11 June 2025
344-25

Call for submissions – Application A1324

A1324 – 3-fucosyllactose as a nutritive substance in infant formula products

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

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) 23 July 2025

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:

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Supporting document

The following document which informed the assessment of this Application is available on the A1324 page on the FSANZ website:

SD1 Risk, technical and benefit assessment – Application A1324

Executive summary

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

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

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

For reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit the use of 3-FL produced from a GM source (*E. coli* K-12) containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori* as a nutritive substance in infant formula products in accordance with the Code. If approved, the draft variation would:

- amend Schedule 29 of the Code by listing the applicant's 3-FL as an optional nutritive substance that may be used in infant formula products up to the specified permitted amount of 80 mg/100 kJ

- amend Schedule 26 of the Code by listing the applicant's 3-FL, a substance derived from a genetically modified microbial source, as a permitted food produced using gene technology that may be added to infant formula products subject to certain conditions, including an exclusive use permission for a period of 15 months linked to the applicant's brand name GlyCare

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

The proposed permission, if approved, would apply to Australia only (see section 2.4.1.3 of the assessment summary).

If approved, the amendments would permit the applicant's 3-FL to be used as a nutritive substance in infant formula products in accordance with the Code.

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

1 Introduction

1.1 The applicant

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

1.2 The application

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

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

1.3 The current standard

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

1.3.1 Infant formula products

Revised regulation of infant formula products came into effect on 13 September 2024 and applies in Australia only.[1]

Infant formula products in Australia are regulated by Standard 2.9.1 which sets out specific requirements for the following infant formula products:

- infant formula (for infants aged 0 to <12 months)
- follow-on formula (for infants aged from 6 to <12 months)
- special medical purpose product for infants[2] (from birth).

1.3.2 Permitted use

1.3.2.1 Food produced using gene technology

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

The applicant's 3-FL is a *food produced using gene technology* (section 1.1.2—2) as it is produced from an organism modified using gene technology (i.e. derived from genetically modified *E. coli*). Consequently, express permission for the applicant's 3-FL to be used in infant formula products in accordance with the Code (or sold for such use) is required in accordance with Standard 1.5.2 (i.e. to be listed in Schedule 26 and to comply with any corresponding conditions including being added only to infant formula products).

[1] For further information on any relevant New Zealand standard see section 2.4.1.3.
[2] Abbreviated as SMPPi

1.3.2.2 Nutritive substances

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance* (as defined in section 1.1.2—12). The applicant's 3-FL would be *used as a nutritive substance* for the purposes of the Code because its use in infant formula products is intended to achieve specific nutritional purposes.

Subsection 2.9.1—9(1) and section 2.9.1—37 provide for the use of optional nutritive substances in infant formula and in Special Medical Purpose Product for infants (SMPPi) respectively. Those sections provide that a substance listed in the table to section S29—7 may 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 minimum and no more than any maximum specified in the table.

Subsection 2.9.1—9(2) provides that a substance listed in the table to section S29—8 may 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 minimum and no more than any maximum specified in the table.

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

Therefore, express permission for the applicant's 3-FL to be *used as a nutritive substance* in infant formula products is also required in accordance with Standard 2.9.1 (i.e. be listed in the tables to section S29—7, S29—8 and S29—9), in addition to the above permission as a *food produced using gene technology* above.

1.3.3 Identity and purity

Section 1.1.1—15 requires that a substance *used as a nutritive substance* must comply with any relevant identity and purity specification in Schedule 3 when added to food in accordance with the Code or sold for use in food. There is no specification specifically relevant for the applicant's 3-FL in Schedule 3 of the Code. Consequently, the draft variation proposes to insert a specification for the applicant's 3-FL into Schedule 3 for this purpose.

1.3.4 Labelling requirements

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

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

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

- a name by which they are commonly known
- a name that describes their true nature, or
- a generic ingredient name if one is specified in Schedule 10 in accordance with any conditions specified in that schedule.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food. Paragraph 1.2.7—4(b) states a nutrition content claim or

health claim must not be made about an infant formula product.

Section 1.5.2—4 sets out the labelling requirements for foods for sale that consist of, or have as an ingredient, food that is a genetically modified food[3].

Division 3 of Standard 2.9.1 provides the labelling and packaging requirements for infant formula and follow-on formula. This includes specific requirements relating to the statement of ingredients, a mandated Nutrition Information Statement (NIS) which must contain specific information and be declared in a prescribed format, and prohibited representations. Paragraph 2.9.1—28(1)(i) prohibits the label on a package of infant formula or follow-on formula to contain (among other things) information relating to the presence of certain substances, including a substance used as a nutritive substance, except for a reference in a statement of ingredients, or in a declaration or statement expressly permitted or required by the Code, such as in the NIS.

Paragraphs 2.9.1—28(1)(e) and (f) set out prohibited representations relating to 'human milk oligosaccharide' (HMO) and 'human identical milk oligosaccharide' (HiMO) (both words and abbreviations) or other words or abbreviations having the same or similar effect.

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

1.4 International standards

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

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

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

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

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

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

Government 2024a), Wales (2024 No. 741 (W. 102)) (UK Government 2024b) and Scotland (2024 No. 156) (UK Government 2024c).

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

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

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

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

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

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

Overall, the available data indicate that intestinal absorption of human milk oligosaccharides, including 3-FL, is limited. A significant proportion reaches the large intestine where they are fermented by the microbiota or excreted unchanged in the faeces. *In vitro* and *in vivo* studies demonstrated that 3-FL does not pose a concern for genotoxicity. No adverse effects were

observed in a 90-day oral toxicity study in neonatal rats at doses up to 4000 mg/kg bw/day, or in older rats at doses ≥ 5900 mg/kg bw/day. There were no adverse effects in neonatal piglets given formula containing up to 2 g/L 3-FL for 21 days.

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

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

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

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

2.2 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 3-FL as a nutritive substance in infant formula products, subject to certain conditions. If approved, the proposed permissions would have to be exercised 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 3-FL as a nutritive substance 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 Use as a nutritive substance in infant formula products

In considering the proposed permission, FSANZ acknowledges that breastfeeding is the recommended way to feed infants and the intent of Standard 2.9.1 is not to replace human milk but to provide a safe, nutritionally replete, functional alternative for where breastfeeding is not possible. Given this, and in accordance with the Ministerial Policy Guideline on infant formula products[4], the composition of infant formula products should as closely as possible aim for nutritional equivalence to human milk.

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

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

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

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

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

The nutritional purpose for adding 3-FL to infant formula products is to create products that better reflect the oligosaccharide profile of human milk. A demonstratable health outcome in conjunction with bringing the composition of infant formula products closer to that of human milk reflects the primary purpose of consumption in supporting the development of infants that cannot be breastfed. In line with specific policy principle (j) of the Ministerial Policy Guideline, FSANZ has considered these requirements in assessing each of the beneficial health effects of 3-FL as stated in the application (i.e. increased bifidogenic effect and a decrease in pathogenic bacteria).

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

2.2.3 Proposed regulatory approval

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

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

If approved, the draft variation prepared by FSANZ would therefore have the effect of permitting this 3-FL, which is also a food produced using gene technology, to be used as a nutritive substance in infant formula products in accordance with the Code. The proposed approach is consistent with FSANZ's risk and technical assessment and the evidence base supporting 3-FL as a nutritive substance.

2.2.4 Total oligosaccharide amounts and cumulative effect

This application, if approved, will add a permission for a new oligosaccharide to infant formula products. This will be permitted to be added either as a single ingredient, or as a

mixture with the other permitted HiMO (Table 1). The proposed maximum amount of 3-FL in infant formula products is consistent with the concentration in human milk (see section 3.3.5 of SD1).

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

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

Table 1: ***Summary of infant formula product oligosaccharide permissions, including the proposed 3-FL***

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

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

Based on the proposed permissions for this 3-FL, 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 complies with carbohydrate permissions 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. The draft variation would insert a new

specification relating specifically to the applicant's 3-FL sourced from *E. coli* K-12 into Schedule 3, which this 3-FL would have to comply with when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use) (see section 2.3 and Table 3 of SD1). This specification would only apply to 3-FL sourced from *E. coli* K-12.

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[5].

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

FSANZ is proposing to provide the applicant with a 15-month exclusive use permission for this 3-FL 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, this 3-FL may only be sold for the purpose of being used as a nutritive substance in infant formula products in accordance with the Code under the brand name 'GlyCare'.

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

An exclusive use permission in the Code does not and cannot prevent approval of second or subsequent applications either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken.

2.2.8 Labelling

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

2.2.8.1 Statement of ingredients

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

Infant formula and follow-on formula

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

Generic ingredient labelling provisions in section 1.2.4—4 require ingredients to be identified using:

- a name by which they are commonly known
- a name that describes its true nature, or

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

- a generic ingredient name if one is specified in Schedule 10 - *Generic names of ingredients and conditions for their use* in accordance with any conditions specified in that Schedule.

A generic ingredient name for 3-FL has not been specified in Schedule 10. These ingredient naming requirements would apply to the applicant's 3-FL, enabling industry to have flexibility in how they declare this ingredient (e.g. using the name '3-fucosyllactose'). It should be noted existing prohibited representations for infant formula and follow-on formula in paragraphs 2.9.1—28(1)(e) and (f) would also apply to the ingredient name (refer to section 2.2.8.3 below) in relation to those products.

SMPPi

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

2.2.8.2 Mandatory nutrition information

Infant formula and follow-on formula

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

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

SMPPi

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

2.2.8.3 Prohibited representations and prohibited claims

Infant formula and follow-on formula

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

having the same or similar effect on the label of a package of infant formula or follow-on formula.

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

SMPPi

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

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

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

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

- a claim that is expressly permitted by this Code, or
- a declaration that is required by a Commonwealth, state or territory food law.

2.2.8.4 Voluntary representations

Paragraph 1.2.7—4(b) states that a nutrition content or health claim must not be made about an infant formula product. This provision would also apply to all infant formula products that contain the applicant's 3-FL.

2.2.8.5 Labelling as 'genetically modified'

The applicant states the production organism *E. coli* K-12 is removed during the processing and purification steps during the production of 3-FL (see section 2.3.1 of SD1). Based on previous FSANZ assessments of similar HiMO substances, it is considered highly unlikely that novel DNA or novel protein from the production organism would be present in an infant formula product containing the applicant's 3-FL as an ingredient. However, where novel protein or novel DNA is present, the requirement to label the 3-FL ingredient 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 permit the use of 3-FL from *E. coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *H. pylori* as a nutritive substance in infant formula products.

If the draft variation is approved, the applicant's 3-FL would be subject to relevant requirements and conditions in the Code, which include (but are not limited to) the following:

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

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

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

- Schedule 3 of the Code would set a specific specification for the applicant's 3-FL, with which it must comply when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

2.3 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, FSANZ's digital channels 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 on 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 members 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 3-FL as a nutritive substance in infant formula products is unlikely to have a significant effect on international trade as this substance is already permitted in similar products in 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

Background to the consideration of costs and benefits

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

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application).

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

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

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

Consumers

The proposed permission, if approved, would apply in Australia only and therefore any impacts would be on consumers in Australia only (see section 2.4.1.3 below).

On the basis of the findings of the risk assessment (see section 2.1 of this report and SD1), FSANZ considers the use of 3-FL as a nutritive substance in infant formula products to be safe for the proposed purpose. Therefore, no negative impacts are expected.

FSANZ's assessment also found that the proposed use as a nutritive substance in infant formula products would have a beneficial health outcome (see section 2.1 of this report and SD1).

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

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

The purpose of granting an exclusive use permission for a specified period of time (the exclusive use period) is to encourage industry innovation and allow applicants to achieve commercial rewards through higher returns on their investment. Any commercial reward from this application's exclusive use permission could come at the expense of consumers in the short-term, through other businesses not being able to compete to supply the applicant's 3-FL in infant formula products at lower prices during the exclusive use period. However, without this incentive this innovation may not have taken place. It is assumed that the greater incentive to innovate will lead to greater benefits in the medium to long term for consumers as more products come to market that may benefit them.

Industry

The proposed permissions that would be provided by the draft variation, if approved, would apply to infant formula products manufactured and /or sold in Australia only (see section 2.4.1.3 below).

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

Granting an exclusive use permission as proposed would prevent other businesses from producing the applicant's 3-FL in the short-term. However, the granting of exclusive use permission does not preclude any other company from applying to amend the Code in relation to the same food or ingredient.

Government

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

Conclusion

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

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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 a new permission for 3-FL to be added as a nutritive substance for the purposes of Standard 2.9.1 of the Code.

Standard 2.9.1 of the Code is an Australian only standard[6]. Schedule 29 of the Code lists the compositional requirements (e.g. permissions, limits, calculations, permitted forms etc.) for the purposes of that Australia only Standard 2.9.1, as well as Standards 2.9.2 to 2.9.5 of the Code. Standards 2.9.2 to 2.9.5 are joint standards that apply in both Australia and New Zealand.

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

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

FSANZ also understands that the consequential amendments made by Proposal P1028 to Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5, and Schedules 8, 15, 19, 25 and 29 of the Code have not been adopted in New Zealand under the *Food Act 2014* (NZ).

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

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.

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

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

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

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

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

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

[6] 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*.

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

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 the addition of 3-FL to infant formula products at the proposed maximum amount of 80 mg/100 kJ.

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

Current labelling requirements outlined in section 2.2.8 of this report would apply to infant formula products containing the applicant's 3-FL 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 2.2.8.3, which aim to prevent misleading or deceptive conduct, would apply to infant formula products containing the applicant's 3-FL.

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

- **the promotion of consistency between domestic and international food standards**

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. 3-FL is permitted in infant formula equivalent products in various countries around the world.

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

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

The proposed permission would support an internationally competitive food industry in relation to the use of 3-FL in infant formula products as a nutritive substance.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

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

- Regulation of Infant Formula Products
- Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods

Noting the food technology aspects, safety, nutritional impact and beneficial health effects 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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EU (2023) Commission Implementing Regulation (EU) 2023/2210 of 20 October 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli K-12 DH1 as a novel food and amending Implementing Regulation (EU) 2017/2470. *Official Journal of the European Union*. Available online at: https://eur-lex.europa.eu/eli/reg_impl/2023/2210/oj

FSANZ (2023) Application A1265: 2′-FL/DFL, LNT, 6′-SL sodium salt and 3′-SL sodium salt as nutritive substances in infant formula products. Approval Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/2023-11/A1265%20Approval%20Report.pdf

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https://www.legislation.gov.uk/ssi/2024/156/contents/made

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

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 A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation

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

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table, after the table item dealing with 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*)

Insert:

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

[2] After section S3—55

Insert:

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

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

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

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

(c) molecular weight—488.44 g/mol;

(d) CAS number—41312-47-4;

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

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

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

(h) L-fucose—not more than 1.0%;

(i) D-lactose—not more than 5.0%;

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

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

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

(m) water—not more than 6.0%;

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

(o) lead—not more than 0.05 mg/kg;

(p) microbiological:

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

Schedule 26—Food produced using gene technology

[3] Subsection S26—3(7) (table)

Insert:

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

Schedule 29—Special purpose foods

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

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg

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

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg

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

Insert:

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

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1324 which seeks to amend the Code to permit the use of 3-fucosyllactose (3-FL), a human-identical milk oligosaccharide (HiMO) produced using a genetically modified (GM) source organism, *Escherichia coli* K-12 to be used as a nutritive substance in infant formula products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance 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. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

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

part of those food laws.

3. Purpose

The Authority prepared the draft variation to amend Schedules 26 and 29 of the Code, which (if approved) would have the effect of permitting this 3-FL from a GM source to be used as nutritive substance in infant formula products in accordance with the Code.

Schedule 26 would also be amended to provide an exclusive use permission to the applicant, where for a period of 15 months commencing on the gazettal date of the draft variation (if approved), this 3-FL could only be sold under the applicant's brand name of GlyCare.

Last, the draft variation (if approved) would also amend Schedule 3 of the Code to add a new specification specifically for this 3-FL with which the 3-FL would have to comply when used as a nutritive substance in infant formula products in accordance with the Code or sold for such use.

4. Documents incorporated by reference

The 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 A1324 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 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 nutritive substances that have been determined to be safe are considered to be minor in impact and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Therefore, FSANZ's assessment is that a RIS is not required for this application.

6. Statement of compatibility with human rights

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 A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation*.

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

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

Items [1] and [2]

Items [1] and **[2]** of the Schedule to the variation 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 and difucosyllactose sourced from *Escherichia coli K-12*, a new entry for '3-fucosyllactose sourced from *Escherichia coli* K-12' and a corresponding reference to new section S3—56 (see item [2] below).

Item [2] would insert a new section S3—56 after section S3—55. The new section sets out the specifications relating specifically to '3-fucosyllactose sourced from *Escherichia coli* K-12', the new substance sought to be permitted by the applicant.

Consequently, if the draft variation is approved and 3-fucosyllactose sourced from *Escherichia coli* K-12 is permitted to be used as a nutritive substance in infant formula products, that substance would have to comply with these specifications when it used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

Item [3]

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

Schedule 26 relates to food produced using gene technology. 3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori* is a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is produced from an organism modified using gene technology.

Paragraph 1.5.2—3(a) permits a food for sale to consist of, or have as an ingredient, a food produced using gene technology if the food produced using gene technology (other than a processing aid or food additive) is listed in Schedule 26 and complies with any corresponding conditions in that Schedule.

The table to subsection S26—3(7) lists food produced using gene technology of microbial origin.

Item [3] would amend that table by adding the following as new table item 8:

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

Associated conditions for the use for 3-fucosyllactose from this source are as follows:

1. the substance may only be added to infant formula products;
2. during the exclusive use period, the substance may only be sold under the brand GlyCare®; and;
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.

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

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

If the variation is approved, the effect of the amendment in item [3] would be to permit the sale and use of the substance, 3-fucosyllactose from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori* as a food produced using gene technology in accordance with the Code, subject to the above conditions for use for the substance.

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

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

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

Item [4]

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

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

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

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

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

Item [5]

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

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

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

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

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

Item [6]

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

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

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

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

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

Proposed effect of the variation (if approved)

If the variation is approved, the amendments set out in the variation would have the effect of permitting 3-FL produced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori* to be used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).