23 January 2026
378-26

Call for submissions – 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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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, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

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

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

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 6 March 2026

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

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

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

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140

AUSTRALIA
Tel +61 2 6228 8226

NEW ZEALAND
Tel +64 4 978 5630

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Supporting document

The following document which informed the assessment of this Application is available on the A1339 page on the FSANZ website:

Supporting Document 1 (SD1)	Risk, technical and benefit assessment – Application A1339

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 seeks 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); and
- 6′-sialyllactose (6′-SL) sodium salt (28 mg/100 kJ in infant formula products).

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

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 proposed 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 for reasons set out in this report, FSANZ has prepared a draft variation to the Code. If approved, the draft variation would:

- 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 would 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. Consequently, these substances would 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 must comply when used as nutritive substances in infant formula products in accordance with the Code (or sold for such use).

If approved, these amendments would apply in Australia only (see section 2.4.1.3 of the assessment summary).

If approved, the effects of the draft variation would be to:

- allow the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from GM strains of *E. coli* BL21 to be used as nutritive substances in infant formula products manufactured and/or sold in Australia in accordance with the Code, and
- increase the maximum amounts specified in Schedule 29 which the following substances (which are permitted in the Code to be used as nutritive substances in infant formula products) must not exceed when added for such use in 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 (this would include the applicant's 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt).

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

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

The purpose of this application is 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. 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. 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt are non-digestible oligosaccharides that are a component of human milk.

This application also seeks 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.

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—3 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[1] 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).

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) would be 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] For further information on any relevant New Zealand standard see section 2.4.1.3 of this report.

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 would be *used as a nutritive substance* for the purposes of the Code because its use in infant formula products is intended to achieve specific nutritional purposes and it is a substance that would be identified in this Code as a permitted nutritive substance (see subsection 1.1.2—12(1)).

The applicant's HiMO would be optional nutritive substances used in infant formula products for the purposes of Standard 2.9.1 as food businesses would be able to decide whether to add the substance to those products. Addition of the applicant's HiMO to infant formula products would 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 has 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 a nutritive substances, individually or in combination, in infant formula products. If the existing maximum amounts for the HiMO are amended, they will be amended for all permitted sources of the HiMO, as listed in Schedule 26—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 for 2′-FL sourced from *E. coli* BL21 under section S3—45. The existing specification is relevant to the applicant's 2′-FL, which was permitted under Application A1190 (FSANZ 2021a). The applicant is not requesting 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 the applicant's 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 is being assessed under the General Procedure in accordance with the FSANZ Act.

2 Summary of the assessment

2.1 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.

The food technology assessment demonstrated that the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt were shown to be 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 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 "5HMO-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 5HMO-Mix for four months. The requested maximum amounts of the 5 HiMO are already approved in the EU, with no reports of adverse effects in that population.

2.2 Risk management

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

2.2.1 Risk management options

The risk management options available to FSANZ after assessment are to either:

- reject the application, or
- prepare a draft variation to the Code.

For the reasons outlined in this report, FSANZ decided to prepare a draft variation to the Code to permit the use of the applicant's HiMO as nutritive substances in infant formula products in accordance with the Code.

On the basis of the findings of the risk assessment (see section 2.1 of this report and SD1), FSANZ considers the use of the applicant's 5 HiMO as nutritive substances in infant formula products to be safe for the proposed purpose. The risk management responses to matters raised by the risk assessment are detailed below.

2.2.2 Maximum amounts in infant formula products

In considering the proposed permission, FSANZ acknowledges that breastfeeding is the recommended way to feed infants and the intent of Standard 2.9.1 is not to replace human milk but to provide a safe, nutritionally replete, functional alternative for where breastfeeding is not possible. Given this, and in accordance with the Ministerial Policy Guideline on infant formula products[2], the composition of infant formula products should as closely as possible aim for nutritional equivalence to human milk.

Application A1339 requested an amendment to the maximum amount of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt in the Code. The proposed regulation of the maximum amounts of these HiMO is based on consideration of multiple factors including:

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

- 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 would mean that 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 would need to be consumed to meet infant energy requirements. Conversely, more would 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 would be similar for formulas with varying energy contents as the amount (volume) of formula consumed is regulated by infant energy needs.

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 applicant has requested that this maximum amount be increased 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. This requested maximum amount for these product categories is permitted in the EU, with a maximum permitted amount of 3.0 g/L in Canada for 2′-FL in all infant formula products. 2′-FL is permitted in infant formula products in the US at 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 has been determined that a single maximum amount for infant formula products be retained.

FSANZ is proposing to amend 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 maximum amount for the combination of 2′-FL and lacto-N-neotetraose (LNnT) listed in the tables to section S29—7 and S29—8 would also need to be amended. 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*. FSANZ is proposing that the total amount for this combined permission be increased to *120 mg/100 kJ which contains not more than 24 mg/100 kJ of LNnT*. This

proposed 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 proposed amendment to increase the maximum amount of 2′-FL would 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. This proposed amendment to the maximum amount of 2′-FL 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.

3-FL

At the time of assessing this Application A1339, FSANZ was assessing Application A1324 which sought a new permission to use 3-FL from a GM source organism as a nutritive substance in infant formula products. As a result, the Code 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). In Application A1339, 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 were requested. 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, that maximum amount for 3-FL would be retained for the purposes of Application A1339.

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 has requested that this maximum amount be 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.

FSANZ is proposing to amend the Code to list a maximum amount of 60 mg/100 kJ (1.50 g/L). This maximum amount is lower than the highest mean concentrations of LNT in human milk, ensuring the composition of infant formula products aligns 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 would also align the Code with the intended use level of LNT in the US and Canada, ensuring international harmonisation of infant formula product regulation.

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 has requested

that this maximum amount be 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.

FSANZ is proposing to amend 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.

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 has requested that this maximum amount be 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.

FSANZ is proposing to amend 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.

2.2.3 Proposed regulatory approval

FSANZ is proposing to amend 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 for use as nutritive substances in infant formula products (as described in Section 2.2.2).

Consequentially, the amount of 2′-FL listed in combination with the permission for LNnT in sections S29—7 and S29—8 would need to also increase for the reasons stated in section 2.2.2 of this report. If approved, the concentration of LNnT would not be amended

This amendment to the maximum amounts would 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. [3]

Application A1339 has 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

[3] FSANZ is concurrently assessing Applications A1334 and A1340, which both seek to amend the Code to permit new GM sources of 2′-FL. If the maximum amount of 2′-FL permitted for use as a nutritive substance in infant formula products is amended under A1339, the new maximum amount would apply to all sources of 2′-FL, including those currently being assessed under A1334 and A1340.

6′-SL sodium salt is considered unnecessary.

FSANZ is therefore proposing to 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 *B. fragilis*)
- LNT (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 (containing the gene for alpha-2,3-sialyltransferase from *H. parahaemolyticus*), and
- 6′-SL sodium salt (containing the gene for alpha-2,6-sialyltransferase from *S. 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.

If the draft variation is approved, the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt would, as GM food, be permitted under Standards 1.5.2 and 2.9.1 to be used as nutritive substances in infant formula products in accordance with the Code.

2.2.4 Total oligosaccharide amounts and cumulative effect

The draft variation, if approved, will increase the maximum amount 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 the other permitted HiMO (Table 2). As described in section 2.2.2, the maximum amounts of each HiMO in infant formula products proposed in the draft variation are consistent with the concentration in human milk.

As reported in the Application A1265 Approval Report, the lower limit of average total oligosaccharide concentration in mature human milk ranges 10 – 15 g/L, or 0.34 – 0.51 g/100 kJ (FSANZ 2023). If the draft variation is approved, the total amount of HiMO permitted to be added to infant formula products would be the combined maximum amount of 2′-FL or 2′-FL/ LNnT, 3-FL, LNT, 3′-SL sodium salt, 6′-SL sodium salt, (noting that the existing maximum amount of 2′-FL/ DFL is lower than proposed increase to the 2′-FL level at a combined total of 96 mg/100 kJ). This would total 0.30 g/100 kJ (Table 2), which is less than the average total oligosaccharide concentration in mature in human milk.

When considering the addition of the maximum permitted inulin-type fructans (ITF) and galacto-oligosaccharides (GOS) amounts as listed in Standard 2.9.1—12, this total would equal 0.7 g/100 kJ (Table 2). As discussed in the A1265 Approval Report, the technology to produce synthetic HMO remains expensive and if used as the only source of oligosaccharides in infant formula products could result in prohibitive prices for consumers (FSANZ 2023). However, as the biochemically and functionally identical HiMO become more available, it is anticipated that ITF and GOS will become an unnecessary component of infant formula products.

Table 2: Summary of proposed infant formula product oligosaccharide permissions, including the proposed maximum amounts.

Oligosaccharide	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
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.

Based on the proposed permissions listed in Table 2, total added oligosaccharides would be a small component of the total carbohydrate content of infant formula products. Total carbohydrate content in infant formula products is calculated by difference based on the prescribed range of fat and protein, and energy density (FSANZ 2024). The calculated carbohydrate range in infant formula products expressed as a percentage of the energy density is 36 – 52% (see Appendix 1 of the A1265 Approval Report) (FSANZ 2023). The calculated amount of oligosaccharides expressed as a percentage of the energy density would be 2.4% for HiMO and 5.6% if ITF and GOS are added to the maximum amount, which contributes only a fraction to the total carbohydrate content. The primary carbohydrate source used in infant formula products is dependent on the protein source upon which the formula is based. The main type of carbohydrate in mammalian milk is lactose (FSANZ 2021b).

Based on the proposed 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.

2.2.5 Specification

Section 1.1.1—15 requires that a substance used as a nutritive substance must comply with any relevant identity and purity specification in Schedule 3 when added to food in accordance with the Code or sold for use in food.

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

The draft variation would 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 would 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 would 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.

2.2.6 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[4].

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.

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

FSANZ is proposing to provide the applicant with 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 draft variation (if approved).

If the draft variation is approved, 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 in accordance with the Code under the relevant brand name for each substance: "MyOli™ 3-FL, MyOli™ LNT, MyOli™ 3′-SL and MyOli™ 6′-SL".

Once the 15-month exclusive use period ends, the exclusive use permissions would revert to general permissions, meaning that this 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.

Exclusivity of the applicant's 2′-FL

FSANZ is not proposing to 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.

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

FSANZ is committed to reviewing any new evidence on the beneficial role of HiMO in the normal growth and development of infants. At the request of Food Ministers[5], FSANZ undertook a Five Year Review of the initial permission gazetted under Application A1155 and findings were considered by Food Ministers in November 2025[6]. The review concluded that the addition of 2′-FL and LNnT to infant formula products plays a beneficial role in the normal

[4] Exclusivity of use for novel foods and nutritive substances
[5] Communiqué of outcomes from the Australia and New Zealand Ministerial Forum on Food Regulation meeting held on 27 November 2020.
[6] Communiqué of outcomes from the Food Ministers' Meeting held on 14 November 2025.

growth and development of infants by contributing to a microbiota profile more similar to breastfed infants and demonstrating anti-pathogenic benefits (FSANZ 2025b).

2.2.8 Labelling

The applicant did not request any changes to existing labelling requirements in the Code. If the draft variation is approved, the general and specific labelling requirements set out in section 1.3.4 of this report would 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 would 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' would apply in accordance with section 1.5.2—4.

2.2.9 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has decided to prepare a draft variation to the Code to:

- 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;
- 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 identify and purity specifications for the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from GM *E. coli* BL21.

If the draft variation is approved, 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, would 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 draft variation (if approved).
- The applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt would 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).

2.3 Risk communication

2.3.1 Consultation

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

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

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

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

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

2.3.2 World Trade Organization (WTO)

As a member of the World Trade Organization (WTO), Australia is obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to voluntarily permit the use of the applicant's HiMO as nutritive substances in infant formula products, is unlikely to have a significant effect on international trade as similar sources of these HiMO are already permitted in similar products in countries overseas. Therefore, a notification to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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 if the draft variation concerned is

approved.

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 proposed in the draft variation. permitting the voluntary use of 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from *E. coli* BL21 for use as nutritive substances in infant formula products.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Community

If the draft variation is approved, the proposed amendments would apply in Australia only and therefore any impacts would be on consumers in Australia only (see section 2.4.1.3 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 2.2.6 above). FSANZ is proposing 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 draft variation if approved.

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

If the draft variation is approved, the proposed amendments in that draft variation would apply to infant formula products manufactured and/or sold in Australia only (see section 2.4.1.3 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 would 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 proposed

amendments to maximum amounts in Schedule 29 are consistent with amounts permitted for those HiMO in some overseas countries, those amendments (if the draft variation is approved) may support additional exports. However, producers of infant formula products may also face greater competition from formula produced overseas.

Granting an exclusive use permission as proposed would 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

If the draft variation is approved, the draft variation 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, if the draft variation is approved, 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, would likely to outweigh the associated costs.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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 draft variation would amend 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.[7] Schedule 29 of the Code lists the compositional requirements (e.g. permissions, limits, calculations, permitted forms etc.) for the purposes of that Australia only Standard 2.9.1, as well as Standards 2.9.2 to 2.9.5 of the Code. Standards 2.9.2 to 2.9.5 are joint standards that apply in both Australia and New Zealand.

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

The New Zealand standard is not part of the Code for the purposes of the FSANZ Act, nor is it covered by the 'Australia New Zealand Food Standards System' established by the Treaty

[7] 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*.

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.

Draft variation amendments of Schedules 3 and 26 of the joint Code

The 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 daft variation would amend 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.

If the draft variation is approved, 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 draft variation would 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. If this amendment is approved, the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt would 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.

If the draft variation is approved, the application of the specification in the draft variation to and in New Zealand would remain a matter for the New Zealand Government.

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ completed a risk and technical assessment (see section 2.1 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.

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

Current labelling requirements outlined in sections 1.3.4 of this report would apply to infant formula products containing the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt and would provide adequate information to enable consumers to make an informed choice.

2.4.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 1.3.4, which aim to prevent misleading or deceptive conduct, would apply to infant formula products containing the applicant's 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the risk analysis framework[8] 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 proposed maximum amounts for 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt from all sources permitted in the Code are also consistent with the permitted maximum amounts in other countries (see sections 1.4 and 2.2.2 of this report).

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

The proposed amendments would support an internationally competitive food industry in relation to the use of 2′-FL, 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt.

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

- **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 2.1 of this report, FSANZ considers these Policy Guidelines have been met.

3 Draft variation

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

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

4 References

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Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

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

Food Standards (Application 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:

(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

[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

Attachment B – Draft Explanatory Statement

DRAFT 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 Authority accepted Application A1339 which seeks 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 prepared 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 draft variation).

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme.

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

3. Purpose

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

However, if approved, the draft variation would vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft Standard/variation) will be open for a six-week period.

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

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

7. Variation

A reference to 'the variation' in this section is a reference to the 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], [2], [3] and [4]

Items [1] - **[4]** of the Schedule to the variation would amend Schedule 3 of the Code.

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

Item [1] would amend the table to subsection S3—2(2) by inserting, after the table item dealing with 2′-fucosyllactose sourced from *Escherichia coli* W, new entries 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 [4] below)
- '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 [4]** below)

Item [2] would amend 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 [4]** below).

Item [3] would amend 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 [4]** below).

Item [4] would insert new sections S3—57, S3—58, S3—59 and S3—60 into Schedule 3, which 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, if the draft variation is approved and 3-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt sourced from those GM strains of *Escherichia coli* BL21 are permitted to be used as nutritive substances in infant formula products, those substances would 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 [5], [6], [7] and [8]

Items [5] - **[8]** of the Schedule to the variation would 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 [5] would amend 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] 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 [6] would amend 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] 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 [7] would amend 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] 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 [8] would amend 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] continues to deal with 3-FL but with the following amendments:

- the 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.

If the variation is approved, the conditions of use related to the exclusive use permissions in **items [5]** – **[8]** 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 would 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.

If the variation is approved, the effect of the amendments in **items [5**] - **[8]** would be 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 proposed amendments that would be made by **items [5]** - **[8]** would not make any substantive change to existing permissions and to other requirements in the Code relating to GM food.

Items [9], [10], [11] and [12]

Items [9] - **[12]** of the Schedule to the variation would amend Schedule 29 of the Code.

Items [9] and **[10]** would 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 [9] would amend 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 [10] would amend 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 proposed amendment is a consequence of the proposed amendment to the maximum amount of 2′-FL in **item [9]** above.

Items [11] and **[12]** would 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 [11] would amend 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 [12] would amend 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 proposed amendment is a consequence of the proposed amendment to the maximum amount of 2′-FL in item [11] above.

The proposed new maximum amounts for the substances identified in items **[9]** – **[12]** would 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.

Proposed effects of the variation (if approved)

If the variation is approved, the amendments set out in the variation would 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 proposed 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 would include the applicant's 2′-FL, LNT, 3′-SL sodium salt and 6′-SL sodium salt produced from GM strains of *Escherichia coli* BL21).