FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Attachment 1
Item 2.1
FSANZ VC 29 Oct 25

10 November 2025
[368-25]

Approval report – Application A1324

3-fucosyllactose as a nutritive substance in infant formula products

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Glycom A/S to amend the Australia New Zealand Food Standards Code to permit the use of 3-fucosyllactose (3-FL), a human-identical milk oligosaccharide (HiMO) produced using a genetically modified source organism, *Escherichia coli* K-12, as a nutritive substance in infant formula products.

On 11 June 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 8 submissions.

FSANZ approved the draft variation on 29/10/2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 10 November 2025.

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 A1324 page on the FSANZ website:

SD1 Risk, technical and benefit assessment – Application A1324 (at Approval)

The published submissions from the call for submissions can be found on the A1324 Consultation Hub page.

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Glycom A/S to amend the Australia New Zealand Food Standards Code (the Code) to permit 3-fucosyllactose (3-FL) produced from genetically modified (GM) *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori* to be used as a nutritive substance in infant formula products. The applicant has also requested an exclusive use permission under the brand name 'GLYCARE®' for a period of 15 months after gazettal of the approved draft variation.

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of 3-FL synthesised from the applicant's GM *E. coli* K-12 to infant formula products at levels up to 80 mg/100 kJ. The applicant's 3-FL is chemically, structurally and functionally identical to the naturally occurring 3-FL present in human milk.

The associated health benefits from the addition of 3-FL to infant formula products for infants include an increase in the abundance of *Bifidobacterium* species in the infant gut microbiota and anti-pathogenic effects.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 11 June 2025 to 23 July 2025. Eight submissions were received. Each was considered as part of our assessment.

For the reasons set out in this report, FSANZ has approved the draft variation proposed at the call for submissions with amendments. The purpose of the approved draft variation is to permit the use of 3-FL produced from GM *E. coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori* as a nutritive substance in infant formula products in accordance with the Code.

The approved draft variation will:

- Amend Schedule 29 of the Code to permit the applicant's 3-FL to be used in infant formula products as a nutritive substance at a maximum level of 80 mg/100 kJ.

- Amend Schedule 26 of the Code to list the applicant's 3-FL as a GM food permitted to be used in infant formula products for sale subject to certain conditions, including an exclusive use period of 15 months linked to the applicant's brand name 'GLYCARE®'.

- Insert a specification for the applicant's 3-FL into Schedule 3 of the Code, with which the applicant's 3-FL will have to comply when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

The effect of those amendments is that the applicant's 3-FL will be permitted to be used as a nutritive substance in infant formula products in accordance with the Code.

1 Introduction

1.1 The applicant

Glycom A/S, controlled by DSM-Firmenich AG, is a Danish food ingredient manufacturer who specialises in the development, synthesis and commercialisation of human-identical milk oligosaccharide (HiMO) substances.

1.2 The application

The purpose of this application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of 3-fucosyllactose (3-FL), a HiMO produced using a genetically modified (GM) source organism, *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*, in infant formula products.

3-FL is a non-digestible oligosaccharide that is a component of human milk. The applicant has applied to add its 3-FL, individually or in combination with other HiMO permitted in the Code, as a nutritive substance to infant formula products. The substance is not expressly permitted by the Code for use as a nutritive substance.

1.3 The current Standard

Australian 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

Revised regulation of infant formula products came into effect on 13 September 2024 and applies in Australia only.[2]

Infant formula products in Australia are regulated by Standard 2.9.1 which sets out specific 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)
- special medical purpose product for infants (from birth).

1.3.2 Permitted use

1.3.2.1 Genetically modified food

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

The applicant's 3-FL is a *genetically modified food* (section 1.1.2—16) as it is a food derived from an organism that contains novel DNA and does not fall within any of the exceptions listed in paragraph 1.1.2—16(1)(b). Consequently, express permission for the applicant's 3-FL to be used in infant formula products in accordance with the Code (or sold for such use) is required in accordance with section 1.5.2—3 (i.e. to be listed in Schedule 26 and to comply with any corresponding conditions including being added only to infant formula products).

[2] For further information on any relevant New Zealand standard see section 2.5.1.3.

Updated definitions for GM food, developed under Proposal P1055 – Definitions for gene technology and new breeding techniques, were gazetted on 2 September 2025. Prior to gazettal, substances such as the applicant's 3-FL were regulated as a *food produced using gene technology*, as described in the Application A1324 call for submissions.

Under the proposal, the definitions for *food produced using gene technology* and other related terms were repealed, with a new definition for *genetically modified food* inserted into the Code (see section 1.1.2—16). The table to Schedule 26 listing nutritive substances permitted for use in infant formula products was also renamed as a consequence of those changes. The term 'foods produced using gene technology' was replaced with 'genetically modified food'. No other amendments from this proposal impact the regulation of substances such as the applicant's 3-FL.

1.3.2.2 Nutritive substances

Paragraph 1.1.1—10(6)(b) 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 3-FL will 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 and it is a substance that will be identified in this Code as a permitted nutritive substance (see section 1.1.2—12(1)).

The applicant's 3-FL will be an optional nutritive substance used in infant formula products for the purposes of Standard 2.9.1 as food businesses will be able to decide whether to add the substance to those products. Addition of the applicant's 3-FL to infant formula products will not be a mandatory requirement in the Code.

Subsection 2.9.1—9(1) and section 2.9.1—37 provide for the use of optional nutritive substances in infant formula and in Special Medical Purpose Product for infants (SMPPi) respectively. Those provisions permit a substance listed in the table to section S29—7 to be used as a nutritive substance in infant formula and SMPPi provided that the amount of the substance in the formula (including any naturally-occurring amount) is no less than any corresponding minimum amount and no more than any maximum amount specified in the table.

Subsection 2.9.1—9(2) provides for the use of optional nutritive substances in follow-on formula. This provision permits a substance listed in the table to section S29—8 to be used as a nutritive substance in follow-on formula provided that the amount of the substance in the formula (including any naturally-occurring amount) is no less than any corresponding minimum amount and no more than any maximum amount specified in the table.

A substance used as a nutritive substance in infant formula, follow-on formula or SMPPi must be added in a permitted form. For nutritive substances that are not vitamins, minerals or electrolytes, paragraphs 2.9.1—10(b) (infant formula and follow-on formula) and 2.9.1—38(b) (SMPPi) provide that the permitted forms are listed in the table to section S29—9.

Therefore, express permission for the applicant's 3-FL to be used as a nutritive substance in infant formula products is also required in accordance with Standard 2.9.1, in addition to the above permission as a GM food.

1.3.3 Identity and purity

Section 1.1.1—15 requires that a substance *used as a nutritive substance* must comply with any relevant identity and purity specification in Schedule 3 when added to food in accordance with the Code or sold for use in food. There is no specification specifically

relevant for the applicant's 3-FL in Schedule 3 of the Code. The application provided a proposed specification for the applicant's 3-FL for this purpose.

1.3.4 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.

Division 3 of Standard 1.2.3 sets out the requirements for mandatory declarations of certain foods or their derivatives when they are present in a food for sale.

The Code requires food for sale to be labelled with a statement of ingredients in accordance with Standard 1.2.4. Subject to Division 3 of Standard 1.2.3, section 1.2.4—4 requires that ingredients be identified 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 in accordance with any conditions specified in that Schedule.

Standard 1.2.7 sets out the restrictions, requirements and conditions for making voluntary nutrition, health and related claims 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 the labelling requirements for genetically modified food.

Division 3 of Standard 2.9.1 contains the labelling and packaging requirements for infant formula and follow-on formula. This includes (among other things) an optional format for the statement of ingredients where a vitamin or mineral is added to the formula in accordance with section 2.9.1—8, and a mandated Nutrition Information Statement (NIS) which must contain specific information and be declared in a prescribed format.

Division 3 of Standard 2.9.1 also sets out what representations are prohibited for infant formula and follow-on formula. Paragraph 2.9.1—28(1)(i) prohibits the label on a package of infant formula or follow-on formula to contain (among other things) information relating to the presence of certain substances, including a substance used as a nutritive substance, except for a reference in a statement of ingredients, or in a declaration or statement expressly permitted or required by the Code, such as in the NIS. Paragraphs 2.9.1—28(1)(e) and (f) set out prohibited representations relating to 'human milk oligosaccharide' (HMO) and 'human identical milk oligosaccharide' (HiMO) (both words and abbreviations) or other words or abbreviations having the same or similar effect.

Labelling requirements that apply to SMPPi are set out in Division 4 of Standard 2.9.1. Some of these requirements are consistent with requirements for infant formula and follow-on formula. For example, paragraphs 2.9.1—45(c) and (d) set out prohibited representations relating to HMO and HiMO (both words and abbreviations), or other words or abbreviations having the same or similar effect. Some other requirements differ to the provisions for infant formula and follow-on formula. For example, subsection 2.9.1—53(1) specifies the nutrition information required to be declared for a SMPPi, including a substance used as a nutritive substance, expressed per given amount of the product.

1.4 International standards

In developing food regulatory measures, Food Standards Australia New Zealand (FSANZ) must have regard to the promotion of consistency between domestic and international food standards.

Internationally, 3-FL produced by microbial fermentation and by chemical synthesis is permitted for use in infant formula products, equivalent products and many other foods at a range of levels.

Codex Alimentarius (Codex) International Food Standards do not currently exist for 3-FL. However, the Codex Standards for 'Infant Formula and Formulas for Special Medical Purposes Intended for Infants' (Codex 2023a) and for 'Follow-up formula for Older Infants and Product for Young Children' (Codex 2023b) contain provisions for 'optional ingredients' which are applicable to 3-FL.

In the European Union (EU), the applicant's 3-FL from microbial fermentation with *E. coli* K-12 DH1 is permitted for use as a novel food ingredient, including in infant formula and follow-on formula at a level of 1.75 g/L (EU 2023).

In the UK, the applicant's 3-FL is permitted for use in infant formula and follow-on formula at a maximum level of 2.0 g/L under statutory instruments from England (2024 No. 685) (UK Government 2024a), Wales (2024 No. 741 (W. 102)) (UK Government 2024b) and Scotland (2024 No. 156) (UK Government 2024c).

In the United States (US), Glycom's 3-FL produced from *E. coli* K-12 DH1 that is the subject of the application has Generally Recognized as Safe (GRAS) status for use in infant formula at a level of 0.75 g/L in non-exempt formula for term infants in addition to a variety of other food uses. Notification of this conclusion was filed under GRAS Notice (GRN) 1037 and has received a letter of 'no questions' from the US Food and Drug Administration (FDA) (US FDA 2022).

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 was assessed under the General Procedure in accordance with the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve the draft variation proposed at the call for submissions with the following amendments:

- amending item [1] of the approved draft variation by adding the gene and donor organism used in the production of the applicant's 3-FL;

- amending item [2] of the approved draft variation by:
  - adding an entry for 'residual protein' and an associated specified limit in the new specification for 3-FL sourced from *Escherichia coli* K-12 (the reasons for this amendment are set out in section 2.3.5 of this report), and
  - adding the gene and donor organism used in the production of the applicant's 3-FL;

- amending item [3] of the approved draft variation by:

    - amending the title of Schedule 26 as a consequence of amendments made by Proposal P1055 – Definitions for gene technology and new breeding techniques, and
    - following clarification from the applicant—revising the brand name referred to in the second condition of use for the new entry of 3-FL which will be inserted into the table to subsection S26—3(7).

The approved draft variation 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.

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 11 June 2025 to 23 July 2025. Eight submissions were received (4 food industry, 2 government, one public health and one individual). The submissions are publicly available on the FSANZ website A1324 Consultation Hub page.

Six submitters supported FSANZ's assessment and/or draft regulatory measure and one submitter did not. One submitter listed their response as 'other' and provided general comments about HiMO permissions in the Code rather than commenting on the current regulatory decision. Submitters provided comments on FSANZ's assessment and/or the draft regulatory measure. FSANZ's responses to submitters comments are provided in Table 1.

Table 1: *Summary of issues*

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
In support of the regulatory amendments		
These submitters noted support for the proposed regulatory amendments based on the assessment of safety, nutrition and beneficial health effect.	a2MC, Glycom, Ind1, INC, Nestlé, NSW FA	FSANZ notes this comment.
HiMO as a nutritive substance in infant formula products		
The submitter noted that the term 'human milk identical' functions as a marketing tool rather than a scientific descriptor and that approving 3-FL may mislead health professionals and parents into believing formula can fully substitute for breastmilk.	LCANZ	FSANZ notes this comment. However, paragraphs 2.9.1—28(1)(e) and 2.9.1—28(1)(f) of the Code prohibit the use of the terms 'human milk identical' and 'human identical milk oligosaccharide', the abbreviations 'HMO' or HiMO', or words or abbreviations of similar effect on the label for infant formula products. See section 2.3.7.3 of this report.
The submitter noted that permitting novel synthetic ingredients in formula without risk communication or breastfeeding support policies risks sending mixed signals and that FSANZ's regulatory role must include safeguarding public health systems and breastfeeding promotion efforts.	LCANZ	FSANZ's functions, powers and obligations are set out in the FSANZ Act. Under that Act, the protection of public health and safety is the primary objective of FSANZ in developing, reviewing or varying food standards. Although breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breast milk is needed for infants who are not breastfed. Infant formula products are the only safe and suitable alternatives to breast milk (see Infant formula products). Other Australian government departments within the Health, Disability and Ageing portfolio have active roles in breastfeeding promotion efforts. The Department of Health, Disability and Ageing have developed the Australian National Breastfeeding

[3] Abbreviations: The a2 Milk Company Limited = a2MC; Glycom A/S = Glycom; Individual 1 = Ind1; Infant Nutrition Council = INC; Lactation Consultants of Australia and New Zealand = LCANZ; Nestlé Australia Ltd and Nestlé New Zealand Limited = Nestlé; New South Wales Food Authority = NSW FA; Queensland Health = QLD Health.

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
		Strategy in addition to educational resources for caregivers. The National Health and Medical Research Council have developed the Infant Feeding Guidelines and other publicly available resources.
The submitter noted that the chemical similarity of 3-FL does not equal biological function and that this compound cannot replicate the complexities and synergistic action of multiple human milk components.	LCANZ	FSANZ has assessed the functional effects of 3-FL compared to the same substance in human milk, and it has been found there are no differences (see section 4 of SD1). 3-FL naturally present in human milk is chemically identical to 3-FL produced from microbial and synthetic processes, and they have physiological effects in the gut which are indistinguishable i.e. they are the same. There is no reason to anticipate any unique physiological effects of 3-FL from a microbial source which is added at a level consistent with human milk.
Quality of evidence		
The submitters noted the limited available evidence, including long term studies, for the safety of 3-FL at the proposed maximum permitted level. The history of safe human exposure of 3-FL was acknowledged, however there was concern that studies reviewed in FSANZ's assessment contained 3-FL up to 0.8 g/L in combination with other HiMO.	LCANZ, NSW FA	FSANZ acknowledges that clinical studies investigating the use of 3-FL in infant formula products are limited, and that no studies have been conducted for 3-FL alone at the proposed maximum permitted level. However, FSANZ considers there are no safety concerns associated with its addition at the proposed level, and longer-term toxicity studies of 3-FL are not required. This conclusion is based on the following considerations: • 3-FL is identical to that found in human milk, and estimated dietary intakes at the proposed maximum permitted amount are comparable to intakes from naturally occurring 3-FL in human milk. This provides a history of safe use by human infants. • Intestinal absorption of 3-FL is limited and a large proportion passes to the large intestine, where it is fermented by the intestinal microbiota or excreted intact in the faeces.

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
		• 3-FL was tested in 90-day toxicity studies in rats. This time period in rats is equivalent to approximately 9 human years (Sengupta 2013[4]). • No adverse effects were observed at very high doses in 90-day oral toxicity studies with neonatal rats or in older rats, and there were no adverse effects in neonatal piglets given formula containing 2 g/L 3-FL. • The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has concluded that safety studies in very young animals are critical for substances used in infant formula. These studies provide a more complete evaluation of safety than human clinical studies. This is because they include detailed investigations that cannot be done in human studies, such as microscopic examination of organs and tissues. • In addition, neonatal rats are likely to be substantially more sensitive to any adverse health effects due to their relative gut immaturity compared to human neonates. • Clinical studies in human infants also found no adverse effects. • Clinical studies in humans found no difference in growth compared to control formula when 3-FL was used at concentrations up to 0.8 g/L. However, based on the limited absorption of 3-FL, and lack of effect at these levels FSANZ does not consider that infant formula products containing 3-FL at levels normally found in breastmilk are likely to have an effect on infant growth. This is further supported by post-marketing surveillance data from other countries, which have not identified any safety issues related to the use of 3-FL in combination with other HiMO.
The submitter noted the evidence to support the beneficial effects of	NSW FA	Human milk contains over 200 HMO, with 10 individual HMO

[4] Sengupta P (2013) The Laboratory Rat: Relating Its Age With Human's. International Journal of Preventive Medicine, 4(6):624-630.

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
3-FL is limited due to the lack of evidence solely investigating 3-FL. This issue also exists for existing HiMO permissions in the Code.		making up over 70% of the total HMO concentration (Soyyılmaz et al. 2021)[5]. These HMO play an important role in infant growth and development, particularly in supporting the maturation of the microbiota. Recent innovations have enabled the synthesis of key HiMO, biochemically identical to those found in human milk, such as the 3-FL requested by the applicant. FSANZ acknowledges that studying individual HiMO like 3-FL can be challenging due to their lower natural abundance and the complexity of human milk composition. However, consistent with other HiMO permitted in the Code, we assess the totality of evidence, including emerging data, mechanistic insights, and broader patterns of benefit to support informed and science-based decision-making.
Preparation of 3-FL		
The submitter noted they do not consider the final 3-FL product to be an enzyme preparation, as is noted in SD1, as the 3-FL is isolated through a series of purification steps.	Glycom	The sentence in section 3.1.1 of SD1 has been amended to reflect this submission.
The submitter considered that the use of genetically engineered *E. coli* in the production of a substance intended for infant consumption is concerning, especially in the absence of robust public understanding or informed consent from caregivers.	LCANZ	FSANZ has conducted a comprehensive safety assessment of the genetically modified (GM) *E. coli* used to produce the 3-FL intended for use in infant formula products. This assessment included a detailed evaluation of the genetic modifications introduced into the production organism, including the nature and stability of the modifications. The safety assessment concluded there are no safety concerns associated with the use of the GM *E. coli* as the production organism. Please refer to section 3.1.3 of the SD1. Furthermore, the 3-FL produced from the GM *E. coli* is chemically, structurally and functionally identical to the 3-FL naturally present in human milk with a history of safe use. The

[5] Soyyılmaz B, Mikš MH, Röhrig CH, Matwiejuk M, Meszaros-Matwiejuk A, Vigsnæs LK (2021) The Mean of Milk: A Review of Human Milk Oligosaccharide Concentrations throughout Lactation. Nutrients, 13(8):2737. doi:10.3390/nu13082737

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
		final product is highly purified, and does not contain any novel DNA, novel proteins, or GM microorganisms (see section 2.3.1 of SD1). As described in section 2.3.7.5 of this report, labelling the applicant's 3-FL as 'genetically modified' is only required in circumstances where novel protein or novel DNA were to remain present. Section 2.3.7 of this report outlines further labelling requirements that will apply for 3-FL when added to infant formula products. These requirements are designed to ensure that caregivers are provided with clear and accurate information to support informed decision-making.
Proposed anti-pathogenic effect		
The submitter disagrees with 'anti-pathogenic effect' being explored as a beneficial role of individual HiMO in the normal growth and development of infants and noted that FSANZ's assessment implies that an anti-infective effect relates to the prevention of infection, which is a therapeutic purpose, and blurs the boundary between food and medicine.	NSW FA	FSANZ notes this comment. The application sought a permission to add manufactured 3-FL to infant formula products for a specific nutritive purpose. That is, to more closely reflect the natural composition of breastmilk and associated benefits, particularly in the development of a gut microbiome closer to that of breastfed infants and by increasing the abundance of beneficial Bifidobacteria and decreasing pathogenic bacteria. FSANZ was required to assess the application in accordance with the FSANZ Act. That required FSANZ to assess whether the stated use of the 3-FL would achieve the stated nutritive purpose. In addition, the Ministerial Policy Guideline on the Regulation of Infant Formula Products issued by the FMM specifies that substances added to infant formula products should have either a technological function, or a beneficial role, with a determined physiological, biochemical or functional effect in the normal growth and development for infancy or childhood. This required FSANZ to assess whether the addition of the 3-FL to infant formula products would have such a beneficial effect, particularly the beneficial effect stated in the application.

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
		FSANZ's evidence-based assessment concluded that the stated use of the 3-FL would achieve the stated nutritive purpose and have the required beneficial effect (see section 4 of SD1). FSANZ notes that increased abundance of beneficial *Bifidobacterium* spp. in the infant gut microbiome and antipathogenic effects have previously been considered by FSANZ as beneficial health effects associated with the addition of HMOs to infant formula. See in this regard, the Approval and Review Reports for A1155 and the Approval Report for A1265. The FMM approved the A1155 and A1265 draft variations to the Code. FSANZ also notes that the Code as applied by the Food Acts prohibits a nutrition content claim, health claim or a therapeutic claim being made about an infant formula product.
Proposed maximum level of 3-FL		
The submitter noted that the proposed maximum level of 3-FL in infant formula products (2 g/L) is higher than the average, but within the recorded range naturally present in human milk. Requests FSANZ's assessment considers the implication of high 3-FL intakes at the proposed maximum level.	NSW FA	The proposed level of 3-FL does not raise public health and safety concerns. Appropriate toxicological studies, in combination with a history of safe use in human milk at this level, have demonstrated the safety of the addition of 3-FL to infant formula products at a level of 2 g/L, or 80 mg/100 kJ. The Ministerial Policy Guideline refers to breastmilk as the primary reference for determining the composition of infant formula products, and to take account levels of comparable substances in breastmilk (specific policy principles h and j). As described in section 3.3.9 of SD1, FSANZ's dietary exposure assessment did not consider intakes of 3-FL at the upper end of the range to be a concern due to variations in factors such as formula intakes, increases in body weight from infant growth, and breastfed infants consuming these levels of 3-FL in human milk containing naturally higher amounts.
The submitter noted that it is an industry decision to no longer add	NSW FA	The voluntary addition of ITF and GOS to infant formula products

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
inulin-type fructans (ITF) and galacto-oligosaccharides (GOS) to infant formula products, and requested information about how FSANZ will monitor international use of oligosaccharide permissions. Suggests setting a maximum limit for total added oligosaccharide amounts in infant formula products based on consistency with specific policy principles d), e) and h) of the Ministerial Policy Guideline.		is a longstanding permission and remains appropriate for use in infant formula products. Amending this permission is out of scope for this application. The permissions for HiMO in the Code allow for an alternative non-digestible oligosaccharide source for manufacturers, supporting international consistency and innovation opportunities. As described in section 2.3.4 of this report, the total carbohydrate content in infant formula products is calculated by difference based on the prescribed range of fat and protein, and energy density. The calculated carbohydrate range in infant formula products expressed as a percentage of energy density is 36 – 52%, with the calculated amount of HiMO expressed as a percentage of energy density being 1.9%, and 5.1% if ITF and GOS are added at the maximum permitted amount. Taking into consideration the additional carbohydrate sources added to infant formula products, the macronutrient distribution results in a limited allowance with which oligosaccharides can be added to the products. Setting a maximum limit for total added oligosaccharide amounts in infant formula products is out of scope for this application, particularly given the restrictions of the prescribed macronutrient distribution. The current regulatory option is also consistent with the principle of minimal effective regulation. Any change to the existing infant formula product composition permissions in the Code would require an application or proposal.
Specification		
The proposed specification in section S3—56 does not list the residual protein content of 3-FL as described in SD1 and requested revision of the proposed specification.	NSW FA, Glycom	FSANZ notes this comment. Item [2] of the approved draft variation in Attachment A of this report has been amended to list the residual protein content in the specification for this 3-FL.
The submitter noted that the proposed specification of 3-FL shows a mixture of multiple HiMO and requested that the issue of 'carry-over' substances is considered under Proposal P1024 - Revision of	NSW FA	FSANZ notes this comment. The nature of the assessment for Proposal P1024 is out of scope for this application.

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
the Regulation of Nutritive Substances and Novel Foods.		
Labelling		
The submitter requested clarification in section 2.2.8.5 of the call for submissions on whether the 3-FL would be exempt from GM labelling due to confirmation provided to FSANZ of the absence of residual DNA from the production organism.	Glycom	As stated in section 2.3.7.5 of this report, FSANZ has considered the available evidence about the presence of novel DNA or novel protein in infant formula products containing the applicant's 3-FL; and concluded that the presence of novel DNA or novel protein in those circumstances is highly unlikely. FSANZ is not responsible for determining whether novel DNA or novel protein would be present in food for sale.
Exclusive use permission		
The submitter clarified that the brand name of the 3-FL product is GLYCARE®, rather than GlyCare®.	Glycom	The brand name 'GLYCARE®' has been amended throughout this report, including in item [3] of the approved draft variation at Attachment A of this report.
The exclusive use period requested by the applicant undermines equitable access to infant nutrition, potentially increasing costs and restricting consumer choice, particularly for low-income families.	LCANZ	The granting of an exclusive use permission does not preclude anyone else from applying for permission to add their HiMO, including 3-FL, to infant formula products, including within the 15 month exclusive permission period (see Exclusivity of use for novel foods and nutritive substances). Further, the approved draft variation relates to an ingredient that infant formula product manufacturers may purchase. The variation does not apply any restrictions on who may purchase the applicant's 3-FL during the 15 month exclusive use period.
A1155 Five Year Review		
The submitter acknowledged the A1155 Five Year Review and principle (j) of the Ministerial Policy Guideline and noted that the scope of the Five Year Review should be extended to review all currently permitted HiMO, individually and in combination.	QLD Health	On 27 November 2020, the Food Ministers' Meeting (FMM) agreed to permit the voluntary addition of 2′-fucosyllactose (2′-FL) alone or in combination with lacto-N-neotetraose (LNnT) in infant formula products in the Code. In conjunction with this decision, the FMM requested a review of the permission within 5 years from gazettal (26 March 2021) to determine whether there

Issue	Raised by[3]	FSANZ response (including any amendments to drafting)
		continues to be sufficient evidence of a 'substantiated beneficial role in the normal growth and development of infants, or a technological role', as per the Ministerial Policy Guideline. The scope of that review is restricted to that permission and extending the scope to 3-FL is a matter for the FMM. FSANZ is progressing work on this review as prescribed by the FMM, and will await confirmation on the outcomes following notification to the FMM by the requested date of 26 March 2026.
New Zealand standards		
The submitter acknowledged the proposed amendment to the Code in relation to infant formula products will apply to Australia only. However, proposed amendments to Schedule 3 and Schedule 26 are joint standards that apply to both Australia and New Zealand, and the New Zealand Government may refer to these in relation to infant formula standards.	INC	See section 2.5.1.3 of this report.
The submitter noted the statement at clause 2.4.1.3: "*There are no relevant New Zealand Standards*" and requests that FSANZ take into consideration the New Zealand domestic standard, as per the obligations of the FSANZ Act.	a2MC	

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with the voluntary addition of 3-FL as a nutritive substance for use in infant formula products up to a maximum permitted amount of 80 mg/100 kJ (2 g/L). The applicant's 3-FL is produced by microbial fermentation from a GM strain of *E. coli* K-12. FSANZ has undertaken an assessment of the food technology, safety and beneficial health effects of the addition of 3-FL to infant formula products.

The applicant's 3-FL is chemically, structurally and functionally identical to the naturally occurring 3-FL present in human milk. Results from a 2-year accelerated trial indicate the applicant's 3-FL is stable under ambient storage conditions, reflecting the typical stability and storage conditions for an infant formula product. Further, interim results from an ongoing 5-year ambient shelf-life trial also indicate the applicant's 3-FL is stable under ambient storage conditions.

The microbiological risk assessment undertaken by FSANZ did not identify any public health and safety concerns associated with the use of *E. coli* K-12 as a production organism for 3-FL. Characterisation of the GM production strain confirmed that the introduced alpha-1,3-fucosyltransferase gene is both genetically stable and functional.

3-FL's presence in human milk provides a history of safe human exposure. Estimated dietary intakes of 3-FL from infant formula products at the proposed maximum permitted amount are comparable to intakes from naturally occurring 3-FL in human milk.

Overall, the available data indicate that intestinal absorption of human milk oligosaccharides, including 3-FL, is limited. A significant proportion reaches the large intestine where they are fermented by the microbiota or excreted unchanged in the faeces. *In vitro* and *in vivo* studies demonstrated that 3-FL does not pose a concern for genotoxicity. No adverse effects were observed in a 90-day oral toxicity study in neonatal rats at doses up to 4000 mg/kg bw/day, or in older rats at doses ≥ 5900 mg/kg bw/day. There were no adverse effects in neonatal piglets given formula containing up to 2 g/L 3-FL for 21 days.

In 3 human clinical studies with infants, formula containing 0.24 to 0.8 g/L of 3-FL in combination with other human-identical milk oligosaccharides (HiMO) (with or without probiotics) was safe, well tolerated and did not affect growth.

Post-marketing surveillance data from other countries have also found no safety concerns from consumption of infant formula products containing 3-FL in combination with up to 5 other HiMO.

Given the absence of any identifiable hazard in toxicological and clinical studies, and noting that estimated dietary intakes of 3-FL from infant formula products are comparable to intakes from human milk, there are no safety concerns from the addition of 3-FL to infant formula products at the proposed maximum permitted amount.

The weight of evidence supports plausible biological mechanisms and the potential for beneficial effects of 3-FL added to infant formula products through an increase in the abundance of *Bifidobacterium* spp. in the infant gut microbiota and anti-pathogenic effects. The inclusion of a wider range of HiMO in infant formula products is likely to support the development of a healthy microbiota.

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.

2.3.1 Risk management options

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 11 June 2025 to 23 July 2025 (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 the draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

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 amendment.

2.3.2 Use as a nutritive substance in infant formula products

In considering the proposed permission, FSANZ acknowledges that breastfeeding is the recommended way to feed infants and the intent of Standard 2.9.1 is not to replace human milk but to provide a safe, nutritionally replete, functional alternative for where breastfeeding is not possible. Given this, and in accordance with the Ministerial Policy Guideline on the regulation of infant formula products[6], the composition of infant formula products should as closely as possible aim for nutritional equivalence to human milk.

To assess the suitability of compositional changes to the Code, FSANZ recognises the importance of demonstrating a link between physiological, biochemical or functional effects of the proposed ingredient to specific health outcomes for formula-fed infants, with appropriate evidence, and to use human milk as the primary reference for determining the composition of infant formula products as per specific policy principles (d) – (h) of the Ministerial Policy Guideline.

The applicant's 3-FL is manufactured using processes that are used for the manufacture of other HiMO currently permitted in the Code. As noted in section 1.4 of this report, infant formula products containing 3-FL are already available in overseas markets.

The technical, safety and health effects assessment (SD1) concluded there are no public health and safety concerns associated with the addition of the applicant's 3-FL to infant formula products at the level proposed, which is comparable to that of human milk.

FSANZ's assessment of potential health effects of 3-FL was consistent with assessments undertaken previously for similar types of substances. In previous applications (A1155, A1190, A1233, A1265), FSANZ considered the weight of available evidence when assessing the beneficial role of the HiMO in the normal growth and development of infants.

The nutritional purpose for adding 3-FL to infant formula products is to create products that better reflect the oligosaccharide profile of human milk. A demonstratable health outcome in

[6] Ministerial policy guideline on the regulation of infant formula products

conjunction with bringing the composition of infant formula products closer to that of human milk reflects the primary purpose of consumption in supporting the development of infants that cannot be breastfed. In line with specific policy principle (j) of the Ministerial Policy Guideline, FSANZ has considered these requirements in assessing each of the beneficial health effects of 3-FL as stated in the application (i.e. increased bifidogenic effect and an anti-pathogenic effect).

Overall, FSANZ's assessment found that 3-FL is a safe and suitable ingredient in infant formula products, and that its proposed use as a nutritive substance in infant formula products is associated with beneficial health outcomes.

2.3.3 Regulatory approval

Application A1324 requested an amendment to the Code to permit the use of 3-FL produced from GM *E. coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori* as a nutritive substance in infant formula products.

The approved draft variation will list 3-FL as an optional nutritive substance in infant formula products in the table to sections S29—7 and S29—8, with '3-fucosyllactose' listed as the permitted form of this 3-FL in the table to section S29—9. The approved draft variation will also list *E. coli* K-12 containing the gene for alpha-1,2-fucosyl-transferase from *H. pylori* as a source of 3-FL in the table to subsection S26—3(7).

The approved draft variation will therefore have the effect of permitting this 3-FL, which is also a GM food, to be used as a nutritive substance in infant formula products in accordance with the Code. This approach is consistent with FSANZ's risk and technical assessment and the evidence base supporting 3-FL as a nutritive substance.

2.3.4 Total oligosaccharide amounts and cumulative effect

The approved draft variation will amend the Code to permit a new oligosaccharide to be used as a nutritive substance in infant formula products. This substance will be permitted to be added either as a single ingredient, or as a mixture with other permitted HiMO (Table 2). The proposed maximum amount of 3-FL in infant formula products is consistent with the concentration in human milk (see section 3.3.5 of SD1).

As reported in the Application A1265 Approval Report, the lower limit of average total oligosaccharide concentration in mature human milk ranges 10 – 15 g/L, or 0.34 – 0.51 g/100 kJ (FSANZ 2023). This information remains relevant for this application. The total amount of HiMO permitted to be added to infant formula products is the combined maximum amount of 3-FL, 2′-fucosyllactose (2′-FL) or 2′-FL/ lacto-N-neotetraose (LNnT) or 2′-FL/ difucosyllactose (DFL), lacto-N-tetraose (LNT), 6′-sialyllactose (6′-SL) sodium salt and 3′-sialyllactose (3′-SL) sodium salt. This totals 0.23 g/100 kJ, which is less than the total in human milk.

When considering the addition of the maximum permitted inulin-type fructans (ITF) and galacto-oligosaccharides (GOS) amounts, this total equals 0.63 g/100 kJ. As discussed in the A1265 Approval Report, the technology to produce synthetic HMO remains expensive and if used as a sole source of oligosaccharides in infant formula products could result in prohibitive prices for consumers (FSANZ 2023). However, as the biochemically and functionally identical HiMO become more available, it is anticipated that ITF and GOS will become an unnecessary component of infant formula products.

Table 2: ***Summary of infant formula product oligosaccharide permissions, including the proposed 3-FL***

Oligosaccharide	Maximum amount (mg/100 kJ)	Amount expressed as %Energy
3-FL	80	0.6
2′-FL or 2′-FL/LNnT or 2′-FL/DFL	96	0.8
LNT	32	0.3
6′-SL sodium salt	16	0.1
3′-SL sodium salt	8	0.1
Total HiMO	232	1.9
ITF	110	0.9
GOS	290	2.3
Total oligosaccharides	632	5.1

Based on the permissions listed in Table 2, total added oligosaccharides would be a small component of the total carbohydrate content. Total carbohydrate content in infant formula products is calculated by difference based on the prescribed range of fat and protein, and energy density (FSANZ 2024). The calculated carbohydrate range in infant formula products expressed as a percentage of the energy density is 36 - 52% (see Appendix 1 of the A1265 Approval Report) (FSANZ 2023). The calculated amount of oligosaccharides expressed as a percentage of the energy density would be 1.9% for HiMO and 5.1% if ITF and GOS are added at the maximum permitted amount, which contributes only a fraction to the total carbohydrate content.

These calculations demonstrate that the potential cumulative increase from the addition of 3-FL to the total oligosaccharide load consumed by infants is aligned with human milk, poses no safety or public health risks, and complies with carbohydrate permissions for infant formula products.

2.3.5 Specification

Section 1.1.1—15 requires that a substance used as a nutritive substance must comply with any relevant identity and purity specification in Schedule 3 when added to food in accordance with the Code or sold for use in food. The approved draft variation will insert a new specification relating specifically to the applicant's 3-FL sourced from *E. coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori* into Schedule 3, which this 3-FL will have to comply with when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use) (see section 2.3 and Table 3 of SD1). This specification will only apply to 3-FL sourced from *E. coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori*.

The proposed specification at the call for submissions did not include the gene (alpha-1,3-fucosyl-transferase) and donor organism (*H. pylori)* for the applicant's 3-FL. This editorial amendment has been made in Attachment A to ensure clarity and consistency in the identification of the gene and donor organism for this 3-FL permission, and any future 3-FL permissions in the Code.

The proposed specification in Table 3 of SD1 at the call for submissions included a limit for residual proteins which was inadvertently omitted from the proposed draft variation (see Attachment C of this report). The specification in the draft variation proposed in the call for submissions has been amended to include the residual protein content. The approved draft variation is in Attachment A.

2.3.6 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[7].

The applicant requested an exclusive use permission for their specific brand of 3-FL.

FSANZ has decided to grant the applicant a 15-month exclusive use permission for this 3-FL commencing on the date of gazettal of the approved draft variation.

This means that, during the 15-month exclusive use period, this 3-FL may only be sold for the purpose of being used as a nutritive substance in infant formula products in accordance with the Code under the brand name 'GLYCARE®'.

Once the 15-month exclusive use period ends, the exclusive use permission will revert to a general permission, meaning that this 3-FL may be sold for the purpose of being used as a nutritive substance in infant formula products in accordance with the Code under any brand name.

An exclusive use permission in the Code does not and cannot prevent approval of second or subsequent applications either within the 15-month 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.

2.3.7 Labelling

Division 3 of Standard 2.9.1 provides specific labelling requirements for infant formula and follow-on formula. Labelling requirements that apply to SMPPi are set out in Division 4 of the same Standard. FSANZ refers to the relevant requirements below that will apply to the applicant's 3-FL if it is added to an infant formula product.

2.3.7.1 Statement of ingredients

Standard 1.2.4 requires food for sale to be labelled with a statement of ingredients unless exempt.

Infant formula and follow-on formula

The label on a package of infant formula or follow-on formula must contain a statement of ingredients in accordance with Standard 1.2.4. Should manufacturers choose to add the applicant's 3-FL to infant formula or follow-on formula in accordance with the Code, then the 3-FL will have to be declared in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require that, subject to Division 3 of Standard 1.2.3, ingredients 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* in accordance with any conditions specified in that Schedule.

A generic ingredient name for 3-FL has not been specified in Schedule 10. These ingredient

[7] Exclusivity of use for novel foods and nutritive substances

naming requirements will apply to the applicant's 3-FL, enabling industry to have flexibility in how they declare this ingredient (e.g. using the name '3-fucosyllactose'). It should be noted existing prohibited representations for infant formula and follow-on formula in paragraphs 2.9.1—28(1)(e) and (f) also apply to the ingredient name (refer to section 2.3.7.3 below) in relation to those products.

SMPPi

Section 2.9.1—51 sets the requirement for information relating to ingredients in SMPPi. This section specifies that ingredient information may be provided on the label of a package of SMPPi in a statement of ingredients (in accordance with the Code), or ingredient information that complies with either the EU or US regulations. These regulatory labelling requirements are intended to facilitate the importation of highly specialised SMPPi that are manufactured in low volumes in Europe and in the United States. Therefore, for the use of the applicant's 3-FL in SMPPi, the ingredient naming requirements of the Code or the EU or US will apply.

2.3.7.2 Mandatory nutrition information

Infant formula and follow-on formula

Section 2.9.1—24 regulates the declaration of nutrition information in a NIS on the label of a package of infant formula or follow-on formula. The NIS is a single statement in which certain information is declared in accordance with section 2.9.1—24, and which must be in the form of a table, as specified in the table to section S29—10 in accordance with section 2.9.1—25.

Subparagraph 2.9.1—24(3)(e)(i) requires the average quantity of any substance used as a nutritive substance (including any naturally-occurring amount) in infant formula and follow-on formula to be declared in the NIS expressed in grams, micrograms or milligrams per 100 mL of formula. Therefore, the applicant's 3-FL will have to be declared accordingly in the NIS when it is used in infant formula or follow-on formula. Subsection 2.9.1—25(3) requires the declaration to be made under the heading 'Additional' in the NIS, using the same format as specified in the table to section 29—10.

SMPPi

Paragraph 2.9.1—53(1)(c) requires the declaration of a substance used as a nutritive substance in a SMPPi and added to that product to achieve that product's intended medical purpose, to be expressed per given amount of the product. Should manufacturers choose to add the applicant's 3-FL to an SMPPi, this provision will apply. However, there are no formatting requirements for this nutrition information, as labelling provisions for SMPPi are generally more flexible compared to infant formula and follow-on formula to ensure the importation of SMPPi is not impeded, noting the majority of these products are not manufactured in Australia.

2.3.7.3 Prohibited representations and prohibited claims

Infant formula and follow-on formula

Paragraph 2.9.1—28(1)(e) prohibits the use of the words 'human milk oligosaccharide', 'human identical milk oligosaccharide' or any word or words having the same or similar effect on the label of a package of infant formula or follow-on formula. In addition, paragraph 2.9.1—28(1)(f) prohibits the use of the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect on the label of a package of infant formula or follow-on formula.

Paragraph 2.9.1—28(1)(i) prohibits information relating to the presence of (among other things) a nutritive substance on the label of a package of infant formula or follow-on formula, except for a reference in a statement of ingredients or in a declaration or statement expressly permitted or required by the Code, such as a NIS.

SMPPi

Paragraphs 2.9.1—45(c) and (d) prohibit the use of HMO and HiMO terminology and abbreviations in the same manner as for infant formula and follow-on formula (see above).

Subsections 2.9.1—46(1) and (2) set out explicit prohibitions for:

- claims that –
    - refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition, or
    - compare the product with a good that is:
        - represented in any way to be for therapeutic use, or
        - likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason, and
- nutrition content and health claims.

These prohibitions will apply in relation to the applicant's 3-FL where it is used as a nutritive substance in SMPPi. However, the prohibitions will not apply in relation to:

- a claim that is expressly permitted by this Code, or
- a declaration that is required by an application Act [8].

2.3.7.4 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. This prohibition will apply to all infant formula products that contain the applicant's 3-FL.

Subparagraph 2.9.1—46(2) explicitly states that a nutrition content claim or health claim must not be made about a SMPPi.

2.3.7.5 Labelling as 'genetically modified'

The applicant states the production organism *E. coli* K-12 is removed during the processing and purification steps during the production of 3-FL (see section 2.3.1 of SD1). Considering the supplied data and previous FSANZ assessments of similar HiMO substances, it is considered highly unlikely that novel DNA or novel protein from the production organism would be present in an infant formula product containing the applicant's 3-FL as an ingredient. However, under circumstances where novel protein or novel DNA were to remain present, the requirement to label the 3-FL ingredient as 'genetically modified' would apply in accordance with section 1.5.2—4.

2.3.8 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has decided to approve the draft variation proposed at the call for submissions with amendments (see section 1.7 of this report), to permit the use of 3-FL from *E. coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori* as a nutritive substance in infant formula products.

[8] An Act or Ordinance of the Commonwealth, or of a State or Territory under which the requirements of the Code are applied.

The applicant's 3-FL will be subject to relevant requirements and conditions in the Code, which include the following:

- It may be voluntarily added to infant formula products up to a maximum level of 80 mg/100 kJ in combination with other HiMO permitted in the Code.

- The existing prohibition for the use of the words 'human identical milk oligosaccharide' or 'human milk oligosaccharide', the abbreviations 'HMO' and 'HiMO', or any word or words, or abbreviation or abbreviations, having the same or similar effect, will apply to infant formula products that contain the applicant's 3-FL.

- An exclusive use permission to use 3-FL produced using *E. coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *H. pylori* will apply for a period of 15 months, linked to the applicant's brand name, 'GLYCARE®', commencing on the date of gazettal of the approved draft variation.

- Schedule 3 of the Code will set a specific specification for the applicant's 3-FL, with which it must comply when used as a nutritive substance in infant formula products in accordance with the Code (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. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's digital channels and Food Standards News.

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 received during the call for submissions period.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

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:

2.5.1.1 Consideration of costs and benefits

Background to the consideration of costs and benefits

Section 29 of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from a 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).

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo.

A regulation impact statement (RIS) has not been prepared for this application. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor in impact and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Therefore, FSANZ's assessment is that a RIS is not required for this application.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Consumers

The permission to add 3-FL to infant formula products has been assessed in Australia only (see section 1.3.1 and 2.5.1.3).

On the basis of the findings of the risk assessment (see section 2.2 of this report and SD1), FSANZ considers the use of 3-FL as a nutritive substance in infant formula products to be safe for the proposed purpose. Therefore, no negative impacts are expected.

FSANZ's assessment also found that the use of 3-FL as a nutritive substance in infant formula products would have a beneficial health outcome (see section 2.2 of this report and SD1).

The applicant requested an exclusive use permission for their specific brand of 3-FL. FSANZ will provide the applicant with a 15-month exclusive use permission for this 3-FL commencing on the date of gazettal of the approved variation.

It is possible that industry may achieve some price premium for this product in the short-term, impacting consumers. However, historically, price premiums typically exist for a short period before useful innovations become a standard feature across the market meaning better quality products for consumers at a similar or sometimes lower price.

The purpose of granting an exclusive use permission for a specified period of time (the exclusive use period) 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 permission could come at the expense of consumers in the short-term, through other businesses not being able to compete to supply the applicant's 3-FL in infant formula products at lower prices during the exclusive use 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 as more products come to market that may benefit them.

Industry
The permission to add 3-FL will apply to infant formula products manufactured and /or sold in Australia only (see section 2.5.1.3 below).

Domestic manufacturers (and exporters to Australia) of infant formula products that contain the applicant's 3-FL will be permitted to sell their products in Australia (where the products

fully comply with the Code), subject to the exclusive use permission described above.

Given the applicant's 3-FL is already approved in some overseas countries (see section 1.4), the permission may support additional exports. However, producers of infant formula products may also face greater competition from formula produced overseas.

Granting an exclusive use permission will prevent other businesses from producing the applicant's 3-FL in the short-term. 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.

Government

The approval of this application may result in a small but likely inconsequential cost to Australian governments in terms of monitoring for compliance.

Conclusion

FSANZ's assessment is that the direct and indirect benefits that will arise from permitting the applicant's 3-FL are likely to outweigh the associated costs.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

New Zealand opt-out of the joint infant formula standard

Paragraph 29(2)(c) of the FSANZ Act requires FSANZ to have regard to any relevant New Zealand standards.

As explained above, the approved draft variation will amend Schedule 29 of the Code to provide a new permission for 3-FL to be added as a nutritive substance for the purposes of Standard 2.9.1 of the Code.

Standard 2.9.1 of the Code is an Australian only standard. Schedule 29 of the Code lists the compositional requirements (e.g. permissions, limits, calculations, permitted forms etc.) for the purposes of that Australia only Standard 2.9.1, as well as Standards 2.9.2 to 2.9.5 of the Code. Standards 2.9.2 to 2.9.5 are joint standards that apply in both Australia and New Zealand.

Standard 2.9.1 as it was in force immediately prior to the gazettal of the variations made by Proposal P1028 remains in force in New Zealand as part of New Zealand law (the New Zealand standard) (i.e. as it previously had been adopted by the New Zealand Government under the *Food Act 2014* (NZ) and no action has been taken to date by that Government to amend or revoke it under section 400 of that Act).

The New Zealand standard is not part of the Code for the purposes of the FSANZ Act, nor is it covered by the 'Australia New Zealand Food Standards System' established by the Treaty and for which FSANZ is authorised to develop draft standards in accordance with the FSANZ Act.

FSANZ also understands that the consequential amendments made by Proposal P1028 to

Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5, and Schedules 8, 15, 19, 25 and 29 of the Code have not been adopted in New Zealand under the *Food Act 2014* (NZ).

The application, interpretation and amendment of the New Zealand standard is a matter for the New Zealand Government.

Approved draft variation's amendment of Schedules 3 and 26 of the joint Code

The approved draft variation will also amend Schedules 3 and 26 of the Code.

Genetically modified foods, such as the applicant's 3-FL, must also be permitted by Standard 1.5.2 and Schedule 26 in order to be used as a nutritive substance in infant formula products. For this reason, the approved draft variation will amend Schedule 26 of the Code to list the applicant's 3-FL as a genetically modified food subject to conditions of use, including that it may only be added to infant formula products.

Schedule 26 of the Code is a joint standard that applies in Australia and New Zealand.

The extent to which the New Zealand standard will permit the use of the applicant's 3-FL as a nutritive substance in infant formula products in New Zealand remains a matter for the New Zealand Government.

The approved draft variation will also amend Schedule 3 of the Code to insert a new specification for the applicant's 3-FL. The applicant's 3-FL will have to comply with this specification when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

Section 1.1.1—15 of the Code provides that food additives, processing aids, nutritive substances and novel foods must comply with a relevant specification in Schedule 3 when added to food in accordance with the Code (i.e. a joint standard), or when sold for such use.

Standard 1.1.1 and Schedule 3 of the Code are joint standards that apply in both Australia and New Zealand.

FSANZ is not aware of any provisions of the joint Code that currently permit the use or sale or the applicant's 3-FL as a food additive, processing aid, nutritive substance or novel food.

The application of the specification in the approved draft variation to and in New Zealand remains a matter for the New Zealand Government.

Advice about the application of the approved draft variation to infant formula products sold in New Zealand can be obtained from the New Zealand Ministry for Primary Industries.

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 three 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 risk and technical assessment (see section 2.2 of this report and SD1)

and concluded there is no evidence of a public health and safety concern associated with the addition of the applicant's 3-FL to infant formula products at the proposed maximum amount of 80 mg/100 kJ.

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

Current labelling requirements outlined in section 2.3.7 of this report will apply to infant formula products containing the applicant's 3-FL and will provide adequate 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 2.3.7.3, which aim to prevent misleading or deceptive conduct, will apply to infant formula products containing the applicant's 3-FL.

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 has used the risk analysis framework[9] and considered the best scientific evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the applicant's 3-FL in infant formula products.

- **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. 3-FL is permitted in infant formula equivalent products in various countries around the world.

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

The approved draft variation will support an internationally competitive food industry in relation to the use of 3-FL in infant formula products as a nutritive substance.

- **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**

FSANZ has regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. Two Ministerial Policy Guidelines specifically apply to this application:

- Regulation of Infant Formula Products

- Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods

Noting the food technology aspects, safety, nutritional impact and beneficial health effects

[9] Risk analysis and assessment | Food Standards Australia New Zealand

assessed in SD1 and section 2.2 of this report, FSANZ considers these Policy Guidelines have been met.

3 References

Codex (2023a) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. Codex CXS 72-1981. Codex Alimentarius Commission, Rome. Available online 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 (2023b) Standard for Follow-up formula for Older Infants and Product for Young Children. Codex CXS 156-1987. Codex Alimentarius Commission, Rome. Available online at: 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

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UK Government (2024c) The Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Scotland) Regulations 2024. Scottish Statutory Instruments No. 156. Available online at: https://www.legislation.gov.uk/ssi/2024/156/contents/made

US FDA (2022) Agency Response Letter GRAS Notice No. GRN 1037 (3-fucosyllactose, Hørsholm, Denmark: Glycom A/S). Silver Spring (MD): US Food and Drug Administration (US FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety. Available online at: https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=1037

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 Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance 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 A1324 – 3-fucosyllactose as a nutritive substance 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, after the table item dealing with 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*)

Insert:

3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*	section S3—56

[2] After section S3—55

Insert:

S3—56 Specification for 3-fucosyllactose sourced from *Escherichia coli* K-12

For 3-fucosyllactose (3-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*, the specifications are the following:

(a) chemical name—β-D-Galactopyranosyl-(1-4)-[α-L-fucopyranosyl-(1-3)]-D-glucose;

(b) chemical formula—$C_{18}H_{32}O_{15;}$

(c) molecular weight—488.44 g/mol;

(d) CAS number—41312-47-4;

(e) description—white to off-white powder or agglomerates;

(f) sum of saccharides (3-FL, D-lactose, L-fucose, 3-fucosyl-lactulose)—not less than 92.0% (water free);

(g) 3-FL—not less than 90.0% (water free);

(h) L-fucose—not more than 1.0%;

(i) D-lactose—not more than 5.0%;

(j) 3-fucosyllactulose—not more than 1.5%;

(k) Sum of other carbohydrates—not more than 5.0%;

(l) pH (20°C, 5% solution)—3.2 to 7.0;

(m) water—not more than 6.0%;

(n) ash, sulphated—not more than 0.5%;

(o) residual proteins—not more than 0.01%;

(p) lead—not more than 0.05 mg/kg;

(q) microbiological:

(i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;

(ii) *Enterobacteriaceae*—absent in 10 g;

(iii) yeasts—not more than 100 cfu/g;

(iv) moulds—not more than 100 cfu/g;

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

Schedule 26—Genetically modified food

[3] Subsection S26—3(7) (table)

Insert:

8	**3-fucosyllactose**	*Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GLYCARE®. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.

Schedule 29—Special purpose foods

[4] Section S29—7 (table, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg

[5] Section S29—8 (table, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg

[6] Section S29—9 (table, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	3-fucosyllactose

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance 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 A1324 which seeks to amend the Code to permit the use of 3-fucosyllactose (3-FL), a human-identical milk oligosaccharide (HiMO) produced using a genetically modified (GM) source organism, *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 in relation to that substance. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation* (the approved draft variation).

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

- Amend Schedule 29 of the Code to permit the use of 3-FL as a nutritive substance in infant formula products at a maximum level of 80 mg/100 kJ
- Amend Schedule 26 of the Code to permit 3-FL produced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori*, to be added to infant formula products subject to certain conditions, including an exclusive use period of 15 months linked to the applicant's brand name 'GLYCARE®'.
- Insert a new specification for this 3-FL into Schedule 3, with which this 3-FL will have to comply when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

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 of the Code when added to food in accordance with the Code or sold for use in food.

Schedule 3 incorporates documents by reference to set specifications for various substances in accordance with requirements 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 A1324 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 11 June 2025 for a 6-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) has not been prepared for this application. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor in impact and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Therefore, FSANZ's assessment is that a RIS is 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

A reference to 'the variation' in this section is a reference to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance 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]

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 subsection S3—2(2) by inserting, after the table item dealing with 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli* K-12, a new entry for '3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*' and a corresponding reference to new section S3—56 (see item [2] below).

Item [2] inserts a new section S3—56 after section S3—55. The new section sets out the specifications relating specifically to '3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*', the new substance sought to be permitted by the applicant.

Consequently, 3-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori* must comply with these specifications when used in infant formula products as a nutritive substance in accordance with the Code (or sold for such use).

Item [3]

Item [3] of the Schedule to the variation amends Schedule 26 of the Code.

Schedule 26 relates to GM food. 3-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori* is a GM food (as defined in section 1.1.2—16 of the Code) because it is a food derived from an organism that contains novel DNA and does not fall within any of the exceptions listed in that section.

Paragraphs 1.1.1—10(5)(c) and (6)(g) of the Code prohibit food for sale from being, or having as an ingredient or a component, a GM food unless expressly permitted by this Code.

Section 1.5.2—3 permits a food for sale to contain, or consist of, a GM food if that GM food is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule.

The table to subsection S26—3(7) lists permitted GM food of microbial origin.

Item [3] amends that table by adding the following entry as new item 8 in that table:

- '3-fucosyllactose' in column 1;
- '*Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori*' in column 2; and
- associated conditions of use in column 3.

Associated conditions for the use of 3-FL from this source are 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 GLYCARE®; and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.

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

Once the exclusive use period ends, the exclusive use permission will revert to a general permission, meaning that 3-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori* may be sold under any brand.

The effect of the amendment in item [3] is to permit the sale and use of the substance, 3-FL from *Escherichia coli* K-12 containing the gene for alpha 1,3-fucosyltransferase from *Helicobacter pylori* as a GM food in accordance with the Code, subject to the above conditions for use for the substance.

The amendment made by item [3] does not make any substantive change to *existing* permissions and to other requirements in the Code relating to GM food.

Items [4], [5] and [6]

Items [4], [5] and **[6]** of the Schedule to the variation amend Schedule 29 of the Code.

Item [4]

Subsection 2.9.1—9(1) and section 2.9.1—37 provide for the use of optional nutritive substances in infant formula and special medical purpose product for infants respectively. Those sections provide that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in infant formula and special medical purpose product for infants, provided the amount of the substance in the product (including any naturally-occurring amount) is no less than any minimum amount specified in Column 2 of the table; and no more than any maximum amount specified in Column 3 of the table.

Item [4] amends the table to section S29—7 by inserting, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2, a new entry for 3-FL into the table as follows:

Column 1 – ‘3-fucosyllactose permitted for use by Standard 1.5.2’ as the substance;

Column 3 – ’80 mg’ as the maximum amount of the substance (per 100 kJ).

There is no entry to column 2 of the table to S29—7 as a minimum amount is not set for 3-fucosyllactose. This was not requested in the application and has not been determined by the Authority.

Item [5]

Subsection 2.9.1—9(2) provides for the use of optional nutritive substances in follow-on formula. This section provides that a substance listed in Column 1 of the table to section S29—8 may be used as a nutritive substance in follow-on formula, provided the amount of the substance in the product (including any naturally-occurring amount) is no less than any minimum amount specified in Column 2 of the table; and no more than any maximum amount specified in Column 3 of the table.

Item [5] amends the table to section S29—8 by inserting, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2, a new entry for 3-FL into the table as follows:

Column 1 – ‘3-fucosyllactose permitted for use by Standard 1.5.2’ as the substance;

Column 3 – ’80 mg’ as the maximum amount of the substance (per 100 kJ).

There is no entry to column 2 of the table to S29—8 as a minimum amount is not set for 3-fucosyllactose. This was not requested in the application and has not been determined by the Authority.

Item [6]

Section 2.9.1—10 requires that a substance used as a nutritive substance in infant formula or follow-on formula in accordance with section 2.9.1—9 (other than a vitamin, mineral or electrolyte) must be added in a permitted form listed in the table to section S29—9.

Section 2.9.1—38 requires that a substance used as a nutritive substance in a special medical purpose product for infants in accordance with section 2.9.1—37 (other than a vitamin, mineral or electrolyte) must be added in a permitted form listed in the table to section S29—9.

Item [6] amends the table to section S29—9 by inserting, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2, a new entry for 3-FL as follows:

Column 1 – ‘3-fucosyllactose permitted for use by Standard 1.5.2’ as the substance; and

Column 2 – ‘3-fucosyllactose’ as the permitted form of the substance.

The effect of the approved draft variation

The amendments set out in the variation have the effect of permitting 3-FL produced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter*

pylori to be used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

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

Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance 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 A1324 – 3-fucosyllactose as a nutritive substance 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, after the table item dealing with 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*)

Insert:

3-fucosyllactose sourced from *Escherichia coli* K-12	section S3—56

[2] After section S3—55

Insert:

S3—56 Specification for 3-fucosyllactose sourced from *Escherichia coli* K-12

For 3-fucosyllactose (3-FL) sourced from *Escherichia coli* K-12, the specifications are the following:

(a) chemical name—β-D-Galactopyranosyl-(1-4)-[α-L-fucopyranosyl-(1-3)]-D-glucose;

(b) chemical formula—$C_{18}H_{32}O_{15;}$

(c) molecular weight—488.44 g/mol;

(d) CAS number—41312-47-4;

(e) description—white to off-white powder or agglomerates;

(f) sum of saccharides (3-FL, D-lactose, L-fucose, 3-fucosyl-lactulose)—not less than 92.0% (water free);

(g) 3-FL—not less than 90.0% (water free);

(h) L-fucose—not more than 1.0%;

(i) D-lactose—not more than 5.0%;

(j) 3-fucosyllactulose—not more than 1.5%;

(k) Sum of other carbohydrates—not more than 5.0%;

(l) pH (20°C, 5% solution)—3.2 to 7.0;

(m) water—not more than 6.0%;

(n) ash, sulphated—not more than 0.5%;

(o) lead—not more than 0.05 mg/kg;

(p) microbiological:

- (i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;
- (ii) *Enterobacteriaceae*—absent in 10 g;
- (iii) yeasts—not more than 100 cfu/g;
- (iv) moulds—not more than 100 cfu/g;
- (v) residual endotoxins—not more than 10 EU/mg.

Schedule 26—Food produced using gene technology

[3] Subsection S26—3(7) (table)

Insert:

8	**3-fucosyllactose**	*Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*	4. May only be added to infant formula products. 5. During the exclusive use period, may only be sold under the brand GlyCare®. 6. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.

Schedule 29—Special purpose foods

[4] Section S29—7 (table, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg

[5] Section S29—8 (table, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg

[6] Section S29—9 (table, after the table item dealing with 2′-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	3-fucosyllactose