a nutritive substance for the purposes of the Code because its use in infant formula products is intended to achieve specific nutritional purposes.

2′-FL is a non-digestible oligosaccharide that is a component of human milk. 2′-FL is currently permitted to be *used as a nutritive substance* in infant formula products at levels up to 96 mg/100 kJ (equivalent to 2.4 g/L) in accordance with section 2.9.1—5 (i.e. if (among other things) 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). The table to section S29—5 lists 2′-fucosyllactose *permitted for use by Standard 1.5.2* (see section 1.3.2.1 of this report above).

The applicant is not requesting any changes to the existing permissions for 2′-FL in section S29—5.

1.3.3 Galacto-oligosaccharides and inulin-type fructans

Section 2.9.1—7 of the Code regulates the addition of galacto-oligosaccharides (GOS) and inulin-type fructans (ITF) (both are defined in subsection 1.1.2—2(3)) to infant formula products. 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). ITF are not present in human milk and GOS is found only in trace amounts (FSANZ 2008).

Section 2.9.1—7 sets out restrictions on the addition of ITF and GOS. Subsection 2.9.1—7(3) permits 2′-FL to be used in combination with ITF and/or GOS in a prescribed infant formula product (as defined in paragraph 2.9.1—7(4)(b)). An exclusive use permission for 2′-FL in combination with ITF and/or GOS is current[1], however will expire 1 June 2024, which is prior to anticipated gazettal of this application.

1.3.4 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 applicant's 2′-FL for this purpose.

1.3.5 Labelling requirements

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Section 1.2.4—2 requires food products to be labelled with a statement of ingredients. Section 1.2.4—4 requires ingredients to be declared using: a name by which they are commonly known; a name that describes their true nature; or a generic ingredient name if one is specified in Schedule 10.

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

Section 1.5.2—4 sets out labelling requirements for foods for sale that consist of, or have as

[1] The effect of this permission is that during the exclusive use period, an infant formula product containing 2′-FL in combination with ITF and/or GOS may only be sold if the infant formula product is the prescribed infant formula product that: is manufactured by Nutricia Australia Pty. Ltd; and contains, as a nutritive substance, 2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126. Exclusive use period means the period commencing on the date of gazettal of the *Food Standards (Application A1251 – 2′-FL combined with galactooligosaccharides and/or inulin-type fructans in infant formula products) Variation* and ending 15 months after that date.

an ingredient, food that is a *genetically modified food*[2] (GM food).

Subparagraph 2.9.1—21(1)(a)(iii) of Standard 2.9.1 requires the average amount of any substance used as a nutritive substance permitted by Standard 2.9.1 to be declared in the nutrition information statement (NIS), expressed in weight/100 mL. Paragraphs 2.9.1—24(1)(ca) and (cb) prohibit the use of: the words 'human milk oligosaccharide', 'human milk identical oligosaccharide'; the abbreviations 'HMO' or 'HiMO'; or any words and abbreviations having the same or similar effect. Paragraph 2.9.1—24(1)(f) 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.

1.4 Regulation in other countries

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards.

2′-FL produced by microbial fermentation and by chemical synthesis is permitted for use in infant formula products, 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.

It is noted that internationally, the permitted levels of 2′-FL for use in infant formula range from 1.2 g/L to 2.4 g/L. FSANZ set the existing permitted maximum levels of 2′-FL in the Code after undertaking a safety, technical and health effects assessment, including estimated dietary intakes and naturally occurring levels in human milk (FSANZ 2019; FSANZ 2021).

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

Country	Max. permitted amount (g/L)
Australia	2.4
New Zealand	2.4
United States	2.4
Canada#	1.2
Singapore	1.2
European Union (EU)	1.2
Israel	2.0
Korea	1.1
Philippines	1.2

Notes to table:
*Infant formula categories vary between countries
Permission as novel food with support for use in infant formula

Codex Alimentarius (Codex) International Food Standards do not currently exist for 2′-FL. However, the Codex Standards for 'Infant Formula and Formulas for Special Medical Purposes Intended for Infants' (Codex Alimentarius 2020) and for 'Follow-up formula for Older Infants and Product for Young Children' (Codex Alimentarius 2023) contain provisions for 'optional ingredients' which are applicable to 2′-FL.

In the United States (US), APTech's 2′-FL produced from *C. glutamicum* APC199 that is the subject of this application has Generally Recognized as Safe (GRAS) status for use in infant formula at a level of 2.4 g/L in non-exempt formula for term infants in addition to a variety of

[2] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a '*food produced using gene technology that
a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

other food uses. Notification of this conclusion was filed under GRAS Notice (GRN) 000932 and has received a letter of “no questions” from the US Food and Drug Administration (FDA) (Advanced Protein Technologies, Corp., 2020; US FDA, 2021a).

In the European Union (EU), the applicants 2′-FL from microbial fermentation with *C. glutamicum* APC199 received a positive scientific opinion from the European Food Safety Authority (EFSA), who concluded that this 2′-FL ingredient is safe for its intended use as a novel food (EFSA, 2022a). Formal approval for the use of APTech’s 2′-FL was subsequently acquired under *Commission Implementing Regulation (EU) 2023/859 of 25 April 2023 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food 2'-Fucosyllactose (microbial source) to authorise its production by a derivative strain of Corynebacterium glutamicum ATCC 13032* (EU, 2023).

Approval for the use of the applicants 2′-FL from *C. glutamicum* APC199 have also been issued in Korea, Thailand, Vietnam, and Malaysia.

1.5 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.

1.6 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

The Code already permits 2′-FL from different source organisms to be used as nutritive substances in infant formula products. The maximum permitted amount is 96 mg/100 kJ, equivalent to 2.4 g/L. FSANZ has previously determined that there are no safety concerns associated with the addition of 2′-FL to infant formula products at concentrations up to 2.4 g/L. The applicant is not requesting a change to the maximum permitted amount. The primary purpose of the present assessment is therefore to assess the safety of 2′-FL produced by the new production strain.

The applicant’s 2′-FL, produced by a microbial fermentation method of production, is chemically and structurally identical to the naturally occurring substance present in human milk. It is also chemically and structurally identical to 2′-FL previously assessed and permitted by FSANZ.

C. glutamicum has a long history of documented use for the production of biomolecules, including food additives, and poses no risks to human health. No safety concerns arising from the gene donors were identified. Characterisation of the production strain confirmed the expression plasmid carrying the introduced genes was both genetically stable and fully functional.

On the basis of the data provided, no potential safety concerns were identified in the assessment of the 2′-FL production strain *C. glutamicum.* Based on previous FSANZ assessments of 2′-FL and the toxicological assessment in the present application, it was concluded that there are no public health and safety concerns associated with 2′-FL produced from the new GM source organism that is the subject of this application.

The dietary intake assessment compared the estimated dietary intake of 2′-FL from infant and follow-on formula to that of mature human milk for 3- and 9-month old infants. As there is no requested change to the current permitted amount of 2′-FL in infant formula products, no extension of use, and no data suggesting a higher concentration in human milk since the most recent FSANZ assessment; estimated dietary intakes of 2′-FL from previous FSANZ assessments were used in this current assessment. These data showed that estimated mean and 90th percentile dietary intakes of 2′-FL at the maximum permitted amount in the Code from infant formula products fall within the range of estimated dietary intakes from mature human milk.

FSANZ has previously concluded that the addition of 2′-FL to infant formula products at levels typically found in human milk does not pose a risk to normal growth of infants. Two studies provided by the applicant reported no difference in growth in infants fed formula containing lacto-N-neotetraose and 2′-FL compared to control, however were not directly relevant to the assessment because any effect (or lack of effect) on growth cannot be attributed to 2′-FL. No new relevant studies were identified for this assessment, and therefore FSANZ maintains the previous conclusion that the addition of 2′-FL to infant formula products at levels normally found in human milk is unlikely to affect growth.

Based on previous microbiological assessments, given the identical chemical structure and that the applicant has not requested any change in the maximum permitted amount of 2′-FL added to infant formula products, the associated health benefits from the use of 2′-FL as a nutritive substance in infant formula products for infants remain the same: (1) an anti-pathogenic effect; (2) immunomodulation and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Overall the safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FL synthesised from the new source organism to infant formula products at the maximum permitted amount in the Code.

2.2 Risk management

Breastfeeding is the recommended way to feed infants. However, a safe and nutritious substitute for human milk is needed for infants when breastfeeding is not possible. As infants are a vulnerable population group, infant formula products are regulated by prescriptive provisions for composition and labelling. Any changes to the composition of these products must be established as safe prior to being permitted.

2.2.1 Proposed regulatory approval

FSANZ is proposing to list *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* as a source of 2′-FL in the table to subsection S26—3(7).

Application A1283 requested an amendment to the Code to provide a permission for 2′-FL produced from GM *C. glutamicum* strain APC199 containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* to be used as a nutritive substance in infant formula products. Such a permission, if granted, would be specific to strain APC199 only.

The draft variation prepared by FSANZ would instead provide a permission for 2′-FL from *C. glutamicum* containing the gene alpha-1,2-fucosyltransferase from *P. saltans*, without specifying the strain of *C. glutamicum*. This approach would provide greater flexibility in terms of strain improvement and avoid the need for new applications to be lodged to provide permissions for new strains of *C. glutamicum*.

The approach is also consistent with current permissions in the Code for 2′-FL which specify the gene insertion alpha-1,2-fucosyltransferase, and the gene donor organism. Given the

applicant's 2′-FL 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, for reasons set out at sections 1.3.2.1 and 1.3.2.2 of this report, FSANZ considers that, if the draft variation is approved, the applicant's 2′-FL would meet requirements under Standard 2.9.1 and Schedule 29 to be *used as a nutritive substance* with a maximum amount of 96 mg/100 kJ in infant formula products.

2.2.2 Specification

Section 1.1.1—15 requires a substance that is *used as a nutritive substance* must comply with any relevant specification set out in Schedule 3. The draft variation would insert a new specification relating specifically to the applicant's 2′-FL sourced from *C. glutamicum*, with which this 2′-FL would have to comply when used as a nutritive substance in infant formula products (or sold for such use).

2.2.3 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 that food, 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.

FSANZ is proposing to provide the applicant with a 15 month exclusive use permission for this 2′-FL commencing on the date of gazettal of the draft variation (if approved).

If the draft variation is approved, this means that, during that 15 month period, the permission would apply exclusively to those substances under the brand name 'Momstamin 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 anyone may use the permitted forms of 2′-FL 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.

2.2.4 The five year review for 2′-FL and LNnT in infant formula products

FSANZ is committed to reviewing any new evidence on the beneficial role of HiMOs in the normal growth and development of infants.

At the request of Food Ministers[3], FSANZ will carry out a five-year review (to be completed by March 2026) of the initial permission gazetted under Application A1155. This will review the evidence of a substantiated beneficial role of 2′-FL and Lacto-N-neotetraose (LNnT) in the normal growth and development of infants. This process will include consultation with a range of stakeholders including experts, industry and government agencies, and will be independently peer reviewed.

Details on the review process, including stakeholder input will be made available on the FSANZ website.

[3] Communiqué of outcomes from the Australia and New Zealand Ministerial Forum on Food Regulation meeting held on 27 November 2020

2.2.5 Labelling

2.2.5.1 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 infant formula products must contain a statement of ingredients. Should manufacturers choose to add the applicant's 2′-FL in infant formula products in accordance with the Code, then the 2′-FL must be declared as an ingredient 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; 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. These ingredient naming requirements would apply to the applicant's 2′-FL, enabling industry to have flexibility in how they declare these ingredients (for example, using the name '2′-fucosyllactose'). However, note that existing prohibited representations in paragraphs 2.9.1—24(1)(ca) and (cb) would also apply to the ingredient name (refer to section 2.2.5.3 below).

2.2.5.2 Mandatory nutrition information

Section 2.9.1—21 regulates the declaration of nutrition information in a NIS on the label of infant formula products. The NIS is a single statement and may be in the form of a table, as indicated in section S29—10.

Subparagraph 2.9.1—21(1)(a)(iii) requires the average amount of any substance used as a nutritive substance permitted by Standard 2.9.1 to be declared in the NIS. Therefore, the applicant's 2′-FL would need to be declared in the NIS when it is voluntarily used in an infant formula product.

2.2.5.3 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 infant formula products. The applicant's 2′-FL would be subject to these provisions regarding prohibited representations.

2.2.5.4 Voluntary representations

Paragraph 1.2.7—4(b) states that a nutrition content or health claim must not be made about an infant formula product. Paragraph 2.9.1—24(1)(f) 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 infant formula products would apply to the applicant's 2′-FL.

2.2.5.5 Labelling as 'genetically modified'

As discussed in section 2.3 of SD1, the applicant's 2′-FL is highly unlikely to contain novel protein or novel DNA due to the purification step used in its production. It is therefore highly unlikely that novel protein or novel DNA would be present in an infant formula product that contains this 2′-FL as an ingredient. However, where novel protein or novel DNA is present, the requirement to label the 2′-FL ingredient as 'genetically modified' would apply in accordance with section 1.5.2—4.

2.2.6 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 has decided to prepare a draft variation to the Code to permit the use of 2′-FL from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* as a nutritive substance in infant formula products.

If the draft variation is approved, the applicant's 2′-FL would be subject to relevant requirements and conditions in the Code, which include the following:

- It may be added alone, or in combination with LNnT, to infant formula products up to a maximum level of 2.4 g/L for 2′-FL, as consumed.
- Once the current exclusive use period granted in relation to Application A1251 ends (see Section 1.3.3), it may be added to infant formula products in combination with ITF and/or GOS.
- 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, would apply to infant formula products that contain the applicant's 2′-FL.
- An exclusive use permission to use 2′-FL produced using *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* would apply for a period of 15 months, linked to the applicant's brand name 'Momstamin 2′-FL', commencing on the date of gazettal of the approved draft variation.
- Schedule 3 of the Code would set a specific specification for the applicant's 2′-FL, with which it must comply when used as a nutritive substance in infant formula products (or sold for such use).

2.3 Risk communication

2.3.1 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 channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

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.

2.3.2 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 not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to permit the use of the applicant's 2′-FL as a nutritive substance in infant formula products 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.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

As explained above, Application A1283 seeks an amendment of the Code required to allow the proposed use of the applicant's 2′-FL as a nutritive substance in infant formula products, in accordance with the Code.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[4]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for the applications relating to nutritive substances OIA Reference: OIA23-06224. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

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 the status quo is rejecting the application). This analysis considers the costs and benefits of permitting the proposed use of the applicant's 2′-FL as a nutritive substance in infant formula products.

The consideration of the costs and benefits in this Section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of the applicant's 2′-FL as a nutritive substance in infant formula products.

Consumers

FSANZ's risk assessment concludes no safety concerns from the addition of the applicant's 2′-FL to infant formula products at the proposed maximum permitted amounts.

[4] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Consumers in Australia and New Zealand may benefit from a larger range and supply of infant formula products for sale that contain the applicant's 2′-FL in one or more infant formula products for sale.

A new source for an already permitted ingredient, 2′-FL, may also lead to overall price reductions in infant formula products containing 2′-FL for consumers. That is if industry passes on any cost efficiencies gained from using 2′-FL from this new source (the applicant's 2′-FL). In the longer term it may also become a more common ingredient that no longer draws any price premium which will provides increased value to all consumers.

The role of granting an exclusive use permission is to encourage industry innovation and allow applicants to achieve commercial rewards through higher returns on their investment. Any commercial reward from this application's exclusive use period could come at the expense of consumers in the short-term, through other businesses not being able to compete to supply the applicant's 2′-FL at lower prices during the exclusivity period. However, without this incentive this innovation may not have taken place. It is assumed that the greater incentive to innovate will lead to greater benefits in the medium to long term for consumers, because innovation encourages more products to come to market that may benefit consumers.

Industry

Industry may benefit from increased choice of sources for 2′-FL permitted to be used as nutritive substances in infant formula products for sale. That may reduce costs of sourcing 2′-FL. Industry may voluntarily use 2′-FL from this new source or buy and sell infant formula products containing 2′-FL from this new source, where they believe a commercial net benefit exists for them.

Given the applicant's 2′-FL is already approved in some overseas countries, approving the applicant's 2′-FL would favour trade and any growth of overseas markets for exporters of infant formula products in Australia and New Zealand. The proposed permission may also support innovation in infant formula products.

Producers of infant formula products in Australia and New Zealand, may however face greater competition in the domestic infant formula products market from overseas-based producers that can also supply Australia-New Zealand with infant formula products containing the applicant's 2′-FL. Any such impacts to domestic producers are assumed to be outweighed by benefits to consumers from greater industry competition.

Granting an exclusive use permission as proposed would prevent other businesses from producing 2′-FL from this additional source in the short-term. There may also be short-term restrictions on numbers of businesses that can access sale of the applicant's 2′-FL, relative to if the exclusive use period had not been granted. However, the granting of exclusive use permission does not preclude any other company from applying to amend the Code in relation to the same food or ingredient. Therefore, the market for this additional source of 2′-FL could be opened during the 15 months' exclusivity for any other companies willing to make an application.

Government

The approval of this application may result in a small but likely inconsequential cost to government in terms of an addition to the current range of 2′-FL from various sources which are monitored for compliance.

Conclusion

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the applicant's 2′-FL as proposed, are likely to outweigh the associated costs.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2.1 of this report. Previous assessments found no safety concerns associated with the use of 2′-FL to infant formula products. New information provided did not change this conclusion.

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

Current labelling requirements discussed in section 2.2.5 would apply to the applicant's 2′-FL when it is used as a nutritive substance in infant formula products, and would provide information to enable consumers to make an informed choice.

2.4.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 2.2.5.3, which aim to prevent misleading or deceptive conduct, would apply when the applicant's 2′-FL is used as a nutritive substance in infant formula products.

2.4.3 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 applicant's 2′-FL.

- **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 infant formula equivalent products; and several other foods across various countries around the world.

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

The proposed permission would support an internationally competitive food industry in relation to the use of 2′-FL as a nutritive substance in infant formula products, 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 Forum on Food Regulation**

As part of A1283, 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

Noting the food technology aspects, safety, associated health benefits, and nutritional impact assessed in SD1 and Section 2.1 of this Report, FSANZ considers these Policy Guidelines have been met.

3 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.

4 References

Advanced Protein Technologies, Corp. (2020). *Determination of the Generally Recognized as Safe (GRAS) Status of 2'-Fucosyllactose as a Food Ingredient [GRAS Notification]: Parts 1 & 2*. (GRN No. 932). Prepared by Clarksville (MD): NutraSource, Inc. Prepared for Hwasung City, Gyeonggi-do, Republic of Korea: Advanced Protein Technologies, Corp. (APTech). Submitted to College Park (MD): U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety. Available at: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=932 [Feb. 18, 2021 - FDA response - no questions].

Codex Alimentarius (2020) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. (CXS 72, adopted in 1981. Amendment: 1983, 1985, 1987, 2011, 2015, 2016 and 2020, Revision: 2007). Rome, Italy: Codex Alimentarius Commission. Available at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

Codex Alimentarius (2023) Standard for Follow-up formula for Older Infants and Product for Young Children. (CXS/156, adopted in 1987. Amendment: 1989, 2011, 2017, Revision: 2023. Rome, Italy: Codex Alimentarius Commission. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B156-1987%252FCXS_156e.pdf

EU (2023). Commission Implementing Regulation (EU) 2023/859 of 25 April 2023 amending

Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food 2′-Fucosyllactose (microbial source) to authorise its production by a derivative strain of Corynebacterium glutamicum ATCC 13032. Off J Eur Union 66(L111):17–21. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0859

FSANZ (2008) First Review Report Proposal P306 Addition of Inulin/FOS and GOS to food. Food Standards Australia New Zealand, Canberra, Australia. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P306%20FOS%20_%20GOS%20FRR%20FINAL.pdf

FSANZ (2013) A1055: Short-chain fructo-oligosaccharides. Supporting Document 1. Risk and technical assessment (at approval). Food Standards Australia New Zealand, Canberra, Australia. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1055%20Addition%20of%20scFOS%20AppR%20SD1%20Risk%20Assess.pdf

FSANZ (2019) Application A1155 - 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Second Call for Submissions. Report prepared by Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1155_SD1_Risk%20assessment%20-%202nd%20CFS.pdf

FSANZ (2021) Application A1190 - 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Approval. Risk and safety assessment. Report prepared by Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1190_SD1%20at%20Approval.pdf

U.S. FDA (2021a). *Agency Response Letter GRAS Notice No. GRN 932 [2'-Fucosyllactose, Hwasung City, Gyeonggi-do, Republic of Korea: Advanced Protein Technologies Corp]*. Silver Spring (MD): U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety. Available at: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=932 [Feb. 18, 2021 - FDA response - no questions].

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 A1283 – 2′-FL from GM *Corynebacterium glutamicum* in infant formula products) 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]

[Insert Delegate's name and position title]
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 A1283 – 2′-FL from GM* Corynebacterium glutamicum *in infant formula products) 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, before the table item dealing with 2′-fucosyllactose sourced from *Escherichia coli* BL21)

Insert:

2′-fucosyllactose sourced from *Corynebacterium glutamicum*	section S3—51

[2] After section S3—50

Insert:

S3—51 Specification 2′-fucosyllactose sourced from *Corynebacterium glutamicum*

For 2′-fucosyllactose (2′-FL) sourced from *Corynebacterium glutamicum*, the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;
(b) chemical formula—$C_{18}H_{32}O_{15;}$
(c) molecular weight—488.44 g/mol;
(d) CAS number—41263-94-9;
(e) description—white to off-white/ivory powder;
(f) 2′-FL—not less than 94% (water free);
(g) D-lactose—not more than 3.0% (water free);
(h) L-fucose—not more than 3.0% (water free);
(i) 3-fucosyllactose—not more than 3.0% (water free);
(j) difucosyl-D-lactose—not more than 2.0% (water free);
(k) glucose—not more than 3.0% (water free);
(l) galactose—not more than 3.0% (water free);
(m) water—not more than 9.0%;
(n) ash, sulphated—not more than 0.5%;
(o) ethanol—not more than 1,000 mg/kg (for crystallised product from solvent only);
(p) residual proteins—not more than 0.005%;
(q) lead—not more than 0.02 mg/kg;
(r) arsenic—not more than 0.03 mg/kg;
(s) cadmium—not more than 0.01 mg/kg;
(t) mercury—not more than 0.05 mg/kg;
(u) microbiological:
  (i) total plate count—not more than 500 cfu/g;
  (ii) coliforms—not more than 10 cfu/g;
  (iii) yeasts and moulds—not more than 100 cfu/g;
  (iv) aflatoxin M1—not more than 0.025 µg/kg;

(v) residual endotoxins—not more than 10 EU/mg

Schedule 26—Food produced using gene technology

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

Insert:

(e)	*Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand Momstamin 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 A1283 - 2′-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation* and ending 15 months after that date.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1283 - 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) 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 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 A1283 which seeks to amend the Code to permit the use of 2'-fucosyllactose (2′-FL) produced from a new genetically modified source as a nutritive substance in infant formula products. The application also seeks a 15 month exclusive use permission.The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1283 - 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation*.

2. Variation will be a legislative instrument

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

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

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

3. Purpose

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

- Amend Schedule 26 of the Code to permit 2′-FL produced from a new genetically modified source i.e. *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*, to be used as a nutritive substance in infant formula products subject to certain conditions, including an exclusive use permission for a period of 15 months linked to the applicant's brand name 'Momstamin 2′-FL'.
- Insert a new specification for this 2′-FL into Schedule 3 with which this 2′-FL would have to comply when used as a nutritive substance in infant formula products (or sold for such use).

4. Documents incorporated by reference

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

However, if approved, the draft variation would 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: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition); and the Commission Regulation (EU) No 231/2012.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1283 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a four-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[5]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement was not required for the applications relating to nutritive substances OIA Reference: OIA23-06224. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards*

[5] Formerly known as the Office of Best Practice Regulation (OBPR)

(Application A1283 - 2′-FL from GM Corynebacterium glutamicum *in infant formula products) Variation.*

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

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

Items [1] and [2] of the Schedule to the draft variation would 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 when added to food in accordance with the Code, or sold for use in food. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [1] would insert into columns 1 and 2 of the table to subsection S3—2(2), in alphabetical order, new references to '2′-fucosyllactose sourced from *Corynebacterium glutamicum* and 'section S3—51' respectively. These new references relate to the new provision that would be inserted by item [2] below.

Item [2] would insert new section S3—51 which sets out the specifications relating specifically to 2′-fucosyllactose sourced from *Corynebacterium glutamicum*, the new substance sought to be permitted by the applicant.

Consequently, the proposed permission for 2′-fucosyllactose sourced from *Corynebacterium glutamicum* to be used as a nutritive substance in infant formula products (or sold for such use) would be subject to the requirement in section 1.1.1—15 that the substance must comply with these specifications.

Item [3] of the Schedule to the draft variation would amend Schedule 26 of the Code.

Schedule 26 relates to food produced using gene technology. 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* is a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is produced 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 [3] would amend item 1 of that table (2′-FL) by inserting new paragraph (e) into the column headed 'Source'. New paragraph (e) would refer to:

'*Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*'.

Associated conditions of use for 2′-FL from this new source would be set out in column 3 of the table as follows:

1. the substance may only be added to infant formula products
2. during the exclusive use period, the substance may only be sold under the brand Momstamin 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 (A1283 - 2′-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation* and ending 15 months after that date.

Condition 2 would mean that 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* may only be sold under the brand 'Momstamin 2′-FL' during the exclusive use period. 'Exclusive use period' would be defined in condition 3 as the period commencing on gazettal of the draft variation and ending 15 months after that date.

If the draft variation is approved, the effect of the amendment in item [3] would be to permit the use of the substance, 2′-FL from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* as a food produced using gene technology, subject to the above conditions of use for the substance.

Once the exclusive use period ends, the permission would revert to a general permission, meaning that the proposed permission would then permit the sale and use of 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* under any brand.

The proposed amendments made by item [3] would not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology.

If the draft variation is approved, the effect of the amendment in item [3] would also be to permit 2′-FL from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* to be used as a nutritive substance in infant formula products.

This is because subsection 2.9.1—5(1) and section S29—5 permit a '2′-fucosyllactose permitted for use by Standard 1.5.2' to be used as a nutritive substances in infant formula products at an amount no greater than 96 mg/100 kJ.