26 March 2024
286-24

Approval report – Application A1277

2′-FL from GM *Escherichia coli* K-12 (gene donor: *Helicobacter enhydrae*) in infant formula products

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Inbiose N.V. to amend the Australia New Zealand Food Standards Code to permit the use of 2′-fucosyllactose produced from a new genetically modified strain of *Escherichia coli* K-12 as a nutritive substance in infant formula products.

On 10 October 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 13 March 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 26 March 2024.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

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

SD1 Supporting document 1 – Risk and technical assessment

Executive summary

Food Standards Australia New Zealand (FSANZ) assessed an application made by Inbiose N.V. to amend the Australia New Zealand Food Standards Code (the Code) to permit 2′-fucosyllactose (2′-FL) produced from a new genetically modified (GM) strain of *Escherichia coli* K-12 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 GM *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* for that purpose. The application therefore seeks to amend the Code to permit 2′-FL from this alternative GM source organism for the above purpose.

The applicant also requested an exclusive use permission under the brand name '2′-FL-Inbiose' 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 and permitted by FSANZ. 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.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 10 October 2023 to 21 November 2023. Four submissions were received, all of which supported the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions with a minor consequential amendment[2]. The purpose of the approved draft variation is to permit the use of 2′-FL produced from GM *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* as a nutritive substance in infant formula products. The approved draft variation will:

- amend Schedule 26 of the Code, so the applicant's 2′-FL will be permitted for use by Standard 1.5.2 subject to certain conditions, i.e. that the 2′-FL may only be added to infant formula products and an exclusive use permission for a period of 15 months will apply to the applicant's brand name '2′-FL-Inbiose', and
- amend Schedule 3 of the Code, particularly the specification for 2′-FL sourced from *E. coli* K-12 (section S3—40), to include 2′-FL from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* in the list of substances to which the specifications in section S3—40 apply.

The effect of those amendments is that the applicant's 2′-FL will be permitted to be used as a nutritive substance in infant formula products in accordance with the Code.

[2] For further details about the amendment made, see Section 1.7 of this report.

1 Introduction

1.1 The applicant

The applicant, Inbiose N.V. is a Belgian company with a focus on development of specialty carbohydrates, including human identical milk oligosaccharides.

1.2 The application

On 25 May 2023, Inbiose N.V. 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 as a nutritive substance in infant formula products. The applicant's 2′-FL is produced by microbial fermentation using a genetically modified (GM) strain of *Escherichia coli* K-12.

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*.

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 *E. coli* K-12).

2′-FL produced from other GM sources is already permitted in the Code as a *food produced using gene technology of microbiological origin* for use in infant formula products including 2′-FL produced from *E. coli* K-12 (subsection S26—3(7)), however not from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae.* Consequently, express permission for the applicant's 2′-FL is 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 will be *used as a nutritive substance* for the purposes of the Code because its addition to 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 1.3.3.1 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) currently 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)) during an exclusive use period ending on 1 June 2024, which is prior to anticipated gazettal of this application[3]. Once that exclusive use period ends, 2′-FL will be permitted to be used in combination with ITF and/or GOS in any infant formula product in accordance with the Code.

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. Schedule 3 currently lists two specifications for 2′-FL, including for 2′-FL sourced from *E. coli* K-12 (section S3—40) and 2′-FL sourced from *E. coli* BL21 (section S3—45).

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.

[3] 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. The exclusive use period relates to an exclusive use permission, the effect of which is that during that 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.

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 an ingredient, food that is a *genetically modified food*[4].

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 level (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	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

[4] 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*).

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 March 2022, Inbiose N.V. submitted a GRAS notice to the Food and Drug Administration (FDA) for approval in the United States for 2′-FL manufactured with *E. coli* K-12 MG1655 INB-2FL_03 (GRAS Notice No 1091)[5], which is the production host assessed under this application.

The FDA has responded with 'no questions' to an earlier production host of *E. coli* K-12 MG1655 INB000846 (GRN No 897)[6] from the applicant. The specification of the latest submission is equivalent to the 2′-FL approved in GRN 897.

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); and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit the applicant's 2′-FL produced from GM *E. coli* K-12 to be used as a nutritive substance in infant formula products.

The draft variation as proposed following assessment was approved with the following amendment.

A minor consequential amendment was made to the table to subsection S3—2(2). This table lists entries consisting of substances for which there are specifications in Schedule 3; and their associated provisions. This amendment will include a reference to '*Helicobacter enhydrae*' as one of three sources of 2′-fucosyllactose associated with section S3—40, and is a consequence of the amendment in item [2] of the approved draft variation at Attachment A of this report.

The approved draft variation (as amended) takes effect on gazettal and is at Attachment A.

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

The draft variation on which submissions were sought is at Attachment C.

[5]GRN No.1091: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=1091&sort=GRN_No&order=DESC&startrow=1&type=basic&se

[6] GRN No. 897: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=897&sort=GRN_No&order=DESC&startrow=1&type=basic&sea

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation to the Code from 10 October 2023 to 21 November 2023. Four submissions were received, including three from industry representative bodies , and one from a government agency (New Zealand Food Safety). All submitters supported the amendment to permit the use of 2′-FL produced from this new GM source organism as a nutritive substance in infant formula products**.**

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Industry submitters opposed the existing prohibition on the use of the words 'human identical milk oligosaccharide' or 'HiMO' as it is counter to building consumer confidence in, and understanding of labelling information.	Australian food & grocery council, Infant nutrition council, New Zealand food & grocery council	Noted. However, the applicant did not request a change to the existing prohibition, therefore a review of this prohibition is not in scope of this application. FSANZ is aware of the views on this issue as they have been raised previously (see submissions to Applications A1155, A1190, A1233, A1251 and A1265). See FSANZ's response provided in item 15 of Table 1 to section 2.1 in the Approval Report for A1190 2′-FL in infant formula and other products.
Industry submitters support exclusive capturable commercial benefit which recognises the value that this has to deliver on investment for the food industry and for innovation. As per previous submissions, industry submitters continue to seek clarity and consideration around the current and future scope of the application of exclusivity in the broader food supply.	Australian food & grocery council, Infant nutrition council, New Zealand food & grocery council	FSANZ notes these comments. See also section 2.3.3 of this report and the FSANZ website: Exclusivity of use for novel foods and nutritive substances.

2.2 Risk assessment

The Code already permits 2′-FL from different source organisms for addition to infant formula products. The maximum permitted level 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 primary purpose of the present assessment was 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, therefore does not raise any safety concerns.

The *E. coli* K-12 host organism has a long history of use for the production of recombinant proteins and other products, and poses no risks to humans. No safety concerns arising from the gene donors were identified. Characterisation of the GM production strain confirmed that all introduced genes were both genetically stable and functional.

On the basis of the data provided, no potential safety concerns were identified in the assessment of the 2′-FL production strain *E. coli* K-12. 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 nutrition assessment concluded that, based on the available evidence, the addition of 2′-FL to infant formula products is unlikely to pose a risk to the normal growth of infants.

Based on these previous microbiological assessments, given the identical chemical structure and that the applicant has not requested any change in the maximum permitted level of 2′-FL added to infant formula products, 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.

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 proposed use levels.

2.3 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.

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 10 October 2023 to 21 November 2023 (the submission period).

The risk management options available to FSANZ after the submission period are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

2.3.1 Regulatory approval

The draft variation prepared by FSANZ listed *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* as a source of 2′-FL in the table to subsection S26—3(7).

Application A1277 requested an amendment to the Code to provide a permission for 2′-FL produced from *E. coli* K-12 strain MG1655 INB-2FL_03 containing the gene alpha-1,2 fucosyltransferase to be used as a nutritive substance in infant formula products. Such a permission, if granted, would be specific to strain MG1655 INB-2FL_03 only, and would not reference the species of the gene donor organism (i.e. *H. enhydrae*).

The approved draft variation instead will provide a permission for 2′-FL from *E. coli* K-12 containing the gene alpha-1,2-fucosyltransferase from *H. enhydrae*, without specifying the strain of *E. coli* K-12. This approach provides greater flexibility in terms of strain improvement and avoids the need for new applications to be lodged to provide permissions for new strains of *E. coli* K-12.

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. The approved draft variation will provide permission for the applicant's 2′-FL to be permitted as a *food produced using gene technology.* Noting the applicant has not requested any changes to current permissions in the Code for 2′-FL, FSANZ considers that the applicant's 2′-FL will then 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 (see Sections 1.3.2.1 and 1.3.2.2 of this report).

2.3.2 Specification

Section 1.1.1—15 requires substances, including substances *used as a nutritive substance*, to comply with any relevant specification set out in Schedule 3 when added to food in accordance with the Code, or sold for use in food. Consequently, when added to infant formula products for use as a nutritive substance (or sold for such use), the applicant's 2′-FL will have to comply with the requirements of the specification for 2′-FL sourced from *E. coli* K-12, set out in section S3—40 (refer Section 2.1.1 of SD1) as amended. The approved draft variation will amend section S3—40 and the table to subsection S3—2(2) to include 2′-FL sourced from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* as a substance to which section S3—40 will apply.

2.3.3 Exclusivity

An applicant may request an exclusive use 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, and the need to achieve return on this investment, thereby supporting innovation.

The applicant requested an exclusive use permission for their specific brand of 2′-FL.

FSANZ has decided to grant the applicant with a 15-month exclusive use permission for the applicant's 2′-FL commencing on the date of gazettal of the approved draft variation.

This means that, during that 15-month period, the permission will apply exclusively to those substances under the brand name '2′-FL-Inbiose' in accordance with the Code.

Once the 15-month period ends, the exclusive use permission will revert to a general permission, meaning that anyone may use the applicant's 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.

2.3.4 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[7], 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.

2.3.5 Labelling

2.3.5.1 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 to an infant formula product 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 will 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) will also apply to the ingredient name (refer to section 2.3.5.3 below).

2.3.5.2 Mandatory nutrition information

Section 2.9.1—21 regulates the declaration of nutrition information in a nutrition information statement (NIS) on the label of infant formula products. 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 Standard 2.9.1 to be declared in the NIS. Therefore, the applicant's 2′-FL will need to be declared in the NIS when it is voluntarily added to an infant formula product.

2.3.5.3 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 will be subject to these provisions regarding prohibited representations.

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

2.3.5.4 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 will apply to the applicant's 2′-FL.

2.3.5.5 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 will 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' will apply in accordance with section 1.5.2—4.

2.3.6 Risk management conclusion

For reasons set out in this report, FSANZ has decided to approve the draft variation to the Code proposed at the call for submissions with a minor consequential amendment[8]. The purpose of the approved draft variation is to permit the use of 2′-FL from GM *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* as a nutritive substance in infant formula products.

The applicant's 2′-FL will be subject to relevant requirements and conditions in the Code, which include the following:

- It may only be added to infant formula products with a maximum level of 2.4 g/L in accordance with the Code, as consumed.
- Once the current exclusive use period for Application A1251 ends, the applicant's 2′-FL 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, will apply to infant formula products that contain the applicant's 2′-FL.
- An exclusive use permission to use the applicant's 2′-FL i.e. 2′-FL produced using *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* will apply for a period of 15 months, linked to the applicant's brand name '2′-FL-Inbiose', commencing on the date of gazettal of the approved draft variation.
- The applicant's 2′-FL will have to comply with the specification in section S3—40 for 2′-FL sourced from *E. coli* K-12 (as amended) when added to infant formula products for use as a nutritive substance (or sold for such use).

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the FSANZ website, Notification Circular, media release, and Food Standards News.

[8] For further details about the amendment made, see section 1.7 of this report.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.5 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.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [9]. 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 and GM food. This is because applications relating to permitting the use of nutritive substances and GM food 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, gave 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 was 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 considered the costs and benefits of permitting 2′-FL from this new GM source organism to be used as a nutritive substance to infant formula products.

The consideration of the costs and benefits in this section was 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 sought to highlight the potential positives and negatives of moving away from the status quo by permitting the use of the applicant's 2′-FL as a nutritive substance in infant formula products.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. No information was received during the call for submissions that has changed this conclusion.

Cost and benefits of permitting the nutritive substance

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

The food industry may benefit from this draft variation being approved. Use of the applicant's 2′-FL as a nutritive substance in infant formula products will be voluntary, and therefore industry will only use this nutritive substance where a commercial net benefit exists for them. The approved draft variation will align Australia and New Zealand with the USA and the European Union and has the potential to enhance international trade in respect of both the import and export of infant formula products.

Granting an exclusive use permission will prevent other businesses from supplying 2′-FL from this additional source in the short-term. However, granting of the exclusive use permission does not preclude any other business from applying to amend the Code in relation to the same ingredient. Therefore, the market for this additional source of 2′-FL could be opened during the 15 month exclusive use period for any other business willing to make an application. At the end of the exclusive use period all businesses will experience the same benefits. See Section 2.3.3 for further information.

There are not expected to be any significant costs for consumers. There are existing permissions in the Code for 2′-FL from other sources, therefore the exclusive use period is not expected to result in higher prices during the period.

Consumers may benefit from the availability of infant formula products containing 2′-FL, a beneficial human milk oligosaccharide. In the longer term, the addition of another source of 2'-FL could lead to savings for consumers if production costs are reduced and these are in part or in full passed on to them. By granting the exclusive use period requested by the applicant, FSANZ hopes to incentivise industry innovation. Consumers will benefit from these incentives where applications arise that otherwise would not have.

There are not expected to be any significant impacts for governments.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the applicant's 2′-FL to be used as a nutritive substance to infant formula products, most likely outweigh the associated costs.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ has also considered the 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2.2 of this report. Previous assessments found no safety concerns associated with the addition of 2′-FL to infant formula products. New information provided did not change this conclusion.

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

Current labelling requirements discussed in Section 2.3.5 will apply to the applicant's 2′-FL when used in infant formula products as a nutritive substance and will provide information to enable consumers to make an informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 2.3.5.3, which aim to prevent misleading or deceptive conduct, will apply to the applicant's 2′-FL when used in infant formula products as a nutritive substance.

2.5.3 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 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 and equivalent products; and several other foods across various countries around the world.

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

The approved permission will support an internationally competitive food industry in relation to the use of 2′-FL in infant formula products as a nutritive substance, 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' Meeting**

As part of A1277, 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 References

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. 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

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 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

Attachments

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

Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1277 – 2′-FL from GM *Escherichia coli* K-12 (gene donor: *Helicobacter enhydrae*) in infant formula products) Variation

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

Dated [To be completed by the Delegate]

[Insert 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 A1277 – 2′-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) 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 item dealing with 2′-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus)*

Omit "either *Helicobacter pylori* or", substitute "either *Helicobacter enhydrae*, *Helicobacter pylori*, or"

[2] Section S3—40

Omit "either *Helicobacter pylori* or", substitute "either *Helicobacter enhydrae*, *Helicobacter pylori*, or"

Schedule 26—Food produced using gene technology

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

Insert:

(d)	*Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand 2′-FL-Inbiose. 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 A1277 – 2′-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) in infant formula products) Variation* and ending 15 months after that date.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1277 – 2'-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) 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 A1277 which sought to amend the Code to permit 2′-fucosyllactose (2′-FL) produced from a new genetically modified (GM) strain of *Escherichia coli* K-12 to be used as a nutritive substance in infant formula products. The application also sought a 15 month exclusive use permission. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1277 - 2'-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) in infant formula products) Variation*.

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

2. Variation is a legislative instrument

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

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

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the

international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved 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. *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*, to be used as a nutritive substance in infant formula products subject to an exclusive use permission for a period of 15 months linked to the applicant's brand name '2′-FL-Inbiose'.
- Amend the current specification in Schedule 3 of the Code for 2′-FL sourced from *Escherichia coli* K-12 (section S3—40) to include 2′-FL from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* in the list of substances to which the specifications in section S3—40 apply.

4. Documents incorporated by reference

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

However, the approved draft variation varies 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 A1277 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment reports. Submissions were called for on 10 October 2023 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[10]. 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 and genetically modified food. This is because applications relating to permitting the use of nutritive substances and genetically modified food 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

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

statement was not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1277 – 2′-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) in infant formula products) Variation*.

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

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

Items [1] and [2] of the Schedule to the variation 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] amends the table to subsection S3—2(2). This table lists entries consisting of substances for which there are specifications in Schedule 3; and their associated provisions.

In particular, item [1] amends the entry in the table to subsection S3—2(2), which is associated with section S3—40 by inserting *Helicobacter enhydrae* as a source of 2′-FL produced from *Escherichia coli* K-12 in that entry. This amendment is consequential to the amendment in item [2] below.

Item [2] amends section S3—40, which sets out the specification for 2′-FL produced from specific sources of *Escherichia coli* K-12.

In particular, item [2] inserts '*Helicobacter enhydrae*' in the list of sources of 2′-FL produced from *Escherichia coli* K-12 for the purposes of that specification.

The effect of the amendments in items [1] and [2] is that 2′-FL produced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* will have to comply with the specification set out in section S3—40 when added to infant formula products for use as a nutritive substance (or sold for such use).

Item [3] of the Schedule to the variation amends 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 *Helicobacter enhydrae* 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] amends item 1 of that table by inserting new paragraph (d) into the column headed 'Source'. Item 1 of the table relates to 2′-FL. New paragraph (d) refers to:

'*Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*'.

Associated conditions of use for 2′-FL from this new source are 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 2′-FL-Inbiose and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (A1277 - 2′-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) in infant formula products) Variation* and ending 15 months after that date.

Condition 2 means that 2′-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* may only be sold under the brand '2′-FL-Inbiose' during the exclusive use period. 'Exclusive use period' is defined in condition 3 as the period commencing on gazettal of the draft variation and ending 15 months after that date.

The effect of the amendment in item [3] is that 2′-FL from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* is a 2′-FL permitted for use by Standard 1.5.2.is In other words, the sale and use of this 2′-FL as a food produced using gene technology is permitted, subject to the above conditions of use for the substance and in accordance with the Code.

Once the exclusive use period ends, the permission will revert to a general permission, meaning that the proposed permission will then permit the sale and use of 2′-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* under any brand.

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

The effect of the amendment in item [3] is also to permit 2′-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* to be used as a nutritive substance in infant formula products in accordance with the Code.

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.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

Food Standards (Application A1277 – 2′-FL from GM *Escherichia coli* K-12 (gene donor: *Helicobacter enhydrae*) in infant formula products) Variation

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

Dated [To be completed by the Delegate]

[Insert 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 A1277 – 2′-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) 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] Section S3—40

Omit "either *Helicobacter pylori* or", substitute "either *Helicobacter enhydrae*, *Helicobacter pylori*, or"

Schedule 26—Food produced using gene technology

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

Insert:

	(d) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand 2′-FL-Inbiose. 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 A1277 – 2′-FL from GM* Escherichia coli *K-12 (gene donor:* Helicobacter enhydrae*) in infant formula products) Variation* and ending 15 months after that date.