16 June 2026
399-26

Approval report – Application A1339

A1339 - 2′-FL, 3-FL, LNT, 3′-SL and 6′-SL from *Escherichia coli* BL21 for use as nutritive substances in infant formula products

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Chr. Hansen A/S to permit the voluntary use of 2′-FL, 3-FL, LNT, 3′-SL and 6′-SL, produced using genetically modified strains of *Escherichia coli* BL21, alone or in combination, as nutritive substances in infant formula products.

On 23 January 2026, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 4 submissions.

FSANZ approved the draft variation on 3 June 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 16 June 2026.

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 are available on the A1339 page on the FSANZ website:

SD1 Risk, technical and benefit assessment – Application A1339 (at Approval)

The published submissions from the call for submissions can be found on the A1339 Consultation Hub page.

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Chr. Hansen A/S to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of 5 human-identical milk oligosaccharides (HiMO) as nutritive substances in infant formula products. The HiMO are produced by microbial fermentation using genetically modified (GM) strains of *Escherichia coli* BL21.

The application sought permission for new sources of the following HiMO at specified maximum amounts:

- 2′-fucosyllactose (2′-FL) (120 mg/100 kJ in infant formula; 145 mg/100 kJ in follow-on formula and special medical purpose product for infants (SMPPi))
- 3-fucosyllactose (3-FL) (36 mg/100 kJ in infant formula; 48 mg/100 kJ in follow-on formula and SMPPi)
- lacto-N-tetraose (LNT) (73 mg/100 kJ in infant formula products)
- 3′-sialyllactose (3′-SL) sodium salt (11 mg/100 kJ in infant formula products)
- 6′-sialyllactose (6′-SL) sodium salt (28 mg/100 kJ in infant formula products).

The applicant also requested an exclusive use permission for its brand of each HiMO for 15 months after gazettal of the approved draft variation.

FSANZ has previously assessed and approved the applicant's 2′-FL for use as a nutritive substance in the Code.

FSANZ's safety and technical assessment concluded that the HiMO are chemically, structurally and functionally identical to the naturally occurring oligosaccharides in human milk. No public health and safety concerns were identified for 2′-FL, 3-FL, 3′-SL sodium salt and 6′-SL sodium salt from all sources already permitted or sought to be permitted (by this application) in the Code at the levels requested, which are within the range found in human milk. However, the requested maximum amount of LNT is greater than naturally occurring levels and the effect on infant growth at this amount could not be established. The associated health benefits of these HiMO are (1) an anti-pathogenic effect; (2) immunomodulation; and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 23 January to 6 March 2026. Four submissions were received and each considered as part of our assessment.

For reasons set out in this report, FSANZ has approved the draft variation proposed at the call for submissions with amendments. The approved draft variation will:

- amend Schedule 29 to set new maximum amounts for HiMO permitted in the Code to be used as nutritive substances in infant formula products as follows: 2′-FL at 120 mg/100 kJ; LNT at 60 mg/100 kJ; 3′-SL sodium salt at 11 mg/100 kJ; and 6′-SL sodium salt at 28 mg/100 kJ. These proposed new maximum amounts will apply to 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from all sources permitted in the Code to be used as nutritive substances in infant formula products, including the applicant's HiMO

- amend Schedule 26 to list the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt as permitted GM foods for use in infant formula products subject to certain conditions, including an exclusive use permission for a period of 15 months linked to

the applicant's brand[2]. Consequently, these substances will also be permitted to be used as nutritive substances in infant formula products in accordance with the Code

- insert new specifications into Schedule 3 for the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt, with which these substances will have to comply when used as nutritive substances in infant formula products in accordance with the Code (or sold for such use).

The effect of the approved draft variation will be that:

- the applicant's 3-FL[3], LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from GM strains of *E. coli* BL21 will be permitted to be used as nutritive substances in infant formula products manufactured and/or sold in Australia in accordance with the Code

- the maximum amounts specified in Schedule 29 which the following nutritive substances must not exceed when added to infant formula products: 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from all sources listed in the table to subsection S26—3(7) of the Code (including the applicant's HiMO) will increase.

[2] A 15-month exclusive use permission for the applicant's 2′-FL has already been granted under Application A1190.
[3] During assessment of Application A1339, the gazettal of Application A1324 resulted in amendments to the Code which had the effect of permitting 3-FL at levels higher than those requested by the A1339 applicant.

1 Introduction

1.1 The applicant

Chr. Hansen A/S, part of Novonesis group, is a Danish food ingredient manufacturer of food cultures, pharmaceuticals, probiotics and human-identical milk oligosaccharides (HiMO).

1.2 The application

Application A1339 sought to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of 5 HiMO for use as nutritive substances, alone or in combination, in infant formula products[4]. The 5 HiMO are 2′-fucosyllactose (2′-FL), 3-fucosyllactose (3-FL), lacto-N-tetraose (LNT), 3′-sialyllactose (3′-SL) sodium salt and 6′-sialyllactose (6′-SL) sodium salt. These HiMO are non-digestible oligosaccharides that are a component of human milk.

This application also sought to permit new genetically modified (GM) strains of *Escherichia coli* BL21 as production organisms for 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt. The applicant's 2′-FL sourced from GM *E. coli* BL21 is already permitted in the Code, following approval in Application A1190 (FSANZ 2021a).

The requested amendments to the proposed maximum amounts and requested production organisms for the 5 HiMO are listed in Table 1.

[4] Includes infant formula, follow-on formula and special medical purpose product for infants.

Table 1: Amendments to the Code requested in Application A1339

HiMO	Current maximum amount	Requested maximum amount	Requested production organism
2′-FL	96 mg/100 kJ (2.4 g/L) in infant formula products	120 mg/100 kJ (3.0 g/L) in infant formula 145 mg/100 kJ (3.64 g/L) in follow-on formula and SMPPi	Not requested. The production organism for the applicant's 2′-FL is already listed in Schedule 26 of the Code
3-FL	80 mg/100 kJ (2.0 g/L) in infant formula products	36 mg/100 kJ (0.9 g/L) in infant formula 48 mg/100 kJ (1.2 g/L) in follow-on formula and SMPPi	*E. coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*
LNT	32 mg/100 kJ (0.8 g/L) in infant formula products	73 mg/100 kJ (1.82 g/L) in infant formula products	*E. coli* BL21 containing the genes for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and for beta-1,3-galactosyltransferase from *Salmonella enterica*
3′-SL sodium salt	8 mg/100 kJ (0.2 g/L) in infant formula products	11 mg/100 kJ (0.28 g/L) in infant formula products	*E. coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*
6′-SL sodium salt	16 mg/100 kJ (0.4 g/L) in infant formula products	28 mg/100 kJ (0.7 g/L) in infant formula products	*E. coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*

SMPPi = special medical purpose product for infants

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

Infant formula products in Australia[5] 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 (SMPPi) (from birth).

[5] For further information on any relevant New Zealand standard see section 2.5.1.3 of this report.

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, LNT, 3′-SL sodium salt and 6′-SL sodium salt are *genetically modified foods* (section 1.1.2—16) as they each are a food derived from an organism that contains novel DNA (subparagraph 1.1.2—16(1)(a)(ii)) and does not fall within any of the exceptions listed in paragraph 1.1.2—16(1)(b).

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 in that Schedule. The table to subsection S26—3(7) lists permitted GM food of microbial origin and sets out specific conditions of use for each permitted GM food. That table does not list the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt.

Consequently, express permission for the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt 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.

The applicant's 2′-FL, produced from GM *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *E. coli* O126, is permitted to be used in infant formula products and is listed in Schedule 26, following approval in Application A1190 (FSANZ 2021a).

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). Section 1.1.2—12 provides that a substance is *used as a nutritive substance* in relation to food if it is added to food to achieve a nutritional purpose and (among other things) is identified in the Code as one that may be used as a nutritive substance. Each of the applicant's HiMO 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 subsection 1.1.2—12(1)).

The applicant's HiMO will be optional nutritive substances 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 HiMO 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 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. The permitted form for each requested HiMO permitted for use by Standard 1.5.2 is listed in the table to section S29—9.

The applicant requested a change to the existing permissions for the maximum amounts of the HiMO listed in the tables to sections S29—7 and S29—8.

2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from other sources are permitted for use by Standard 1.5.2 and are listed in the tables to sections S29—7 and S29—8 as being permitted for use as nutritive substances, individually or in combination, in infant formula products. Amendment of existing maximum amounts will apply to all permitted sources of the HiMO, as listed in subsection S26—3(7).

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.

Schedule 3 currently lists 5 specifications for 2′-FL, including one specification set by section S3—45 for 2′-FL sourced from *E. coli* BL21. The existing specification is relevant to the applicant's 2′-FL, which was permitted under Application A1190 (FSANZ 2021a). The applicant did not request an amendment to this specification.

There is no specification specifically for the applicant's 3-FL, LNT, 3′-SL sodium salt or 6′-SL sodium salt in Schedule 3 of the Code. The application provided a proposed specification for their 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt 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.

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.

No generic ingredient names for HiMO have been specified in Schedule 10.

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 GM food. Section 1.5.2—4 requires a food for sale to be labelled 'genetically modified' in conjunction with the name of the GM food, where the food for sale:

- contains, or consists of, a GM food that is listed in Schedule 26, and
- the GM food:
  - contains novel DNA or novel protein, or
  - is listed in section S26—3 as being subject to a condition that its labelling must comply with section 1.5.2—4 (these foods are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not a GM food), and
- is not any of these foods:
  - a food for sale that contains a GM food that is:
    - unintentionally present in the food for sale; and
    - present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient,
  - a food for sale that is:
    - intended for immediate consumption; and
    - prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).

Division 3 of Standard 2.9.1 sets out the specific labelling and packaging requirements for infant formula and follow-on formula. These include but are not limited to:

- requirements that a package of infant formula or follow-on formula must not 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 Nutrition Information Statement (NIS) (paragraph 2.9.1—28(1)(i)),
  - 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 (paragraphs 2.9.1—28(1)(e) and (f)),
- a mandated NIS which must contain specific information and be declared in a prescribed format (sections 2.9.1—24 and 25).

Division 4 of Standard 2.9.1 sets out the specific labelling requirements that apply to SMPPi. These include (amongst other things) the following:

- requirements that the label on a SMPPi must not contain (among other things) representations relating to HMO and HiMO (both words and abbreviations), or other words or abbreviations having the same or similar effect (paragraphs 2.9.1—45(c) and (d))

- claims in relation to a SMPPi must not refer to (among other things) the prevention, diagnosis, cure or alleviation of a disease, disorder or condition, or compare the product with a good that is represented as or likely to be taken for therapeutic use (subsection 2.9.1—46(1))

- a prohibition from making nutrition content and health claims about the product (subsection 2.9.1—46(2)).

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, 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced by microbial fermentation and by chemical synthesis are permitted for use in infant formula products, equivalent products and many other foods at a range of levels.

Codex Alimentarius
Codex Alimentarius (Codex) International Food Standards do not currently exist for 2′-FL, 3-FL, LNT, 3′-SL sodium salt or 6′-SL sodium salt. However, the Codex Standards for 'Infant Formula and Formulas for Special Medical Purposes Intended for Infants' (Codex 2024) and for 'Follow-up Formula for Older Infants and Product for Young Children (Codex 2023) contain provisions for 'optional ingredients' which are applicable to the HiMO.

European Union
In the European Union (EU), the applicant's HiMO from microbial fermentation with *E. coli* BL21 are permitted for use as novel food ingredients. The HiMO are permitted at the following levels in infant formula products: 2′-FL at 3.0 g/L (infant formula) and 3.64 g (follow-on formula) (EU 2024); 3-FL at 1.75 g/L (EU 2023a; EU 2025); LNT at 1.82 g/L (EU 2023b); 3′-SL sodium salt at 0.28 g/L (EU 2023c); and 6′-SL sodium salt at 0.70 g/L (EU 2023d).

United States of America
The applicant's HiMO produced from *E. coli* BL21 that are the subject of this application have Generally Recognized as Safe (GRAS) status for use in infant formula in non-exempt formula for term infants in the United States (US) at the following levels: 2′-FL at 2.0 g/L (US FDA 2015); 3-FL at 0.9 g/L (US FDA 2021a; US FDA 2023); LNT at 0.8 g/L (US FDA 2021b); 3′-SL sodium salt at 0.28 g/L (US FDA 2020); and 6′-SL sodium salt at 0.4 g/L (US FDA 2021c).

These GRAS notifications have all received 'no questions' responses from the US Food and Drug Administration (FDA). GRAS status has been achieved for an increase in the intended use level of LNT to 1.5 g/L (US FDA 2025), and a response from the US FDA is pending.

Canada
The applicant's HiMO produced by *E. coli* BL21 strains are permitted for use in Canada as part of a blend at the following intended use levels: 2′-FL at 3.0 g/L, 3-FL at 0.75 g/L, LNT at 1.5 g/L, 3′-SL sodium salt at 0.23 g/L and 6′-SL sodium salt at 0.28 g/L (Health Canada 2025).

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:

- amended item [1] of the draft variation by deleting the new entry for LNT so that item [1] will only insert a new entry for 3-fucosyllactose sourced from *Escherichia coli* BL21 into the table to subsection S3—2(2) after the table item dealing with '2'-fucosyllactose sourced from *Escherichia coli* W'
- created a new item [2] that will insert the new entry for LNT after the table item dealing with '3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori*'
- renumbered all subsequent item numbers as a consequence of the above amendments
- amended item [4] of the draft variation (now item [5]) by:
  - decapitalising the 'A' in 'Acetyl' in paragraphs S3—58(a) and S3—59(a)
  - decapitalising the 'G' in 'Galactopyranosyl' in paragraphs S3—57(a) and S3—60(a)
  - deitalicising 'Enterobacteriaceae' in subparagraphs S3—57(s)(ii), S3—58(t)(ii), S3—59(t)(ii) and S3—60(s)(ii).

The approved draft variation will take effect on gazettal and is at Attachment A.

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

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ received a total of 4 submissions to the call for submissions (CFS) (see Table 2 below). Submitters provided comments on FSANZ's assessment and/or draft regulatory measure. The submissions are publicly available on the FSANZ website A1339 Consultation Hub page.

Of the stakeholders who provided their views on FSANZ's assessment and draft regulatory measure, one government and one industry submitter supported it, one public interest advocacy group did not support it and one industry submitter expressed support for most of the draft variation. FSANZ's response to submitter comments are provided in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Maximum amount permitted		
Requested an increase of the permitted maximum amount of LNT from 1.50 g/L to 1.82 g/L as sought in the application. This increase reflects the variability in human milk concentrations for which distribution-based measures such as the interquartile range or 90th percentile is more appropriate than mean concentration.	Chr. Hansen A/S	The requested maximum amount of LNT (1.82 g/L) was not proposed in the draft variation at CFS for the reasons set out below. FSANZ considers the mean concentration in human milk the most appropriate reference point because it is consistently reported across studies and provides a robust central estimate for setting maximum amounts. FSANZ's assessment found that estimated mean and 90th percentile dietary intakes of LNT at 1.82 g/L in infant formula products were higher than the estimated intakes from human milk (see section 3.3.4.3 of SD1). As the effect of this higher intake on infant growth could not be determined based on the evidence available, FSANZ has proposed a maximum amount of 1.50 g/L in line with mean human milk concentration. This also aligns with permissions in the US and Canada (see section 2.3.2 of this report). The proposed maximum amount of 1.50 g/L is higher than the current maximum amount in the Code of 0.8 g/L in infant formula products. FSANZ considers the risk management approach proposed at CFS to remain appropriate.
Queried why an increase in the permitted maximum amounts of 2′-FL, 3-FL, 3′-SL sodium salt and 6′-SL sodium salt were proposed if safety could not be established for the requested maximum amount of LNT.	GeneEthics	The differences in approval of requested maximum amounts are because each substance is assessed individually (see section 2.3.2 of this report). FSANZ's assessment concluded that the requested maximum amounts for 2′-FL, 3-FL, 3′-SL sodium salt and 6′-SL sodium salt are lower than the highest mean concentrations reported in human milk and no public health and safety concerns were identified with their addition to infant formula products at these levels. LNT was assessed using the same approach as 2′-FL, 3-FL, 3′-SL sodium salt and 6′-SL sodium salt. However, the requested maximum amount for LNT was higher than the highest mean

Issue	Raised by	FSANZ response (including any amendments to drafting)
		concentration from human milk used in the dietary intake assessment. As the available evidence did not allow the effects of this higher intake on infant growth to be determined with confidence, FSANZ proposed a lower maximum amount aligned with the mean concentration in human milk, rather than supporting the full requested level.
Asked for further rationale for the maximum amount proposed for 6′-SL sodium salt, noting it exceeds amounts tested in human studies.	NSW Food Authority	While the maximum amount of 6′-SL sodium salt exceeds amounts tested in human intervention studies, FSANZ's assessment was based on dietary intake comparisons rather than study dose levels alone. The Ministerial Policy Guideline on the Regulation of Infant Formula Products[6] identifies breastmilk as the primary reference point for determining the composition of infant formula products and requires consideration of levels of comparable substances in breastmilk (specific policy principles h and j). FSANZ concluded that estimated dietary intakes of 6′-SL sodium salt in infant formula products at the proposed maximum amount fall within the range of intakes for infants consuming human milk with high 6′-SL sodium salt concentrations (see section 3.3.4.5 of SD1). On this basis and given the absence of identified adverse effects at these intake levels, the use of 6′-SL sodium salt at the proposed maximum amount was not considered to pose a public health and safety risk.
Evidence-base		
Recommended setting a maximum amount for total oligosaccharides, stating there is limited knowledge about the combined effects of permitted HiMO, inulin-type fructans (ITF) and galacto-oligosaccharides (GOS) in infant formula products.	NSW Food Authority	As set out in section 2.3.4 of this report, the potential cumulative increase to the total oligosaccharide load consumed by infants is aligned with human milk, poses no safety or public health concerns and remains controlled by broader macronutrient requirements prescribed for infant formula products. Total oligosaccharides constitute only a small proportion of the total

[6] Ministerial Policy Guideline on the Regulation of Infant Formula Products

Issue	Raised by	FSANZ response (including any amendments to drafting)
		carbohydrate content of infant formula products if added at the maximum amounts currently permitted by the Code and proposed in the approved draft variation. It is not expected that HiMO will be added to infant formula products in combination with ITF/GOS (see section 2.3.4.2 of this report).
Recommended proactive post-market monitoring of the use of permitted oligosaccharides in infant formula products and the review of emerging evidence on safety and health outcomes as it becomes available.	NSW Food Authority, GeneEthics	Establishing post-market monitoring arrangements is out of scope for this application. As detailed above, FSANZ assesses each application individually and considers the potential cumulative impact of permitted oligosaccharides on total dietary exposure, including alignment with levels found in human milk. Across assessments to date, the cumulative oligosaccharide load consumed by infants remains within the range observed in human milk, poses no safety or public health concerns and remains controlled by broader macronutrient requirements prescribed for infant formula products.
Provided their view that the evidence supporting beneficial effects and functional equivalence of HiMO to HMO is limited, and stronger independent evidence on impact of GM foods is needed.	GeneEthics	As detailed in section 3 of SD1, FSANZ has determined that the applicant's HiMO are chemically and structurally identical to HMO found in human milk. The literature search carried out for this assessment found that HiMO have similar functions as HMO in the infant gut. There is no reason to expect unique functions from the applicant's HiMO when used at concentrations within the ranges observed in human milk.
Raised their view that infant formula is an ultra-processed food (UPF) and expanding permissions increase reliance on UPF with potential long-term public health implications.	GeneEthics	Breastfeeding is the recommended way to feed infants, but a safe and nutritious substitute for human milk is needed for infants when breastfeeding is not possible. FSANZ's risk assessment concluded there are no public health and safety concerns associated with the addition of the applicant's HiMO at the amounts proposed in the draft variation. The assessment also concluded the addition of these HiMO to infant formula products would have associated health benefits. The assessment and those conclusions were based on the best available scientific evidence (see SD1). The Ministerial Policy Guideline on the Regulation of Infant Formula Products identifies human milk as the primary reference point for

Issue	Raised by	FSANZ response (including any amendments to drafting)
		determining the composition of infant formula products and requires consideration of levels of comparable substances in human milk. The proposed permissions align with this approach. Broader considerations relating to dietary patterns or food classification systems are not within the scope of this application.
Labelling		
Requested clearer and more prominent labelling to support informed consumer choice regarding the use of HiMO from GM sources in infant formula products.	GeneEthics	As set out in section 2.3.8 of this report, FSANZ considers it highly unlikely that novel DNA or novel protein from the production organism will be present in an infant formula product containing the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt as ingredients. However, under circumstances where novel DNA or novel protein are present, the requirement to label these HiMO ingredients as 'genetically modified' will apply in accordance with section 1.5.2—4.
Requested clarification if referring to the anti-pathogenic effect of HiMO in SMPPi would be permitted as a medical purpose statement or prohibited as a therapeutic or health claim.	NSW Food Authority	Sections 2.9.1—49 and 2.9.1—50 of the Code require SMPPi to bear a label with a statement indicating the medical purpose of the product. The rationale for this medical purpose statement is to provide an explanation of who the product is for and how it is to be used nutritionally. Statements mandated by the Code do not constitute a voluntary *claim* for Code purposes.
Use of trade mark		
Requested clarification on whether the term '5HMO-Mix' is both a trade mark and a prohibited representation under the Code for infant formula products. Further requested FSANZ avoid using 'HMO' or '5HMO-Mix' in approval documents.	NSW Food Authority	The A1339 CFS and SD1 used the term '5HMO-Mix' only as a shorthand reference to the applicant's combination of HiMO. The draft variation proposed at CFS made no reference to '5HMO-Mix', nor does the approved draft variation. The shorthand use of '5HMO-Mix' has been amended to '5 HiMO Mix' in the Approval Report and SD1 at Approval. FSANZ notes NSW Food Authority advice that its view, as regulator, is that the name '5HMO-Mix' would be prohibited on a label and/or an advertisement of infant formula products by sections 2.9.1–28 and 2.9.1–45 of the Code as applied by the NSW Food Act. FSANZ is not aware of any statement or proposal by the applicant

Issue	Raised by	FSANZ response (including any amendments to drafting)
		for '5HMO-MIX' to appear on the label of an infant formula product.
Requested clarification on how the brand name MyOli may be used in relation to granting the associated exclusive use permissions.	NSW Food Authority	Exclusive use permissions for GM food of microbial origin are listed in the table to subsection S26—3(7) of the Code and apply to an individual substance and its specific method of production, rather than to a substance name or blend alone. As such, FSANZ requested that the applicant nominate a distinct brand name identifier for each individual HiMO for which an exclusive use permission was sought. During the exclusive use period, the applicant's 3-FL, LNT, 3'-SL, and 6'-SL may be added to infant formula products, alone or in combination, only if obtained from the applicant and used in accordance with relevant requirements and conditions set out in the Code.
FSANZ application assessment approach		
Concerned with FSANZ's approach to the assessment of applications to change the Code, specifically the protection of CCI information and granting of exclusive use permissions.	GeneEthics	The FSANZ Act requires FSANZ to protect information that meets the definition of CCI, disclosure of that information is restricted by and under that Act and other Australian laws. Exclusive use permissions are granted only where permitted under the FSANZ Act and where applicants have supplied the necessary supporting data. These provisions do not affect FSANZ's ability to use all data to undertake an independent risk assessment.
Raised their view that the two matters addressed in the draft variation (new GM sources and increases to permitted maximum amounts of HiMO) should not be assessed together and changes to Schedule 29 maximum amounts should proceed through a separate process.	GeneEthics	Assessing new GM source organisms and proposed changes to the permitted maximum amounts of HiMO together ensures that source-specific safety considerations and potential dietary exposure impacts are evaluated in an integrated and proportionate manner. Progressing related changes through the same process supports coherent risk assessment and regulatory consistency. The scope of A1339 was clearly and consistently articulated in all public materials, including the media release and consultation documents. The scope of the application is explicitly described as covering multiple HiMO, multiple source organisms and proposed changes to maximum permitted amounts.
Raised their view that the precautionary principle must be applied and stronger independent evidence is required before expanding permissions for oligosaccharides from GM sources	GeneEthics	FSANZ's assessment was undertaken in accordance with the FSANZ Act, under which the protection of public health and safety is the primary objective. The Act also requires FSANZ to have regard

Issue	Raised by	FSANZ response (including any amendments to drafting)
in infant formula products.		to the need for risk analysis using the best available scientific evidence. This approach ensures that, where there is scientific uncertainty, potential risks to public health and safety are appropriately considered. In assessing Application A1339, FSANZ applied an evidence-based risk assessment using risk analysis of the best available scientific evidence and implemented appropriate risk management measures (see section 2.3 of this report).
Editorial amendments		
Requested clarification regarding the use of chemical names in the proposed specifications which are inconsistent with those in existing specifications for the same HiMO from different sources in the Code. The inconsistencies relate to: • use of 'D-glucose' versus 'D-glucopyranose' suffix for 3-FL and LNT • use of arrows versus a hyphen for glycosidic linkages • capitalisation of chemical names for LNT, 3′-SL and 6′-SL.	NSW Food Authority	In relation to the use of two different suffixes, **D-glucose versus D-glucopyranose for 3-FL (section S3—57) and LNT (section S3—60)**, FSANZ notes they are alternative ways to name the glucose portion of 3-FL and LNT. D-glucopyranose specifies the structure of the glucose monomer as a 6-membered ring (termed a pyranose), whereas D-glucose is a more general way of describing glucose as it can exist in multiple forms (linear, pyranose or furanose). The suffix glucopyranose explicitly states what form the glucose is in. The differences in the two chemical names due to the suffix (3-FL and LNT – as proposed and compared to sections S3—56 and S3—48, respectively) do not imply any chemical or functional difference. FSANZ notes the proposed usage of the suffix D-glucopyranose in sections S3—58 and S3—60 is consistent with the specifications in the relevant EU Regulations. FSANZ has therefore retained the suffix D-glucopyranose for both 3-FL (section S3—57) and LNT (section S3—60) in the draft variation. In relation to the **use of arrows versus hyphen for glycosidic linkages** (for example, 1→4 versus 1-4), while both are valid ways of indicating a glycosidic linkage, the IUPAC[7] prefers the use of an arrow as it shows the direction of the glycosidic bond formation. FSANZ has therefore retained the arrows in the chemical names for the new specifications relevant to this application.

[7] The International Union of Pure and Applied Chemistry

Issue	Raised by	FSANZ response (including any amendments to drafting)
		In relation to the **capitalisation of chemical** names (Acetyl vs acetyl for 3′-SL at S3—58(a) and 6′-SL at S3—59(a), and Galactopyranosyl vs galactopyranosyl for LNT at S3—60(a)), FSANZ agrees that lower case is appropriate. Although the chemical names for 3'-SL, 6'-SL and LNT are capitalised in the corresponding EU regulations, FSANZ chose to amend the names to reflect the current IUPAC convention, where chemical names are not capitalised as they are not considered proper nouns. The draft variation has been amended with the following updates: • 'Acetyl' amended to 'acetyl' in the specification for 3′-SL (S3—58) and 6′-SL (S3—59) • 'β-D Galactopyranosyl' amended to 'β-D galactopyranosyl' in the specification for LNT (S3—60). For consistency, FSANZ has also amended the draft variation to update 'β-D Galactopyranosyl' with 'β-D galactopyranosyl' in the specification for 3-FL (S3—57). This ensures that all HiMO under A1339 have consistent capitalisation of chemical names.
Noted an editorial error in section 3.2.2.2 of the SD1 concerning the reporting of 3-FL concentrations assessed under Application A1324.	NSW Food Authority	Section 3.2.2.2 of the SD1 has been amended.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with:

- Permitting the addition of the applicant's HiMO for use as nutritive substances, alone or in combination, in infant formula products. The applicant's HiMO are produced by microbial fermentation using GM strains of *E. coli* BL21.
- Increasing the maximum amount of the HiMO from all permitted GM sources in the Code.

The HiMO and their proposed maximum amounts are:

- 2′-FL (3.0 g/L in infant formula; 3.64 g/L in follow-on formula and special medical purpose product for infants)
- 3-FL (0.9 g/L in infant formula; 1.2 g/L in follow-on formula and special medical purpose product for infants)
- LNT (1.82 g/L in infant formula products)
- 3′-SL sodium salt (0.28 g/L in infant formula products)
- 6′-SL sodium salt (0.7 g/L in infant formula products).

FSANZ has previously assessed and approved the applicant's 2′-FL for use as a nutritive substance. FSANZ has determined that the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt are chemically, structurally and functionally identical to the naturally occurring forms of these substances in human milk.

FSANZ's food technology assessment concluded the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt are stable in infant formula products, with an adequate shelf-life. Multi-batch analyses showed the oligosaccharides can be consistently produced to meet their proposed specifications.

FSANZ's microbiological risk assessment did not identify any public health and safety concerns associated with the use of *E. coli* BL21 as a host organism. The GM *E. coli* BL21 strain used to produce 2′-FL conforms to the permitted source organism listed in Schedule 26 of the Code and was therefore not further assessed. The GM *E. coli* BL21 production strains used to manufacture 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt were characterised to confirm the presence of the introduced genes and to demonstrate that each production strain was genetically and phenotypically stable.

Building on previous FSANZ assessments, recent literature and a weight of evidence approach, the associated health benefits from the use of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt as nutritive substances in infant formula products at the proposed amounts are recognised as: (1) an anti-pathogenic effect; (2) immunomodulation and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp. There is evidence from clinical and *in vitro* studies that the HiMO concentrations discussed in this application can provide these benefits.

The public health and safety risks associated with the requested maximum amounts of the following HiMO from all sources permitted in the Code to be used as nutritive substances in infant formula products were considered:

2′-FL
No public health and safety concerns have been identified associated with the addition of 2′-FL in infant formula products at the proposed amounts. Toxicological studies confirm that 2′-FL is safe and well tolerated in infant formula products. The addition of 2′-FL at

concentrations up to 3 g/L in infant formula and 3.64 g/L in follow-on formula, which is within the range found in human milk, is unlikely to affect normal infant growth.

3-FL
No public health and safety concerns have been identified associated with the addition of 3-FL to infant formula products at the proposed amounts. Toxicological studies confirm that 3-FL is safe and well tolerated in infant formula products. The addition of 3-FL at a concentration of 0.9 g/L in infant formula and 1.2 g/L in follow-on formula, which is within the range found in human milk, is unlikely to affect normal infant growth.

LNT
Toxicological studies confirm that LNT is safe and well tolerated in infant formula products. The addition of LNT at concentrations up to 1.6 g/L in infant formula and up to 1.37 g/L in follow-on formula is unlikely to affect normal infant growth. However, the requested concentration of 1.82 g/L in infant formula products is greater than that found in human milk and therefore its effect on infant growth at these concentrations could not be determined.

3′-SL sodium salt
No public health and safety concerns have been identified associated with the addition of 3′-SL sodium salt to infant formula products at the proposed amount. Toxicological studies confirm that 3′-SL sodium salt is safe and well tolerated in infant formula products. The addition of 3′-SL sodium salt at a concentration of 0.28 g/L in infant formula products, which is within the range found in human milk, is unlikely to affect normal infant growth.

6′-SL sodium salt
No public health and safety concerns have been identified associated with the addition of 6′-SL sodium salt to infant formula products at the proposed amount. Toxicological studies confirm that 6′-SL sodium salt is safe and well tolerated in infant formula products. The addition of 6′-SL sodium salt at a concentration of 0.7 g/L in infant formula products, which is within the range found in human milk, is unlikely to affect normal infant growth.

Combination of 5 HiMO
The safety of the 5 HiMO in combination was also considered. No adverse effects of the applicant's 5 HiMO mix were observed in a 13-week dietary toxicity study in rats or a 21-day neonatal piglet study and no treatment-related adverse events were observed in infants consuming a formula containing the 5 HiMO mix for 4 months. The requested maximum amounts of the 5 HiMO are already approved in the EU, with no reports of adverse effects in that population.

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 23 January to 6 March 2026 (the submission period). The risk management options available to FSANZ after the submission period were to either:

- approve the draft variation proposed following assessment

- approve that draft variation subject to such amendments as FSANZ considers necessary
- reject the draft variation.

For the reasons outlined in this report, FSANZ has decided to approve the draft variation to the Code proposed at the call for submissions with amendments. The approved draft variation will permit the use of the applicant's HiMO as nutritive substances in infant formula products in accordance with the Code.

Further details on the approved permission and associated conditions are provided below. FSANZ has had regard to the requirements of the FSANZ Act in developing and approving the draft variation, see section 2.5 of this report.

2.3.2 Maximum amounts in infant formula products

In approving the draft variation, 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 infant formula products[6], the composition of infant formula products should as closely as possible aim for nutritional equivalence to human milk.

Application A1339 sought an amendment to increase the maximum amount of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt permitted in the Code. The maximum amounts of these HiMO in the approved draft variation are based on consideration of multiple factors, including:

- Ministerial Policy Guidance on infant formula products, which requires that the composition of human milk should be used as a reference when determining the composition of infant formula and follow-on formula. This guidance also requires the promotion of consistency between domestic and international food standards.

- Outcomes of the safety and benefit assessment (SD1), including the toxicology, dietary exposure assessment and nutrition assessment.

- Regulatory framework of infant formula products. FSANZ considers that the nutrient composition for follow-on formula should only deviate from infant formula where there is substantiated science to support the differences in requirements between age groups (FSANZ 2022). Similarly, the composition of SMPPi should not deviate from infant formula, except where necessary to achieve the product's intended medical purpose (FSANZ 2024).

The minimum energy content of 2,510 kJ/L currently permitted for infant formula and follow-on formula in the Code (section 2.9.1—5) was used to convert the proposed amounts in g/L to mg/100 kJ. This approach, based on mg/100 kJ, means the actual amount of HiMO in infant formula products could vary depending on the energy content of the formula. For example, a formula with a higher energy content per 100 mL may contain more HiMO than a formula with a lower energy content. However, where a formula has a higher energy content, less formula will need to be consumed to meet infant energy requirements. Conversely, more will need to be consumed to meet infant energy requirements for a formula with a lower energy content. As such, the respective dietary intakes for HiMO will be similar for formulas with varying energy contents as the amount (volume) of formula consumed is regulated by infant energy needs.

2.3.2.1 2′-FL

The Code currently permits the voluntary addition of 2′-FL to infant formula products up to a maximum amount of 96 mg/100 kJ (2.4 g/L). The application sought to increase this maximum amount to 120 mg/100 kJ (3.0 g/L) for infant formula and 145 mg/100 kJ (3.64 g/L) in follow-on formula and SMPPi. The requested maximum amounts for these product categories are permitted in the EU. In comparison, Canada permits up to 3.0 g/L for 2′-FL in all infant formula products, while the US permits 2′-FL at up to 2.0 g/L.

Both requested maximum amounts are lower than the highest mean concentrations of 2′-FL in human milk (see Table 4 in SD1) and no public health and safety risks were identified with the addition of 2′-FL to infant formula products at these levels. However, no substantiated evidence was identified to suggest the maximum amount of 2′-FL in infant formula products should differ between products. As such, it was determined that a single maximum amount for infant formula products be retained.

The approved draft variation amends the Code to list a maximum amount of 120 mg/100 kJ for 2′-FL for all infant formula products, since there is no substantiated evidence to support a deviation from the requested maximum amount for infant formula. This level aligns with some international permissions, remains aligned with mean concentrations naturally present in human milk and poses no identified public health or safety concerns.

As a consequence of that amendment, the approved draft variation also amends the maximum amount for the combination of 2′-FL and lacto-N-neotetraose (LNnT) listed in the tables to section S29—7 and S29—8. Currently, this combination is permitted to be added to infant formula products up to a maximum amount of *96 mg/100 kJ which contains not more than 24 mg/100 kJ of LNnT*. The approved draft variation increases the total amount for this combined permission to *120 mg/100 kJ which contains not more than 24 mg/100 kJ of LNnT*. This consequential amendment will not increase the amount of LNnT permitted to be added to infant formula products. The application did not seek an increase to the maximum amount of LNnT.

The increase to the maximum amount of 2′-FL in the approved draft variation will not increase the maximum amount of combined 2′-FL/difucosyllactose (DFL) at 96 mg/100 kJ listed in Schedule 29. These HiMO are permitted in combination as they are produced in the same fermentation and are isolated together to produce the 2′-FL/DFL mixture. The specification for this permission at section S3—47 also lists the addition of these HiMO as a percentage of the final product. If an increase in the maximum amount of 2′-FL was amended for this combined permission, it would result in an increase in the amount of DFL. The amendment to the maximum amount of 2′-FL in the approved draft variation will not increase the amount of the combination of 2′-FL/DFL permitted. The application did not seek an increase to the maximum amount of 2′-FL/DFL.

2.3.2.2 3-FL

After submission of this Application A1339, a variation to the Code was gazetted to permit the voluntary use of 3-FL from a GM source organism as a nutritive substance in infant formula products (assessed under Application A1324). As a result, the Code now currently permits the voluntary addition of 3-FL to infant formula products up to a maximum amount of 80 mg/100 kJ (2.0 g/L). Application A1339 requested a maximum amount of 36 mg/100 kJ (0.9 g/L) for infant formula and 48 mg/100 kJ (1.2 g/L) in follow-on formula and SMPPi. These requested amounts are permitted in the US, while the EU and Canada permit a maximum of 1.75 g/L and 0.75 g/L of 3-FL in infant formula products, respectively.

FSANZ’s assessment of Application A1324 concluded that there was no public health or

safety risk associated with the addition of that 3-FL to all infant formula products up to a maximum amount of 80 mg/100 kJ (FSANZ 2025a). No new evidence was provided or assessed for this application that warranted a change to that conclusion. Therefore, the current maximum amount for 3-FL will be retained for the purposes of Application A1339.

2.3.2.3 LNT

The Code currently permits the voluntary addition of LNT to infant formula products up to a maximum amount of 32 mg/100 kJ (0.8 g/L). The applicant requested that this maximum amount is increased to 73 mg/100 kJ (1.82 g/L) for infant formula products. This requested maximum amount is permitted in the EU, however the US and Canada permit a maximum amount of 1.5 g/L of LNT in infant formula products.

The requested maximum amount is higher than the concentration of LNT naturally occurring in human milk, which ranges from 0.64 g/L – 1.60 g/L (see Table 4 in SD1). Consequently, the effect of the requested maximum amount on infant growth cannot be determined.

The approved draft variation amends the Code to list a maximum amount of 60 mg/100 kJ (1.50 g/L) for LNT in infant formula products. This maximum amount is lower than the highest mean concentrations of LNT in human milk, ensuring the composition of infant formula products align with human milk. Further, no public health and safety risks were identified with the addition of LNT to infant formula products at this level. This will also align the Code with the intended use level of LNT in the US and Canada, ensuring international harmonisation of infant formula product regulation.

2.3.2.4 3'-SL sodium salt

The Code currently permits the voluntary addition of 3′-SL sodium salt to infant formula products up to a maximum amount of 8 mg/100 kJ (0.2 g/L). The applicant requested that this maximum amount is increased to 11 mg/100 kJ (0.28 g/L) for infant formula products. This requested maximum amount is permitted in the EU and US, however the maximum amount of 3′-SL sodium salt in Canada is 0.23 g/L.

The requested maximum amount is lower than the highest mean concentrations of 3′-SL in human milk (see Table 4 in SD1) and no public health and safety risks were identified with the addition of 3′-SL sodium salt to infant formula products at this level.

The approved draft variation amends the Code to list a maximum amount of 11 mg/100 kJ for 3′-SL sodium salt for infant formula products, as this aligns with some international permissions, remains aligned with mean concentrations naturally present in human milk and poses no identified public health or safety concerns.

2.3.2.5 6'-SL sodium salt

The Code currently permits the voluntary addition of 6′-SL sodium salt to infant formula products up to a maximum amount of 16 mg/100 kJ (0.4 g/L). The applicant requested that this maximum amount is increased to 28 mg/100 kJ (0.7 g/L) for infant formula products. This requested maximum amount is permitted in the EU, however the US and Canada permit a maximum of 0.4 g/L and 0.28 g/L of 6′-SL sodium salt in infant formula products, respectively.

The requested maximum amount is lower than the highest mean concentrations of 6′-SL in human milk (see Table 4 in SD1) and no public health and safety risks were identified with the addition of 6′-SL sodium salt to infant formula products at this level.

The approved draft variation amends the Code to list a maximum amount of 28 mg/100 kJ for 6′-SL sodium salt for infant formula products, as this aligns with the EU permission, remains aligned with mean concentrations naturally present in human milk and poses no identified public health or safety concerns.

2.3.3 Regulatory approval

The approved draft variation amends the tables to sections S29—7 and S29—8 of the Code to increase the maximum amount of 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt permitted for use as nutritive substances in infant formula products (as described in section 2.3.2 of this report).

Consequentially, the amount of 2′-FL listed in combination with the permission for LNnT in sections S29—7 and S29—8 will also increase for the reasons stated in section 2.3.2 of this report. The approved draft variation does not amend the concentration of LNnT.

This amendment to the maximum amounts will have the effect that all currently permitted sources of 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt in the Code listed in the table to subsection S26—3(7) could be voluntarily added to infant formula products at that new amount[8].

Application A1339 requested an amendment to the Code to permit the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt, produced from GM *E. coli* BL21(DE3), to be used as nutritive substances in infant formula products. FSANZ maintains the approach of using nomenclature in the Code that identifies parental strains, such as BL21, when no public health or safety concerns have been identified. Consequently, inclusion of the applicant's particular strain (DE3) in a permission for their 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt is considered unnecessary.

The approved draft variation will amend the table to subsection S26—3(7) to list GM *E. coli* BL21 as a permitted source for the applicant's HiMO with the following gene donor organisms:

- 3-FL (containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*)
- LNT (containing the genes for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and for beta-1,3-galactosyltransferase from *Salmonella enterica*)
- 3′-SL sodium salt (containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*), and
- 6′-SL sodium salt (containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*).

This approach is consistent with current HiMO permissions in the Code that have more than one source organism, which also specify the gene and gene donor organism.

The approved draft variation will have the effect of permitting the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt, as GM food, to be used as nutritive substances in infant formula products under Standards 1.5.2 and 2.9.1 in accordance with the Code.

[8] FSANZ is concurrently assessing Application A1340, which seeks to amend the Code to permit a new GM source of 2′-FL. The new maximum amount approved under A1339 will apply to all sources of 2′-FL, including that currently being assessed under A1340.

2.3.4 Total oligosaccharide amounts and cumulative effect

2.3.4.1 Total HiMO amounts

The approved draft variation will increase the maximum amounts of HiMO currently permitted for voluntary use as nutritive substances in the Code. These nutritive substances are permitted to be added either as single ingredients or as a mixture with other permitted HiMO. As outlined in section 2.3.2, the maximum amounts of each HiMO in infant formula products in the approved draft variation are consistent with the concentration in human milk.

Based on the combined maximum amounts of 2′-FL (or 2′-FL/LNnT), 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt in the approved draft variation, the total HiMO content in infant formula products would be approximately 0.30 g/100 kJ (Table 3). While this is below the lower bound of the average total oligosaccharide concentration in mature human milk (0.34 – 0.51 g/100 kJ) as reported in the Application A1265 Approval Report (FSANZ 2023), it reflects that permissions include only a limited number of HiMO. Human milk contains a much broader mixture (over 200 oligosaccharides) and the permitted amounts for each individual HiMO are consistent with concentrations observed in human milk.

Table 3: ***Summary of infant formula product HiMO permissions, including the approved maximum amounts***

HiMO	Maximum amount (mg/100 kJ)	Amount expressed as %Energy
2′-FL or 2′-FL/LNnT[1]	120	1.0
3-FL	80	0.6
LNT	60	0.5
3′-SL sodium salt	11	0.1
6′-SL sodium salt	28	0.2
Total HiMO	**299**	**2.4**

[1] 2′-FL/DFL not included in calculation due to the maximum amount being lower than the permission for proposed amount of 2′-FL.

These comparisons demonstrate that, even at maximum permitted levels, the cumulative HiMO content of infant formula products remains comparable with the range observed in human milk. Accordingly, the proposed permissions are not expected to result in an oligosaccharide load that exceeds physiologically typical levels for breastfed infants.

2.3.4.2 Interaction between existing oligosaccharide permissions and total carbohydrates

Under Standard 2.9.1—12, infant formula products may also contain inulin-type fructans (ITF) and galacto-oligosaccharides (GOS). If these substances were added in combination with HiMO at their respective maximum amounts, the total oligosaccharide content would increase to approximately 0.7 g/100 kJ (Table 4). As discussed in the A1265 Approval Report, the technology to produce HiMO remains expensive and, if used as the only source of oligosaccharides in infant formula products, could result in prohibitive prices for consumers (FSANZ 2023). Accordingly, FSANZ has retained the existing permission for the use of ITF/GOS in infant formula products to support ongoing access to products containing oligosaccharides.

Table 4: ***Summary of infant formula product oligosaccharide permissions, including the approved maximum amounts***

Oligosaccharide	Maximum amount (mg/100 kJ)	Amount expressed as %Energy
Total HiMO[1]	299	2.4
ITF	110	0.9
GOS	290	2.3
Total oligosaccharides	**699**	**5.6**

[1] 2′-FL/DFL not included in calculation due to the maximum amount being lower than the permission for proposed amount of 2′-FL.

FSANZ market data indicate that manufacturers typically use either HiMO or ITF/GOS and do not combine these ingredients at their maximum amounts. As biochemically and functionally identical HiMO become more available it is anticipated that ITF and GOS will become unnecessary components of infant formula products. Therefore, the simultaneous use of all permitted oligosaccharides at maximum amounts is considered unlikely in practice.

Although unlikely, if all permitted HiMO and ITF/GOS were used together at their maximum amounts, total oligosaccharides would remain a small component of the total carbohydrate content of infant formula products. In infant formula products, total carbohydrate content is determined by difference, based on the prescribed ranges of fat, protein and energy density (FSANZ 2024). On this basis, carbohydrate contributes between 36 – 52% of energy in infant formula products (see Appendix 1 of the A1265 Approval Report) (FSANZ 2023). At the approved maximum amounts, HiMO would contribute 2.4% of energy and HiMO in combination with ITF and GOS would contribute a total of 5.6% of energy. The primary carbohydrate source in infant formula products is dependent on the formulation's protein source; in mammalian milk, lactose is the predominant carbohydrate (FSANZ 2021b).

Based on the approved maximum amounts for the HiMO, these calculations demonstrate that the potential cumulative increase to the total oligosaccharide load consumed by infants is aligned with human milk, poses no safety or public health risks and remains controlled by broader macronutrient requirements prescribed for infant formula products.

2.3.5 Specifications

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.

A specification for the applicant's 2′-FL is listed at section S3—45 as a result of Application A1190.

The approved draft variation will insert new specifications relating specifically to the applicant's HiMO into Schedule 3, as follows:

- 3-FL sourced from *E. coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *B. fragilis*
- LNT sourced from *E. coli* BL21 containing the genes for beta-1,3-N-acetylglucosaminyltransferase from *N. meningitidis* and for beta-1,3-galactosyltransferase from *S. enterica*
- 3′-SL sodium salt sourced from *E. coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *H. parahaemolyticus*

- 6′-SL sodium salt sourced from *E. coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *S. suis.*

These HiMO will have to comply with their relevant specifications 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 2 of SD1). These specifications will only apply to 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt sourced from *E. coli* BL21 and the specified gene donors as stated in the specification.

The specifications proposed at the call for submissions capitalised 'acetyl' in the chemical name for the applicant's 3′-SL sodium salt and 6′-SL sodium salt and 'galactopyranosyl' in the chemical name for the applicant's 3-FL and LNT. This approach is consistent with the relevant EU Regulations, however, the IUPAC convention, where chemical names are not capitalised, is considered appropriate. The specifications in the draft variation proposed at the call for submissions have been amended to reflect the IUPAC convention and the approved draft variation is at Attachment A.

The specifications proposed at the call for submissions invertedly italicised the bacteria 'Enterobacteriaceae' under microbiological limits for the applicant's 3-FL, 3′-SL sodium salt, 6′-SL sodium salt and LNT. These specifications have been amended and 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[9].

The applicant requested an exclusive use permission for their specific brand of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt, alone or in combination, in infant formula products. This exclusive use permission was sought on the basis that the HiMO are highly refined products obtained via a proprietary manufacturing process.

Exclusivity of use of the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt

The approved draft variation grants the applicant a 15-month exclusive use permission for their 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt commencing on the date of gazettal of the approved draft variation.

This means that, during the 15-month exclusive use period, the applicant's HiMO may only be sold for use as a nutritive substance in infant formula products under the relevant brand name for each substance: "MyOli™ 3-FL", "MyOli™ LNT", "MyOli™ 3′-SL" and "MyOli™ 6′-SL" in accordance with the Code.

Once the 15-month exclusive use period ends, the exclusive use permissions will revert to general permissions, meaning that the 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt 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 exclusive use period for the use of the same food or ingredient by other food companies, providing the usual application process is undertaken.

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

Exclusivity of the applicant's 2′-FL

The approved draft variation does not provide the applicant with a 15-month exclusive use permission for their 2′-FL, as requested for the purposes of Application A1339. This is because an exclusive use period has been granted for the applicant's 2′-FL under Application A1190 under the brand name "CHR. HANSEN™ 2′-FL", as listed in the table to subsection S26—3(7). The exclusive use period commenced on gazettal of the *Food Standards (Application A1190 – 2′-FL in infant formula and other products) Variation* (21 January 2022) and ended 15 months after that date (20 April 2023). Subsequently, the exclusive use permission for the applicant's 2′-FL has reverted to a general permission, i.e. the applicant's 2′-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.

Based on this, FSANZ has determined the 'first to market advantage' has already been recognised for the applicant's 2′-FL and an additional period of exclusivity cannot be granted.

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

At the request of Food Ministers[10], FSANZ undertook a Five Year Review of the initial permission gazetted under Application A1155 and findings were considered by Food Ministers in November 2025[11]. The review concluded that the addition of 2′-FL and LNnT to infant formula products plays a beneficial role in the normal growth and development of infants by contributing to a microbiota profile more similar to breastfed infants and demonstrating anti-pathogenic benefits (FSANZ 2025b).

2.3.8 Labelling

The applicant did not request any changes to existing labelling requirements in the Code. The general and specific labelling requirements set out in section 1.3.4 of this report will therefore apply to the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt when added as nutritive substances to infant formula, follow-on formula or SMPPi.

The applicant provided batch analyses that demonstrate viable cells as well as residual DNA from each of the production strains are absent from the final product (see section 3.1.1 of SD1). Based on 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 will be present in an infant formula product containing the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt as ingredients. However, under circumstances where novel DNA or novel protein are present, the requirement to label these HiMO ingredients as 'genetically modified' will apply in accordance with section 1.5.2—4.

2.3.9 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 to the Code that will:

- amend the maximum amounts of 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from all sources, which are permitted in the Code to be used as nutritive substances in infant formula products in accordance with the Code;

[10] Communiqué of outcomes from the Australia and New Zealand Ministerial Forum on Food Regulation meeting held on 27 November 2020.
[11] Communiqué of outcomes from the Food Ministers' Meeting held on 14 November 2025.

- permit the voluntary addition of the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from GM *E. coli* BL21 as nutritive substances in infant formula products in accordance with the Code; and
- amend Schedule 3 of the Code to include identity and purity specifications for the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from GM *E. coli* BL21.

The applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt will be subject to relevant requirements and conditions in the Code, which include the following:

- They may be voluntarily added to infant formula products up to the proposed maximum amounts 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', '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 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt.
- An exclusive use permission to use the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt would apply for a period of 15 months, linked to the applicant's brand name for each HiMO (i.e. MyOli™ 3-FL, MyOli™ LNT, MyOli™ 3′-SL and MyOli™ 6′-SL), commencing on the date of gazettal of the approved draft variation.
- The applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt will have to comply with the new specifications inserted to Schedule 3 when used as nutritive substances 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. The call for submissions was notified via a Food Standards Notification Circular, media release 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/proposal.

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

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

FSANZ had regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (as per paragraph 29(2)(a) of the FSANZ Act).

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).

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because applications relating to permitting the use of GM food and 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.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by amending the Code as per the approved draft variation.

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

Community

Amendments in the approved draft variation would apply in Australia only and therefore any impacts would be on consumers in Australia only (see section 2.5.13 below).

The applicant requested an exclusive use permission for their specific brand of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt (see section 2.3.6 above). FSANZ has decided to provide the applicant with a 15-month exclusive use permission for their specific brand of 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt commencing on the date of gazettal of the approved draft variation.

It is possible that industry might achieve some price premium for this product in the short-term, impacting consumers (compared to no exclusive use permission). 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 is to encourage industry innovation and allow applicants to achieve commercial rewards through higher returns on their investment. Any commercial reward from this applicant'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 specific brand of 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt in infant formula products at lower prices during the exclusive use period. However, without this incentive this innovation might not have taken place. It is assumed that the greater incentive to innovate would lead to greater benefits in the medium to long term for consumers as more products come to market that may benefit them.

Industry

Amendments in the approved draft variation would apply to infant formula products manufactured and/or sold in Australia only (see section 2.5.1.3 below).

Australian domestic manufacturers and importers to Australia of infant formula products that contain the applicant's specific brand of 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt 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 specific brand of 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt are already approved in some overseas countries (see section 1.4 above) and the amendments to maximum amounts in Schedule 29 in the approved draft variation are consistent with amounts permitted for those HiMO in some overseas countries, those amendments may support additional exports. However, producers of infant formula products may also face greater competition from formula produced overseas.

An exclusive use permission will prevent other businesses from producing the applicant's specific brand of 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt 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 might result in a small but likely inconsequential cost to Australian governments in terms of monitoring for compliance.

Conclusion from the cost benefit analysis

FSANZ's assessment is that the direct and indirect benefits to the community, government or industry, which would arise from the proposed amendments to the Code as a result of Application A1339, 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 would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

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 amends Schedule 29 of the Code to provide new maximum amounts for the HiMO 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt for the purposes of Standard 2.9.1 of the Code.

Standard 2.9.1 of the Code is an Australian only standard.[12] 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).

[12] On 5 August 2024, the New Zealand Government formally opted out of Standard 2.9.1 under *Annex D* of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*.

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 amendments of Schedules 3 and 26 of the joint Code

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

GM foods, such as the applicant's HiMO, must also be permitted by Standard 1.5.2 and Schedule 26 in order to be used as nutritive substances in infant formula products. For this reason, the approved draft variation amends Schedule 26 of the Code to list the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt as GM foods subject to conditions of use including that they 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, LNT, 3′-SL sodium salt and 6′-SL sodium salt as nutritive substances 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 new specifications for the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt. The applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt will have to comply with their relevant specification when used as nutritive substances 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 of the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt as food additives, processing aids, nutritive substances or novel foods.

The application of the specification in the approved draft variation to and in New Zealand would remain 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 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ completed a 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 permitting the applicant's HiMO to be used as nutritive substances in infant formula products in accordance with the Code; nor with increasing the maximum amounts for 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from all sources permitted in the Code to be used as nutritive substances in infant formula products.

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 1.3.4 of this report will apply to infant formula products containing the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt 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 1.3.4, which aim to prevent misleading or deceptive conduct, will apply to infant formula products containing the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt.

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[13] and considered the best scientific evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the proposed amendments.

- **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. As stated in section 1.4 above, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt are permitted to be used as nutritive substances in infant formula equivalent products in various countries around the world. The amended maximum amounts for 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from all sources permitted in the Code in the approved draft variation are also consistent with the permitted maximum amounts in other countries (see sections 1.4 and 2.3.2 of this report).

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

The amendments in the approved draft variation will support an internationally competitive

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

food industry in relation to the use of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt.

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

3 References

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Attachments

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

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

Food Standards (Application A1339 – 2′-FL, 3-FL, LNT, 3′-SL and 6′-SL from *Escherichia coli* BL21 for use as nutritive substances 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]

[name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances 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 sourced from *Escherichia coli* W")

Insert:

3-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*	section S3—57

[2] Subsection S3—2(2) (table, after the table item dealing with "3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori*")

Insert:

lacto-N-tetraose sourced from *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*	section S3—60

[3] Subsection S3—2(2) (table, after the table item dealing with "6′-sialyllactose sodium salt sourced from *Escherichia coli* K-12")

Insert:

3′-sialyllactose sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*	section S3—58

[4] Subsection S3—2(2) (table, after the table item dealing with "lacto-N-tetraose sourced from *Escherichia coli* K-12")

Insert:

6′-sialyllactose sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*	section S3—59

[5] After section S3—56

Add:

S3—57 Specification for 3-fucosyllactose sourced from *Escherichia coli* BL21

For 3-fucosyllactose (3-FL) sourced from *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*, the specifications are the following:

(a) chemical name—β-D-galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]-D-glucopyranose;

(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;

(f) 3-FL—not less than 90% (water free);

(g) D-lactose—not more than 5.0% (water free);

(h) D-glucose—not more than 3.0% (water free);

(i) D-galactose—not more than 3.0% (water free);

(j) L-fucose—not more than 3.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 5.0% (water free);

(l) water—not more than 9.0%;

(m) ash, sulphated—not more than 1.0%;

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

(o) lead—not more than 0.02 mg/kg;

(p) arsenic—not more than 0.2 mg/kg;

(q) cadmium—not more than 0.1 mg/kg;

(r) mercury—not more than 0.5 mg/kg;

(s) microbiological:

(i) aerobic mesophilic total plate count—not more than 1000 cfu/g;

(ii) Enterobacteriaceae—not more than 10 cfu/g;

(iii) aflatoxin M1—not more than 0.025 µg/kg;

(iv) yeasts—not more than 100 cfu/g;

(v) moulds—not more than 100 cfu/g;

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

S3—58 Specification for 3′-sialyllactose sodium salt sourced from *Escherichia coli* BL21

For 3′-sialyllactose (3′-SL) sodium salt sourced from Escherichia coli BL21 containing the gene for alpha-2,3-sialyltransferase from Haemophilus parahaemolyticus, the specifications are the following:

(a) chemical name—N-acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula—$C_{23}H_{38}NO_{19}Na$;

(c) molecular weight—655.53 g/mol;

(d) CAS number—128596-80-5;

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

(f) 3′-SL sodium salt—not less than 88% (water free);

(g) 3′-sialyl-lactulose—not more than 5.0% (water free);

(h) D-lactose—not more than 5.0% (water free);

(i) sialic acid—not more than 1.5% (water free);

(j) N-acetyl-D-glucosamine—not more than 1.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – 3′-SL sodium salt (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 5.0% (water free);

(l) sodium—not more than 4.2%;

(m) water—not more than 9.0%;

(n) ash, sulphated—not more than 8.5%;
(o) residual proteins—not more than 0.01%;
(p) lead—not more than 0.02 mg/kg;
(q) arsenic—not more than 0.2 mg/kg;
(r) cadmium—not more than 0.1 mg/kg;
(s) mercury—not more than 0.5 mg/kg;
(t) microbiological:
    (i) aerobic mesophilic total plate count—not more than 1000 cfu/g;
    (ii) Enterobacteriaceae—not more than 10 cfu/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.

S3—59 Specification for 6′-sialyllactose sodium salt sourced from *Escherichia coli* BL21

For 6′-sialyllactose (6′-SL) sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*, the specifications are the following:

(a) chemical name—N-acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;
(b) chemical formula—$C_{23}H_{38}NO_{19}Na$;
(c) molecular weight—655.53 g/mol;
(d) CAS number—157574-76-0;
(e) description—white to off-white powder, or agglomerates;
(f) 6′-SL sodium salt—not less than 90% (water free);
(g) 6′-sialyl-lactulose—not more than 3.0% (water free);
(h) D-lactose—not more than 5.0% (water free);
(i) sialic acid—not more than 2.0% (water free);
(j) N-acetyl-D-glucosamine—not more than 3.0% (water free);
(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – 6′-SL sodium salt (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 5.0% (water free);
(l) sodium—not more than 4.2%;
(m) water—not more than 9.0%;
(n) ash, sulphated—not more than 8.5%;
(o) residual proteins—not more than 0.01%;
(p) lead—not more than 0.02 mg/kg;
(q) arsenic—not more than 0.2 mg/kg;
(r) cadmium—not more than 0.1 mg/kg;
(s) mercury—not more than 0.5 mg/kg;
(t) microbiological:
    (i) aerobic mesophilic total plate count—not more than 1000 cfu/g;
    (ii) Enterobacteriaceae—not more than 10 cfu/g;
    (iii) aflatoxin M1—not more than 0.025 µg/kg;
    (iv) yeasts—not more than 100 cfu/g;
    (v) moulds—not more than 100 cfu/g;
    (vi) residual endotoxins—not more than 10 EU/mg.

S3—60 Specification for lacto-N-tetraose sourced from *Escherichia coli* BL21

For lacto-N-tetraose (LNT) sourced from *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*, the specifications are the following:

(a) chemical name—β-D-galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(b) chemical formula—$C_{26}H_{45}NO_{21}$;

(c) molecular weight—707.63 g/mol;

(d) CAS number—14116-68-8;

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

(f) LNT—not less than 75%;

(g) D-lactose—not more than 5.0% (water free);

(h) lacto-N-triose II—not more than 5.0% (water free);

(i) *para*-lacto-N-hexaose—not more than 5.0% (water free);

(j) sum of D-galactose and D-glucose—not more than 5.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 15% (water free);

(l) water—not more than 9.0%;

(m) ash, sulphated—not more than 1.0%;

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

(o) lead—not more than 0.02 mg/kg;

(p) arsenic—not more than 0.2 mg/kg;

(q) cadmium—not more than 0.1 mg/kg;

(r) mercury—not more than 0.5 mg/kg;

(s) microbiological:

  (i) aerobic mesophilic total plate count—not more than 1000 cfu/g;

  (ii) Enterobacteriaceae—not more than 10 cfu/g;

  (iii) aflatoxin M1—not more than 0.025 µg/kg;

  (iv) yeasts—not more than 100 cfu/g;

  (v) moulds—not more than 100 cfu/g;

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

Schedule 26—Genetically modified food

[6] Subsection S26—3(7) (table item dealing with "Lacto-N-tetraose")

Repeal the item, substitute:

5	**Lacto-N-tetraose**	(a) *Escherichia coli* K-12 containing the gene for beta-1,3 -N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,3-galactosyltransferase from *Helicobacter pylori*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare LNT8001. 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 A1265 – 2′-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
		(b) *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ LNT. 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 A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

[7] Subsection S26—3(7) (table item dealing with "6′-sialyllactose sodium salt")

Repeal the item, substitute:

6	**6′-sialyllactose sodium salt**	(a) *Escherichia coli* K-12 containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 6SL 9001. 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
		(b) *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ 6′-SL. 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 A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant*

			formula products) Variation and ending 15 months after that date.

[8] Subsection S26—3(7) (table item dealing with "3′-sialyllactose sodium salt")

Repeal the item, substitute:

7	**3′-sialyllactose sodium salt**	(a) *Escherichia coli* K-12 containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 3SL 9001. 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
		(b) *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ 3′-SL. 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 A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

[9] Subsection S26—3(7) (table item dealing with "3-fucosyllactose")

Repeal the item, substitute:

8	**3-fucosyllactose**	(a) *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 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.
		(b) *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ 3-FL. 3. For the purposes of condition 2 above, **exclusive use period** means the

period commencing on the date of gazettal of the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Schedule 29—Special purpose foods

[10] Section S29—7 (table)

The maximum amount per 100 kJ in column 3 for each substance listed in the following table is amended as set out in the table:

Substance	Omit	Substitute
2′-fucosyllactose permitted for use by Standard 1.5.2	96 mg	120 mg
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2	8 mg	11 mg
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2	16 mg	28 mg
lacto-N-tetraose permitted for use by Standard 1.5.2	32 mg	60 mg

[11] Section S29—7 (table item dealing with "A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2", column 3)

Omit:

96 mg which contains not more than 24 mg of lacto-N-neotetraose

substitute:

120 mg which contains not more than 24 mg of lacto-N-neotetraose

[12] Section S29—8 (table)

The maximum amount per 100 kJ in column 3 for each substance listed in the following table is amended as set out in the table:

Substance	Omit	Substitute
2′-fucosyllactose permitted for use by Standard 1.5.2	96 mg	120 mg

3′-sialyllactose sodium salt permitted for use by Standard 1.5.2	8 mg	11 mg
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2	16 mg	28 mg
lacto-N-tetraose permitted for use by Standard 1.5.2	32 mg	60 mg

[13] Section S29—8 (table item dealing with "A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2", column 3)

Omit:

96 mg which contains
not more than 24 mg
of lacto-N-neotetraose

substitute:

120 mg which contains
not more than 24 mg
of lacto-N-neotetraose

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL, and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances 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 purpose of application A1339 was to amend the Code to permit the voluntary use of 2′-fucosyllactose (2′-FL), 3-fucosyllactose (3-FL), lacto-N-tetraose (LNT), 3′-sialyllactose (3′-SL) sodium salt and 6′-sialyllactose (6′-SL) sodium salt produced by specific genetically modified (GM) *Escherichia coli* BL21 strains, alone or in combination, as nutritive substances in infant formula products at specified maximum amounts.

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL, and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances 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 approved draft variation.

2. Variation is a legislative instrument

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

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). 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 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:

- Amend Schedule 26 of the Code to permit the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from specific GM *Escherichia coli* BL21 strains, to be used as GM foods for the purposes of the Code, and consequently to be used as nutritive substances in infant formula products for the purposes of the Code. These permissions will be subject to certain conditions, including exclusive use permissions for a period of 15 months linked to the applicant's brand of each substance. The applicant's 2′-FL produced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126 is already permitted in the Code.
- Amend Schedule 3 of the Code to include identity and purity specifications for the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt referred to in the dot point above.
- Amend Schedule 29 of the Code to increase the maximum amount of 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from all sources listed in the Code, which are permitted for use as nutritive substances in infant formula products in accordance with the Code.

4. Documents incorporated by reference

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

However, the approved draft variation will vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3 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 A1339 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 23 January 2026 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 GM food and 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, the Authority'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 A1339 - 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances 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] - [5]

Items [1] - **[5]** of the Schedule to the variation amend Schedule 3 of the Code.

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

Item [1] amends the table to subsection S3—2(2) by inserting, after the table item dealing with '2′-fucosyllactose sourced from *Escherichia coli* W', a new entry for '3-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*' and a corresponding reference to new section S3—57 (see **item [5]** below).

Item [2] amends the table to subsection S3—2(2) by inserting, after the table item dealing with '3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyltransferase from *Helicobacter pylori*', a new entry for 'lacto-N-tetraose sourced from *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*' and a corresponding reference to new section S3—60 (see **item [5]** below)

Item [3] amends the table to subsection S3—2(2) by inserting, after the table item dealing with 6′-sialyllactose sodium salt sourced from *Escherichia coli* K-12, a new entry for '3′-sialyllactose sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*' and a corresponding reference to new section S3—58 (see **item [5]** below).

Item [4] amends the table to subsection S3—2(2) by inserting, after the table item dealing

with lacto-N-tetraose sourced from *Escherichia coli* K-12, a new entry for '6′-sialyllactose sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*' and a corresponding reference to new section S3—59 (see **item [5]** below).

Item [5] inserts new sections S3—57, S3—58, S3—59 and S3—60 after existing section S3—56 in Schedule 3. The new sections set out specifications for the new substances sought to be permitted by the applicant.

New section S3—57 sets out the specifications relating specifically to '3-fucosyllactose (3-FL) sourced from *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*'.

New section S3—58 sets out the specifications relating specifically to '3′-sialyllactose (3′-SL) sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*'.

New section S3—59 sets out the specifications relating specifically to 6′-sialyllactose (6′-SL) sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*'.

New section S3—60 sets out the specifications relating specifically to lacto-N-tetraose (LNT) sourced from *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*'.

Consequently, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt sourced from those GM strains of *Escherichia coli* BL21 will have to comply with these specifications when used as nutritive substances in infant formula products in accordance with the Code (or sold for such use).

Items [6] - [9]

Items [6] - **[9]** of the Schedule to the variation amend Schedule 26 of the Code.

Schedule 26 relates to GM food. Each of the above mentioned 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt sourced from the specified GM strains of *Escherichia coli* BL21 are GM foods (as defined in section 1.1.2—16 of the Code) because they are each 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. This includes the applicant's 2′-FL produced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126.

Item [6] of the Schedule to the variation amends the table to subsection S26—3(7) by repealing item [5] of the table (the item dealing with LNT) and substituting that repealed item with an amended item [5].

Amended item [5] of the table to subsection S26—3(7) continues to deal with LNT but with the following amendments:

- the existing source of LNT is re-inserted but is now preceded by '(a)',
- the new source of LNT is listed with associated conditions of use.

The new source is referred to as '*Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*' and is preceded by '(b)'.

The intention is to list the sources of this substance chronologically.

The conditions of use associated with LNT from the new source are:

- this substance may only be added to infant formula products,
- during the exclusive use period, this substance may only be sold under the brand MyOli™ LNT, and
- 'Exclusive use period' means the period commencing on the date of gazettal of the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Item [7] of the Schedule to the variation amends the table to subsection S26—3(7) by repealing item [6] of that table (the item dealing with 6′-SL sodium salt) and substituting that repealed item with an amended item [6].

Amended item [6] of the table to subsection S26—3(7) continues to deal with 6′-SL sodium salt but with the following amendments:

- the existing source of 6′-SL sodium salt is re-inserted but is now preceded by '(a)',
- the new source of 6′-SL sodium salt is listed with associated conditions of use.

The new source is referred to as '*Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*' and is preceded by '(b)'.

The intention is to list the sources of this substance chronologically.

The conditions of use associated with 6′-SL sodium salt from the new source are:

- This substance may only be added to infant formula products.
- During the exclusive use period, this substance may only be sold under the brand MyOli™ 6′-SL.
- 'Exclusive use period' means the period commencing on the date of gazettal of the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Item [8] of the Schedule to the variation amends the table to subsection S26—3(7) by repealing item [7] of that table (the item dealing with 3′-SL sodium salt) and substituting that repealed item with an amended item [7].

Amended item [7] of the table to subsection S26—3(7) continues to deal with 3′-SL sodium salt but with the following amendments:

- the existing source of 3′-SL sodium salt is re-inserted but is now preceded by '(a)',
- the new source of 3′-SL sodium salt is listed with associated conditions of use.

The new source is referred to as '*Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*' and is preceded by '(b)'.

The intention is to list the sources of this substance chronologically.

The conditions of use associated with 3′-SL sodium salt from the new source are:

- This substance may only be added to infant formula products.
- During the exclusive use period, this substance may only be sold under the brand MyOli™ 3′-SL.
- 'Exclusive use period' means the period commencing on the date of gazettal of the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Item [9] of the Schedule to the variation amends the table to subsection S26—3(7) by repealing item [8] of that table (the item dealing with 3-FL) and substituting that repealed item with an amended item [8].

Amended item [8] of the table to subsection S26—3(7) continues to deal with 3-FL but with the following amendments:

- the existing source of 3-FL is re-inserted but is now preceded by '(a)',
- the new source of 3-FL is listed with associated conditions of use.

The new source is referred to as '*Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*' and is preceded by '(b)'.

The intention is to list the sources of this substance chronologically.

The conditions of use associated with 3-FL from the new source are:

- This substance may only be added to infant formula products.
- During the exclusive use period, this substance may only be sold under the brand MyOli™ 3-FL.
- 'Exclusive use period' means the period commencing on the date of gazettal of the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

The conditions of use related to the exclusive use permissions in **items [6]** – **[9]** of the Schedule to the variation mean that the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from the specified GM strains of *Escherichia coli* BL21 may only be sold under the brand name specified for each substance during the period commencing on the gazettal date of the variation and ending 15 months after that date.

Once the exclusive use period ends, each exclusive use permission will revert to a general permission, meaning that the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from the specified GM strains of *Escherichia coli* BL21 may be sold under any brand.

The effect of the amendments in **items [6]** - **[9]** of the Schedule to the variation is to permit

the sale and use of the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from the specified GM strains of *Escherichia coli* BL21 as GM foods in accordance with the Code, subject to the above conditions for use for each substance.

The amendments made by **items [6]** - **[9]** of the Schedule to the variation do not make any substantive change to existing permissions and to other requirements in the Code relating to GM food.

Items [10] - [13]

Items [10] - **[13]** of the Schedule to the variation amend Schedule 29 of the Code.

Items [10] and **[11]** amend the table to section S29—7 relating to infant formula and special medical purpose product for infants.

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 [10] amends the maximum amount per 100 kJ in column 3 of the table to section S29—7 for each substance listed in the following table as set out in the following table:

Substance	Omit	Substitute
2′-FL permitted for use by Standard 1.5.2	96 mg	120 mg
3′-SL sodium salt permitted for use by Standard 1.5.2	8 mg	11 mg
6′-SL sodium salt permitted for use by Standard 1.5.2	16 mg	28 mg
LNT permitted for use by Standard 1.5.2	32 mg	60 mg

Item [11] amends the table item dealing with 'A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2' by omitting the following text in column 3:

'96 mg which contains not more than 24 mg of lacto-N-neotetraose',

and substituting with:

'120 mg which contains not more than 24 mg of lacto-N- neotetraose'.

This amendment is a consequence of the amendment to the maximum amount of 2′-FL in **item [10]** above.

Items [12] and **[13]** amend the table to section S29—8 relating to follow-on formula.

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 [12] amends the maximum amount per 100 kJ in column 3 of the table to section S29—8 for each substance listed in the following table as set out in the following table:

Substance	Omit	Substitute
2′-FL permitted for use by Standard 1.5.2	96 mg	120 mg
3′-SL sodium salt permitted for use by Standard 1.5.2	8 mg	11 mg
6′-SL sodium salt permitted for use by Standard 1.5.2	16 mg	28 mg
LNT permitted for use by Standard 1.5.2	32 mg	60 mg

Item [13] amends the table item dealing with 'A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2' by omitting the following text in column 3:

'96 mg which contains not more than 24 mg of lacto-N-neotetraose',

and substituting with:

'120 mg which contains not more than 24 mg of lacto-N- neotetraose'.

This amendment is a consequence of the amendment to the maximum amount of 2′-FL in **item [12]** above.

The new maximum amounts for the substances identified in **items [10]** – **[13]** apply to those substances produced from all sources listed in the table to subsection S26—3(7) of the Code and which are permitted to be used as nutritive substances in infant formula products in accordance with the Code.

The effects of the approved variation

The amendments set out in the variation have the following effects:

- permitting the 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from GM strains of *Escherichia coli* BL21 and that are the subject of Application A1339 to be used as nutritive substances in infant formula products in accordance with the Code (or sold for such use),
- the amount of the following substances (including any naturally-occurring amount) must not exceed the new maximum amounts listed in Schedule 29: 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from all permitted sources listed in the table to subsection S26—3(7) of the Code (this includes the applicant's 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from GM strains of *Escherichia coli* BL21).

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

Food Standards (Application A1339 – 2′-FL, 3-FL, LNT, 3′-SL and 6′-SL from *Escherichia coli* BL21 for use as nutritive substances 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]

[name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1339 – 2′-FL, 3-FL, LNT, 3′-SL and 6′-SL from* Escherichia coli *BL21 for use as nutritive substances 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 sourced from *Escherichia coli* W")

Insert:

3-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*	section S3—57
lacto-N-tetraose sourced from *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*	section S3—60

[2] Subsection S3—2(2) (table, after the table item dealing with "6′-sialyllactose sodium salt sourced from *Escherichia coli* K-12")

Insert:

3′-sialyllactose sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*	section S3—58

[3] Subsection S3—2(2) (table, after the table item dealing with "lacto-N-tetraose sourced from *Escherichia coli* K-12")

Insert:

6′-sialyllactose sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*	section S3—59

[4] After section S3—56

Add:

S3—57 Specification for 3-fucosyllactose sourced from *Escherichia coli* BL21

For 3-fucosyllactose (3-FL) sourced from *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*, the specifications are the following:

(a) chemical name—β-D-galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]-D-glucopyranose;

(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;

(f) 3-FL—not less than 90% (water free);

(g) D-lactose—not more than 5.0% (water free);

(h) D-glucose—not more than 3.0% (water free);

(i) D-galactose—not more than 3.0% (water free);

(j) L-fucose—not more than 3.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 5.0% (water free);

(l) water—not more than 9.0%;

(m) ash, sulphated—not more than 1.0%;

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

(o) lead—not more than 0.02 mg/kg;

(p) arsenic—not more than 0.2 mg/kg;

(q) cadmium—not more than 0.1 mg/kg;

(r) mercury—not more than 0.5 mg/kg;

(s) microbiological:

(vii) aerobic mesophilic total plate count—not more than 1000 cfu/g;

(viii) *Enterobacteriaceae*—not more than 10 cfu/g;

(ix) aflatoxin M1—not more than 0.025 µg/kg;

(x) yeasts—not more than 100 cfu/g;

(xi) moulds—not more than 100 cfu/g;

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

S3—58 Specification for 3′-sialyllactose sodium salt sourced from *Escherichia coli* BL21

For 3′-sialyllactose (3′-SL) sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*, the specifications are the following:

(a) chemical name—N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula—$C_{23}H_{38}NO_{19}Na$;

(c) molecular weight—655.53 g/mol;

(d) CAS number—128596-80-5;

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

(f) 3′-SL sodium salt—not less than 88% (water free);

(g) 3′-sialyl-lactulose—not more than 5.0% (water free);

(h) D-lactose—not more than 5.0% (water free);

(i) sialic acid—not more than 1.5% (water free);

(j) N-acetyl-D-glucosamine—not more than 1.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – 3′-SL sodium salt (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 5.0% (water free);

(l) sodium—not more than 4.2%;

(m) water—not more than 9.0%;

(n) ash, sulphated—not more than 8.5%;

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

(p) lead—not more than 0.02 mg/kg;

(q) arsenic—not more than 0.2 mg/kg;

(r) cadmium—not more than 0.1 mg/kg;

(s) mercury—not more than 0.5 mg/kg;

(t) microbiological:

(i) aerobic mesophilic total plate count—not more than 1000 cfu/g;

(ii) *Enterobacteriaceae*—not more than 10 cfu/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.

S3—59 Specification for 6′-sialyllactose sodium salt sourced from *Escherichia coli* BL21

For 6′-sialyllactose (6′-SL) sodium salt sourced from *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*, the specifications are the following:

(a) chemical name—N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula—$C_{23}H_{38}NO_{19}Na$;

(c) molecular weight—655.53 g/mol;

(d) CAS number—157574-76-0;

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

(f) 6′-SL sodium salt—not less than 90% (water free);

(g) 6′-sialyl-lactulose—not more than 3.0% (water free);

(h) D-lactose—not more than 5.0% (water free);

(i) sialic acid—not more than 2.0% (water free);

(j) N-acetyl-D-glucosamine—not more than 3.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – 6′-SL sodium salt (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 5.0% (water free);

(l) sodium—not more than 4.2%;

(m) water—not more than 9.0%;

(n) ash, sulphated—not more than 8.5%;

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

(p) lead—not more than 0.02 mg/kg;

(q) arsenic—not more than 0.2 mg/kg;

(r) cadmium—not more than 0.1 mg/kg;

(s) mercury—not more than 0.5 mg/kg;

(t) microbiological:

(i) aerobic mesophilic total plate count—not more than 1000 cfu/g;

(ii) *Enterobacteriaceae*—not more than 10 cfu/g;

(iii) aflatoxin M1—not more than 0.025 µg/kg;

(iv) yeasts—not more than 100 cfu/g;

(v) moulds—not more than 100 cfu/g;

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

S3—60 Specification for lacto-N-tetraose sourced from *Escherichia coli* BL21

For lacto-N-tetraose (LNT) sourced from *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*, the specifications are the following:

(a) chemical name—β-D-Galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-

glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(b) chemical formula—$C_{26}H_{45}NO_{21}$;

(c) molecular weight—707.63 g/mol;

(d) CAS number—14116-68-8;

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

(f) LNT—not less than 75%;

(g) D-lactose—not more than 5.0% (water free);

(h) lacto-N-triose II—not more than 5.0% (water free);

(i) *para*-lacto-N-hexaose—not more than 5.0% (water free);

(j) sum of D-galactose and D-glucose—not more than 5.0% (water free);

(k) sum of other carbohydrates (100 (% (w/w) of dry matter) – quantified carbohydrates (listed above) (% (w/w) of dry matter) – Ash (% (w/w) of dry matter))—not more than 15% (water free);

(l) water—not more than 9.0%;

(m) ash, sulphated—not more than 1.0%;

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

(o) lead—not more than 0.02 mg/kg;

(p) arsenic—not more than 0.2 mg/kg;

(q) cadmium—not more than 0.1 mg/kg;

(r) mercury—not more than 0.5 mg/kg;

(s) microbiological:

(i) aerobic mesophilic total plate count—not more than 1000 cfu/g;

(ii) *Enterobacteriaceae*—not more than 10 cfu/g;

(iii) aflatoxin M1—not more than 0.025 µg/kg;

(iv) yeasts—not more than 100 cfu/g;

(v) moulds—not more than 100 cfu/g;

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

Schedule 26—Genetically modified food

[5] Subsection S26—3(7) (table item dealing with "Lacto-N-tetraose")

Repeal the item, substitute:

5	**Lacto-N-tetraose**	(a) *Escherichia coli* K-12 containing the gene for beta-1,3 -N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,3-galactosyltransferase from *Helicobacter pylori*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare LNT8001. 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 A1265 – 2′-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
		(b) *Escherichia coli* BL21 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitidis* and the gene for beta-1,3-galactosyltransferase from *Salmonella enterica*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ LNT. 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 A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

[6] Subsection S26—3(7) (table item dealing with "6′-sialyllactose sodium salt")

Repeal the item, substitute:

6	**6′-sialyllactose sodium salt**	(a) *Escherichia coli* K-12 containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 6SL 9001. 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
		(b) *Escherichia coli* BL21 containing the gene for alpha-2,6-sialyltransferase from *Streptococcus suis*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ 6′-SL. 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 A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant*

			formula products) Variation and ending 15 months after that date.

[7] Subsection S26—3(7) (table item dealing with "3′-sialyllactose sodium salt")

Repeal the item, substitute:

7	**3′-sialyllactose sodium salt**	(a) *Escherichia coli* K-12 containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 3SL 9001. 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
		(b) *Escherichia coli* BL21 containing the gene for alpha-2,3-sialyltransferase from *Haemophilus parahaemolyticus*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ 3′-SL. 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 A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

[8] Subsection S26—3(7) (table item dealing with "3-fucosyllactose")

Repeal the item, substitute:

8	**3-fucosyllactose**	(a) *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 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.
		(b) *Escherichia coli* BL21 containing the gene for alpha-1,3-fucosyltransferase from *Bacteroides fragilis*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand MyOli™ 3-FL. 3. For the purposes of condition 2 above, **exclusive use period** means the

period commencing on the date of gazettal of the *Food Standards (Application A1339 – 2'-FL, 3-FL, LNT, 3'-SL and 6'-SL from* Escherichia coli *BL21 for use as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Schedule 29—Special purpose foods

[9] Section S29—7 (table)

The maximum amount per 100 kJ in column 3 for each substance listed in the following table is amended as set out in the table:

Substance	Omit	Substitute
2′-fucosyllactose permitted for use by Standard 1.5.2	96 mg	120 mg
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2	8 mg	11 mg
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2	16 mg	28 mg
lacto-N-tetraose permitted for use by Standard 1.5.2	32 mg	60 mg

[10] Section S29—7 (table item dealing with "A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2", column 3)

Omit:

96 mg which contains not more than 24 mg of lacto-N-neotetraose

substitute:

120 mg which contains not more than 24 mg of lacto-N-neotetraose

[11] Section S29—8 (table)

The maximum amount per 100 kJ in column 3 for each substance listed in the following table is amended as set out in the table:

Substance	Omit	Substitute
2′-fucosyllactose permitted for use by Standard 1.5.2	96 mg	120 mg

3′-sialyllactose sodium salt permitted for use by Standard 1.5.2	8 mg	11 mg
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2	16 mg	28 mg
lacto-N-tetraose permitted for use by Standard 1.5.2	32 mg	60 mg

[12] Section S29—8 (table item dealing with "A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2", column 3)

Omit:

96 mg which contains
not more than 24 mg
of lacto-N-neotetraose

substitute:

120 mg which contains
not more than 24 mg
of lacto-N-neotetraose