16 June 2026
399-26

Approval report – Application A1340

A1340 - 2′-FL from GM *Escherichia coli* BL21 (gene donor: *Akkermansia muciniphila)* for use as a nutritive substance in infant formula products

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Suzhou Yixi Biotech Co., Ltd. to amend the Australia New Zealand Food Standards Code. The application seeks to permit 2′-fucosyllactose (2′-FL) produced from a new genetically modified source organism, *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila*, for use as a nutritive substance in infant formula products.

On 15 January 2026, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 3 submissions.

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

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

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

Table of contents

Supporting document

The following document which informed the assessment of this application are available on the A1340 page on the FSANZ website:

SD1 Risk and technical assessment – Application A1340

The published submissions from the call for submissions can be found on the A1340 Consultation Hub page.

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Suzhou Yixi Biotech Co., Ltd. to amend the Australia New Zealand Food Standards Code (the Code). The application sought to permit 2′-fucosyllactose (2′-FL) produced from a new genetically modified (GM) source organism, *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila*, for use as a nutritive substance in infant formula products. The applicant also requested an exclusive use permission under the brand name 'Synbilac' for a period of 15 months after gazettal of the approved draft variation.

The Code already permits 2′-FL from several GM sources for use in infant formula products. This application sought to permit 2′-FL produced from this new source organism.

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of the applicant's 2′-FL to infant formula products at the current maximum amount permitted for 2′-FL in the Code. The applicant's 2′-FL is chemically, structurally and functionally identical to the naturally occurring substance present in human milk. There is an existing specification for 2′-FL sourced from *E. coli* BL21 in the Code with which the applicant's 2′-FL will have to comply when it is added to infant formula products in accordance with the Code or sold for such use. The associated health benefits from the addition of 2′-FL to infant formula products for infants remain unchanged to those previously assessed by FSANZ: (1) an antipathogenic effect; (2) immunomodulation; and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 15 January to 12 February 2026. Three submissions were received and each was considered as part of our assessment.

FSANZ has approved the draft variation proposed at the call for submissions with one amendment. The approved draft variation will permit the use of 2′-FL produced from a new GM source organism as a nutritive substance in infant formula products in accordance with the Code.

The approved draft variation will:

- list the applicant's 2′-FL in Schedule 26 as a permitted GM food for use in infant formula products subject to associated conditions of use, including a 15-month exclusive use permission linked to the applicant's brand 'Synbilac'
- amend the specification for 2′-FL produced from *E. coli* BL21 in Schedule 3 to specify that the specification applies to 2′-FL sourced from *E. coli* BL21 containing the gene alpha-1,2-fucosyltransferase from either *A. muciniphila* or *E. coli* O126 (an already permitted donor organism)
- remove the 'no GMO detection' criterion from the current specification in Schedule 3 to align with other 2′-FL permissions.

The existing maximum amount and labelling requirements for 2′-FL in infant formula products in the Code will remain unchanged as a result of this application.

The effect of the approved draft variation is that the applicant's 2′-FL produced from this new GM source organism will be permitted for use as a nutritive substance in infant formula products manufactured and/or sold in Australia in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant, Suzhou Yixi Biotech Co., Ltd., is a manufacturer of food ingredients.

1.2 The application

Application A1340 sought to amend Schedule 3 and Schedule 26 of the Australia New Zealand Food Standards Code (the Code) to permit 2′-fucosyllactose (2′-FL) produced from a new genetically modified (GM) source organism for use as a nutritive substance in infant formula products[2]. This 2′-FL is sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila*.

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[3].

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 (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 GM food (as defined in section 1.1.2—16) or have as an ingredient or component a GM food.

The applicant's 2′-FL is a GM food as it is 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. 2′-FL produced from various sources is already permitted by the Code to be added only to infant formula products. However, 2′-FL from *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *A. muciniphila*

[2] Includes infant formula, follow-on formula and special medical purpose product for infants.
[3] For further information on any relevant New Zealand standard see section 2.5.1.3 of this report.

(the applicant's 2′-FL) is not listed in the table to subsection S26—3(7), and express permission is therefore required in accordance with section 1.5.2—3.

1.3.2.2 Nutritive substances

2′-FL is a non-digestible oligosaccharide found in human milk. Several human-identical milk oligosaccharides (HiMO), including 2′-FL, have previously been assessed by FSANZ and found to be functionally identical to the naturally occurring substance.

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. The applicant's 2′-FL will be used as a nutritive substance for the purposes of the Code. The use of the substance in infant formula products is intended to achieve a specific nutritional purpose, and the substance will be identified in the Code as a permitted nutritive substance (see section 1.1.2—12(1)).

Standard 2.9.1 and Schedule 29 already permit '2′-fucosyllactose permitted for use by Standard 1.5.2' to be used as an optional nutritive substance in infant formula products. Express permission of the applicant's 2′-FL by Standard 1.5.2 (see section 1.3.2.1 of this report) will also permit the applicant's 2′-FL to be used as an optional nutritive substance in infant formula products. Addition of the applicant's 2′-FL to infant formula products will not be a mandatory requirement in the Code as food businesses will be able to decide whether to add the applicant's 2′-FL.

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.

The maximum amount of 2′-FL permitted for use in infant formula products is 96 mg per 100 kJ (2.4 g/L) (see the tables to sections S29—7 and S29—8). There is no minimum amount specified for 2′-FL in these tables.

A substance used as a nutritive substance in infant formula products 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 listed form for 2′-FL permitted for use by Standard 1.5.2 is '2′-fucosyllactose' (see the table to section S29—9).

The applicant did not request any changes to existing permissions for 2′-FL in Standard 2.9.1 or Schedule 29.

1.3.3 Identity and purity

Section 1.1.1—15 requires a substance that is *used as a nutritive substance* to comply with any relevant identity and purity specification set out 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. This specification applies to any 2′-FL sourced from *E. coli* BL21 permitted in the Code. Currently, 2′-FL sourced from *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *E. coli* O126 is the only 2′-FL sourced from *E. coli* BL21 permitted in the Code is (see the table to subsection S26—7(3).

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 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,
- is not 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) (see 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 2.9.1—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 package 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 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.

2′-FL produced by microbial fermentation and by chemical synthesis is permitted for use in infant formula products, equivalent products and many other foods in at least 37 overseas countries at a range of amounts. Table 1 outlines some international permissions for 2′-FL.

Internationally, the permitted amounts of 2′-FL for use in infant formula range from 1.2 g/L to 3.0 g/L. FSANZ set the existing permitted maximum levels of 2′-FL in the Code after undertaking an assessment of safety, technical and health effects, including estimated dietary intakes and naturally occurring levels in human milk (FSANZ 2019; FSANZ 2021; FSANZ 2024).

Table 1: International permissions for use of 2′-FL in infant formula*

Country	Max. permitted amount (g/L)
Australia	2.4
New Zealand	2.4
United States (US FDA 2015, 2024)	2.0–2.4#
Canada (Health Canada 2023, 2025a & 2025b)	1.2–3.0#
Singapore (SFA 2024)	2.4
European Union (EU) (EU Commission 2024)	3.0
Israel (Israel MOH 2017)	2.0

Notes to table:
* Infant formula categories vary between countries
# Permitted maximum amounts are specific to each source of 2′-FL

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

In the United States, the applicant achieved self-Generally Recognized as Safe (GRAS) status, notified the Food and Drug Administration (FDA) and has received a response of 'no questions' (US FDA 2026).

1.5 Reasons for accepting application

The Application was accepted for assessment because:

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

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

The draft variation as proposed following assessment was approved with one amendment. The amendment was made to item [3] of the draft variation to correct a typographical error. Amended item [3] now makes clear that the 15-month exclusive use period commences *on the date of gazettal of the* approved draft variation. The approved draft variation will take effect on the date of gazettal of the variation. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ received a total of 3 submissions to the call for submissions (CFS) (see Table 2 below). The submissions are publicly available on the FSANZ website A1340 Consultation Hub page.

One industry submitter supported FSANZ's assessment and draft regulatory measure, one individual submitter did not and another industry submitter listed their response as 'other'. FSANZ's responses to submitter comments are provided in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
Request for clarification on toxicity study dosing		
Clarification sought on the 90-day sub-chronic toxicity study, specifically the route of administration and the methodology for calculating the body-weight dose.	Chr. Hansen A/S	FSANZ confirms the toxicity study was administered via the diet. Further clarification of the dose calculation is not considered necessary as it does not affect FSANZ's overall safety conclusions (see section 2.2 of this report).
Detection of Bacillus cereus and cereulide toxin		
The application does not specify methods for detection of *Bacillus cereus* or its toxin (cereulide), noting the recent global recall of infant formula products due to potential cereulide contamination.	Individual	FSANZ notes the submitter's concern. *B. cereus* is a known and managed food safety consideration in infant formula products. The recent global recall is not associated with the addition of purified carbohydrate ingredients such as the applicant's 2′-FL.

2.2 Risk assessment

The Code already permits 2′-FL from several source organisms to be used as a nutritive substance in infant formula products. FSANZ has determined that the applicant's 2′-FL is chemically, structurally and functionally identical to 2′-FL naturally present in human milk. No public health or safety concerns were identified and the established health benefits remain unchanged.

Analytical data confirm that the applicant's 2′-FL is chemically and structurally identical to the naturally occurring substance in human milk, similar to 2′-FL previously assessed and permitted by FSANZ. There is an appropriate specification for 2′-FL from *E. coli* BL21 in the Code. The applicant's 2′-FL is stable under ambient storage conditions.

FSANZ's previous assessments found no safety concerns for 2′-FL at concentrations up to 2.4 g/L in infant formula products. Newly available data support this conclusion. No adverse effects were observed in a 90-day oral toxicity study in rats and a prenatal developmental toxicity study in rats. Human clinical studies further confirm that infant formula products containing 2′-FL are safe and well tolerated. 2′-FL was not genotoxic in vitro or in vivo.

FSANZ's safety assessment did not identify any public health and safety concerns associated with the use of the applicant's GM strain of *E. coli* BL21 as a production organism for 2′-FL. Characterisation of the production strain confirmed that all introduced genes were genetically stable and functional.

Based on previous benefit assessments and given that the 2′-FL is chemically, structurally and functionally identical to 2′-FL naturally present in human milk, with no change requested to the maximum amount in infant formula products, the associated health benefits from the use of 2′-FL remain unchanged. These benefits are: (1) an anti-pathogenic effect; (2) immunomodulation; and (3) development of the gut microbiome by supporting growth of *Bifidobacteria* spp.

FSANZ has previously concluded that the addition of 2′-FL in infant formula products at levels typically found in human milk does not pose a risk to normal growth. One new study was reviewed for the current assessment, however due to a number of study limitations, this was not included in the body of evidence. Therefore, FSANZ maintains its previous conclusion.

Based on the available data, there are no public health and safety concerns associated with the addition of 2′-FL produced from the new source organism to infant formula products under the proposed conditions.

2.3 Risk management

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

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 15 January to 12 February 2026. The risk management options available to FSANZ after the submission period were to either:

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

For the reasons set out in this report, FSANZ decided to approve the draft variation with a minor change (see section 1.7 of this report). The approved draft variation will permit the use of the applicant's 2′-FL as a nutritive substance in infant formula products in accordance with the Code.

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

2.3.1 Regulatory approval

Application A1340 sought an amendment to the Code to permit the applicant's 2′-FL, a GM food, to be used as a nutritive substance in infant formula products. The applicant requested inclusion of the specific strain of their production organism, *E. coli* BL21(DE3), in this permission. FSANZ maintains an approach of using terminology in the Code that identifies parental strains, such as BL21, when no public health or safety concerns have been identified. Consequently, FSANZ considered inclusion of the applicant's particular strain (DE3) unnecessary, and it is not included in the approved draft variation.

The table to subsection S26—3(7) in the Code lists permitted GM food of microbial origin for

the purposes of Standard 1.5.2. This table includes a listing for 2′-FL produced from various sources, but not from *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *A. muciniphila*. The approved draft variation will amend the Code by listing *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *A. muciniphila* as a source of 2′-FL in the table to subsection S26—3(7).

The table to section S29—7 in the Code lists permitted nutritive substances in infant formula and SMPPi, and the table to section S29—8 lists permitted nutritive substances in follow-on formula. Those tables currently refer to '2′-fucosyllactose permitted for use by Standard 1.5.2'.

The approved draft variation will therefore have the effect of permitting:

- infant formula products for sale to consist of, or have as an ingredient or component, the applicant's 2′-FL as a GM food permitted under Standard 1.5.2
- the applicant's 2′-FL to be used as a nutritive substance at a maximum amount of 96 mg/100 kJ in infant formula products in accordance with the Code, for reasons set out in sections 1.3.2.1 and 1.3.2.2 of this report[4].

2.3.2 Specification

Section 1.1.1—15 requires that a substance that is *used as a nutritive substance* must comply with any relevant specification set out in Schedule 3 when added to food in accordance with the Code or sold for use in food. The specification for 2′-FL sourced from *E. coli* BL21 in section S3—45 is relevant to the applicant's 2′-FL. However, the applicant sought to either amend this existing specification or insert a new proposed specification to alter 3 parameters: 2′-FL purity, fucosyl-galactose byproduct allowance and no GMO detection.

Specifically, the applicant sought to increase the 2′-FL purity under paragraph S3—45(e) from 90.0% to 94.0% and to remove the allowance for up to 3% fucosyl-galactose byproduct under paragraph S3—45(j) (see section 2.3 of SD1). FSANZ's assessment concluded that:

- the applicant's 2′-FL was adequately identified by section S3—45
- there were no safety or technological concerns regarding the current limits for 2′-FL and fucosyl-galactose
- retaining these criteria will not impact on the permission for use sought by the applicant.

The applicant also sought removal of the requirement for no GMO detection in subparagraph S3—45(u)(viii). FSANZ's assessment verified that residual DNA is not present in the applicant's final product (see SD1), making the criterion redundant and the ongoing requirement for GMO testing an unnecessary burden on manufacturers. Furthermore, the presence of this requirement was found to be inconsistent with other 2′-FL specifications within the Code (sections S3—40, S3—51, S3—54(A)). Accordingly, the approved draft variation will omit the requirement for no GMO detection from subparagraph S3—45(u)(viii).

[4] FSANZ is concurrently assessing Application A1339, which seeks to amend the maximum amount of 2′-FL permitted for use as a nutritive substance in infant formula products. The assessment of A1340 is based on the current requirements in the Code.

The approved draft variation will also amend section S3—45 and the table to subsection S3—2(2) to refer to '2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase' from both of the following the donor organisms:

- *A. muciniphila*
- *E. coli* O126.

The amended specification will apply to both the existing permission in the Code for 2′-FL sourced from *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *E. coli* O126 (approved under Application A1190), as well as the permission sought by the applicant. These amendments ensure clarity and consistency in the identification of the gene and donor organism for 2′-FL permissions in the Code and will have no impact on existing permissions in the Code for 2′-FL to be used as nutritive substances in infant formula products.

The applicant's 2′-FL will have to comply with the specification set out in section S3—45 (as amended) when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

2.3.3 Exclusivity

An applicant may request exclusive permission to use and sell a food (including a substance) for a certain period of time. This permission is to recognise the investment made in the development of the food and the need to achieve return on investment, thereby supporting innovation[5].

The applicant sought an exclusive use permission for their specific brand of 2′-FL. The approved draft variation will grant the applicant a 15-month exclusive use permission commencing on the date of gazettal of the approved draft variation.

This means that, during the 15-month exclusive use period, the applicant's 2′-FL may only be sold for use as a nutritive substance in infant formula products in accordance with the Code under the brand name 'Synbilac'.

Following the conclusion of the 15-month exclusive use period, the exclusive use permission will revert to a general permission. As a result, this 2′-FL may be sold under any brand name for the purpose of being used as a nutritive substance in infant formula products in accordance with the Code.

An exclusive use permission in the Code does not, and cannot, prevent approval of subsequent applications by other food businesses for the use of the same food or ingredient within the 15-month exclusive use period, providing the usual application process is undertaken.

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

FSANZ is committed to reviewing any new evidence on the beneficial role of HiMO in the normal growth and development of infants. At the request of Food Ministers[6], FSANZ undertook a Five Year Review of the initial permission gazetted under Application A1155 and findings were considered by Food Ministers in November 2025[7]. The review concluded that

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

the addition of 2′-FL and lacto-N-neotetraose (LNnT) to infant formula products plays a beneficial role in the normal growth and development of infants by contributing to a microbiota profile more similar to breastfed infants and demonstrating anti-pathogenic benefits.

2.3.5 Labelling

The applicant did not request any changes to existing labelling requirements in the Code. The general and specific labelling requirements set out in section 1.3.4 of this report will therefore apply to the applicant's 2′-FL when used as a nutritive substance in infant formula, follow-on formula or SMPPi.

The applicant states that no residual DNA or proteins from the production organism remains in the final product (see section 2.3.2 of this report and section 2.3.1 of SD1). Based on the supplied data and previous FSANZ assessments of similar HiMO products, it is considered unlikely that novel DNA or novel protein from the production organism will be present in an infant formula product containing the applicant's 2′-FL as an ingredient. However, under circumstances where novel DNA or novel protein are present, the requirement to label the 2′-FL ingredient as 'genetically modified' will apply in accordance with section 1.5.2—4.

2.3.6 Risk management conclusion

Having considered and weighed all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines and current permissions for 2′-FL in the Code, FSANZ has decided to approve a draft variation to the Code that will:

- list the applicant's 2′-FL in Schedule 26 (table to subsection S26—3(7)) as a permitted GM food for use in infant formula products subject to associated conditions of use, including a 15-month exclusive use permission linked to the applicant's brand 'Synbilac'
- amend the specification for 2′-FL produced from *E. coli* BL21 in Schedule 3 (section S3—45) to specify that the specification applies to 2′-FL derived from *E. coli* BL21 containing the gene from alpha-1,2-fucosyltransferase from either *A. muciniphila* or *E. coli* O126 (an already permitted donor organism)
- amend the table to subsection S3—2(2) as a consequence of the above amendment to section S3—45
- remove the 'no GMO detection' criterion from the specification in section S3—45 to align with other 2′-FL permissions.

The applicant's 2′-FL will be subject to relevant requirements and conditions in the Code, which include (but are not limited to) the following:

- It may be added alone, or in combination with lacto-N-neotetraose (LNnT) to infant formula products as a nutritive substance up to a maximum amount of 96 mg per 100 kJ (2.4 g/L).
- The existing prohibition for the use of the words 'human identical milk oligosaccharide' or 'human milk oligosaccharide', the abbreviations 'HMO', 'HiMO', or any word or words, or abbreviation or abbreviations, having the same or similar effect, will apply to infant formula products that contain the applicant's 2′-FL.
- An exclusive use permission to use 2′-FL produced using *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *A. muciniphila* will apply for a period of 15 months, linked to the applicant's brand name 'Synbilac', commencing on the date of gazettal of the approved draft variation.

- The applicant's 2′-FL will have to comply with the specification in section S3—45 for 2′-FL sourced from *E. coli* BL21 (as amended) when used as a nutritive substance in infant formula products (or sold for such use).

2.4 Risk communication

2.4.1 Consultation

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

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

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

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

2.5.1.1.1 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 was 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 sought 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 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, 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.

2.5.1.1.2 Impacts on consumers

The approved permission will apply in Australia only and therefore any impacts would be on consumers in Australia only (see sections 1.3.1 and 2.5.1.1.3 of this report).

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FL produced from the applicant's GM source organism to infant formula products at the current permitted levels in the Code. Therefore, no negative impacts are expected for consumers.

There are no additional health benefits, because the associated health benefits from the addition of 2′-FL to infant formula products for infants are the same as other sources of 2′-FL.

The removal of the no GMO detection requirement from subparagraph S3—45(u)(viii) of the Code is not expected to negatively impact consumers. FSANZ's assessment has confirmed that residual DNA from the GM production organism is not present in the final 2′-FL product, ensuring that the safety and quality of infant formula products remain unchanged.

The applicant requested an exclusive use permission for their specific brand of 2′-FL. FSANZ has decided to provide the applicant with a 15-month exclusive use permission for this 2′-FL commencing on the date of gazettal of the approved draft variation.

It is possible that industry may achieve some price premium for products using this ingredient 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. As this source of 2′-FL is a substitute for other sources already in the market, the likelihood of a price premium negatively impacting consumers is reduced.

The purpose of granting an exclusive use permission for a specified period (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 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 2′-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.

2.5.1.1.3 Impacts on industry

The permissions provided by the approved draft variation will apply to infant formula products manufactured and/or sold in Australia only.

Domestic manufacturers (and exporters to Australia) of infant formula products that contain the applicant's specific brand of 2′-FL will be permitted to sell their products in Australia (where the products fully comply with the Code), subject to the exclusive use permission described above. This may result in more competition, which may benefit consumers.

Given the applicant's specific brand of 2′-FL is already permitted 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 products produced overseas.

The grant of an exclusive use permission to the applicant will prevent other businesses from producing the applicant's specific brand of 2′-FL in the short-term. However, this exclusive

use permission will not preclude any other company from applying to amend the Code in relation to the same food or ingredient.

The removal of the no GMO detection requirement from subparagraph S3—45(u)(viii) of the Code is expected to reduce unnecessary technical burdens for manufacturers of 2′-FL sourced from *E. coli* BL21. FSANZ's assessment has verified that residual DNA from the genetically modified production organism is not present in the final product, making the ongoing requirement for GMO testing technically redundant. Aligning this specification with other 2′-FL permissions in the Code promotes consistency and streamlines compliance processes, allowing manufacturers to avoid recurring costs associated with routine batch release testing for GMO residues. This change supports industry efficiency without compromising product safety or quality.

2.5.1.1.4 Impacts on governments

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

2.5.1.1.5 Conclusion of cost and benefit analysis

FSANZ's assessment is that the direct and indirect benefits that will arise from permitting use of the applicant's 2′-FL as a nutritive substance in infant formula products are likely to outweigh the associated costs.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

New Zealand opt-out from joint infant formula standard

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

Standard 2.9.1 is an Australian only standard regulating infant formula products[8]. Schedule 29 contains provisions for special purpose foods including infant formula products. Among other things, Schedule 29 lists the permissions, limits, calculations, permitted forms etc., for the purposes of 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). That is, 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 'Australian 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.

[8] 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 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 and 2.9.5, and Schedules 8, 15, 19, 25 and 29 of the Code have not been adopted in New Zealand under the *Food Act 2014* (NZ).

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

Approved draft variation amendments of Schedule 26 of the joint Code

Standard 1.5.2 sets out when food for sale may consist of, or have as an ingredient, a GM food and outlines associated labelling requirements. Schedule 26 lists permitted GM food, including GM food of microbial origin, and any associated conditions of use.

As outlined in section 1.3 of this report, Standard 2.9.1 and Schedule 29 currently permit 2′-FL permitted for use by Standard 1.5.2 to be used as a nutritive substance in infant formula products. As the applicant's 2′-FL is a GM food, permission to use that 2′-FL as a nutritive substance in infant formula products also requires express permission in accordance with Standard 1.5.2 and Schedule 26.

For this reason, the approved draft variation will amend Schedule 26 of the Code to list the applicant's 2′-FL as a permitted GM food subject to conditions of use, including that it may only be added to infant formula products.

Standard 1.5.2 and Schedule 26 are joint standards that apply in Australia and New Zealand.

However, the extent to which the New Zealand standard will permit the use of the applicant's 2′-FL as a GM food and nutritive substance in infant formula products in New Zealand remains a matter for the New Zealand Government.

FSANZ is not aware of any provisions of the joint Code that currently permit the use or sale of the applicant's 2′-FL as a food additive, processing aid or novel food.

Approved draft variation amendments of Schedule 3 of the joint Code

As described in section 1.3 of this report, section 1.1.1—15 of the Code requires that a substance that is *used as a nutritive substance* must comply with any relevant identity and purity specification set out in Schedule 3 when added to food in accordance with the Code or when sold for such use.

The approved draft variation will amend section S3—45 to specify the identity of the gene (alpha-1,2-fucosyltransferase) and donor organism (*A. muciniphila*) of the applicant's 2′-FL. The approved draft variation will also amend section S3—45 to specify the identity of the donor organism (*E. coli* O126) previously approved for the purposes of Application A1190.

These amendments to Schedule 3 aim to ensure consistency and clarity in the Code and will have no impact on existing permissions in the Code for 2′-FL to be used as a nutritive substance in infant formula products.

Standard 1.1.1 and Schedule 3 of the Code are joint standards that apply in both Australia and New Zealand. The application of the amended specification in the approved draft variation in New Zealand remains a matter for the New Zealand Government.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in section 2.2 of this report. The assessment concluded there is no evidence of a public health and safety concern associated with the use of the applicant's 2′-FL in infant formula products at the maximum amount of 96 mg/100 kJ.

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

Current labelling requirements outlined in section 1.3.4 of this report will apply to infant formula products containing the applicant's 2′-FL and will provide adequate information to enable consumers to make an informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 1.3.4, which aim to prevent misleading or deceptive conduct, will apply to infant formula products containing the applicant's 2′-FL.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the risk analysis framework[9] and considered the best available scientific evidence to reach its conclusions on the safety, technical and beneficial health outcomes of adding the applicant's 2′-FL to 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. 2′-FL is permitted in infant formula equivalent products and several other foods across various countries around the world.

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

The approved draft variation will support an internationally competitive food industry in relation to the use of 2′-FL as a nutritive substance in infant formula products and is consistent with existing permissions in the Code for 2′-FL.

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

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

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

- **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. The following Ministerial Policy Guidelines specifically apply to this application:

  - Regulation of Infant Formula Products
  - Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods
- Noting the food technology aspects, safety, nutritional impact and beneficial health effects assessed in SD1 and section 2.2 of this report, FSANZ considers that these Ministerial Policy Guidelines have been met.

3 References

Codex Alimentarius (2023) Standard for Follow-up formula for Older Infants and Product for Young Children. (CXS/156, adopted in 1987. Amendment: 1989, 2011, 2017, Revision: 2023. Codex Alimentarius Commission, Rome. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B156-1987%252FCXS_156e.pdf

Codex Alimentarius (2024) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. (CXS 72, adopted in 1981. Amendment: 1983, 1985, 1987, 2011, 2015, 2016, 2020, 2023 and 2024. Revision: 2007). Codex Alimentarius Commission, Rome. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

EU Commission (2024) Commission Implementing Regulation (EU) 2024/2102 of 30 July 2024 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 2′-Fucosyllactose and as regards the specifications of the novel food 2′-Fucosyllactose produced with a derivative strain of Escherichia coli BL-21. Official Journal of the European Union. http://data.europa.eu/eli/reg_impl/2024/2102/oj

FSANZ (2019) Application A1155 - 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Second Call for Submissions. Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1155_SD1_Risk%20assessment%20-%202nd%20CFS.pdf

FSANZ (2021) Application A1190 - 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Approval. Risk and safety assessment. Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1190_SD1%20at%20Approval.pdf

FSANZ (2024). Application A1283 - 2′-FL from GM Corynebacterium glutamicum in infant formula products. Supporting Document 1 at Call for Submissions. Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/2024-02/A1283%20SD1.pdf

Health Canada (2023) Novel Food Information: 2′-Fucosyllactose (Escherichia coli BL21 (DE3) Strain #1242). Health Canada, Ottawa. https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/2-fucosyllactose-escherichia-coli-strain-

1242/document.html

Health Canada (2025a) Novel Food Information: 2′-Fucosyllactose (Escherichia coli K-12 strain INB-2FL_03). Health Canada, Ottawa. https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/fucosyllactose-escherichia-coli-inb-strain/document.html

Health Cananda (2025b) Novel Food Information (2′-Fucosyllactose, 3-Fucosyllactose, Lacto-N-Tetraose, 3′-Sialyllactose and 6′-Sialyllactose Blend Produced by Escherichia coli BL21(DE3) Strains). Health Canada, Ottawa. https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/2-fucosyllactose-3-fucosyllactose-lacto-n-tetraose-3-sialyllactose-6-sialyllactose-blend/document.html

Israel MoH (2017) New Food Guideline: Fucosyllactose-O'-2 Oligosaccharide. Israel Ministry of Health, Jerusalem. https://www.gov.il/he/pages/fcs-07302717

SFA (2024) Food Regulations, Part IV Regulation 252—6(g) (Special Purpose foods: Infant formula). Singapore Food Agency, Singapore. https://sso.agc.gov.sg/SL/SFA1973-RG1?ProvIds=pr252-

US FDA (2015) Agency Response Letter GRAS Notice No. GRN 571 (2′-fucosyllactose, Reinbreitbach, Germany: Jennewein Biotechnologie, GmgH). U.S. Food and Drug Administration, Silver Spring. https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=571

US FDA (2024) Agency Response Letter GRAS Notice No. GRN 571 (2′-fucosyllactose, Shanghai, China: Synaura Biotechnology (Shanghai) Co., Ltd.). U.S. Food and Drug Administration, Silver Spring. https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=1157

US FDA (2026) GRAS Notices, GRN No. 1157 (2'-fucosyllactose, Suzhou, China: Suzhou Yixi Biotech Co., Ltd.). U.S. Food and Drug Administration, Silver Spring. https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=1261

Attachments

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

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

Food Standards (Application A1340 – 2′-FL from GM *Escherichia coli* BL21 (gene donor: *Akkermansia muciniphila*) for use as a nutritive substance in infant formula products) Variation

---

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

Dated [To be completed by Delegate]

[Insert name 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 A1340 – 2′-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) for use 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 item dealing with 2′-fucosyllactose sourced from *Escherichia coli* BL21)

Repeal the item, substitute:

2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126	section S3—45

[2] Section S3—45

Repeal the section, substitute:

S3—45 Specification for 2′-fucosyllactose sourced from *Escherichia coli* BL21

For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126*,* the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

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

(c) CAS number—41263-94-9;

(d) description—either a white to ivory powder, or a colourless to slightly yellow liquid;

(e) 2′-FL—not less than 90.0%;

(f) D-lactose—not more than 5.0%;

(g) L-fucose—not more than 3.0%;

(h) 3-fucosyllactose—not more than 5.0%;

(i) difucosyllactose—not more than 5.0%;

(j) fucosyl-galactose—not more than 3.0%;

(k) glucose—not more than 3.0%;

(l) galactose—not more than 3.0%;

(m) water—not more than 9.0% for powder, not applicable for liquid;

(n) solids—45% w/v (± 5%) dry matter in water, not applicable for powder;

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

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

(q) lead—not more than 0.02 mg/kg;

(r) arsenic—not more than 0.2 mg/kg;

(s) cadmium—not more than 0.1 mg/kg;

(t) mercury—not more than 0.5 mg/kg;

(u) microbiological:

(i) *Salmonella*—absent in 100 g for powder, absent in 200 mL for liquid

(ii) total plate count—not more than 10000 cfu/g for powder, not more than 5000 cfu/g for liquid;

(iii) coliform/Enterobacteriaceae—absent in 11 g for powder, absent in 22 mL for liquid;

(iv) *Cronobacter sakazakii*—absent in 100 g for powder, absent in 200 mL for liquid;

(v) yeast and mould—not more than 100 cfu/g for powder, not more than 50 cfu/g for liquid;

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

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

Schedule 26— Genetically modified food

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

Insert:

	(h) *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyl-transferase from *Akkermansia muciniphila*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand Synbilac. 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 A1340 – 2'-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) Variation* and ending 15 months after that date.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1340 - 2'-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) for use 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 purpose of the Application A1340 was to amend the Code to permit 2′-fucosyllactose (2′-FL) produced from a new genetically modified (GM) source organism, *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila,* to be used as a nutritive substance in infant formula products. The application also sought a 15-month exclusive use permission in relation to that substance. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1340 - 2'-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) for use as a nutritive substance in infant formula products) Variation* (the approved draft variation).

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

2. Variation is a legislative instrument

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

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

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

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

3. Purpose

The Authority has approved the draft variation to:

- Amend Schedule 26 of the Code to permit the sale and use of 2′-FL produced from a new GM source, *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila*, as a GM food for the purposes of Standard 1.5.2 of the Code. This permission is subject to certain conditions, including an exclusive use permission for a period of 15 months linked to the applicant's brand name 'Synbilac'. This amendment to Schedule 26 consequently permits 2′-FL produced from the new GM source to be used as a nutritive substance in infant formula products for the purposes of Standard 2.9.1 subject to those conditions.
- Amend Schedule 3 of the Code to:
  - specify that the specification in section S3—45 for 2′-FL sourced from *Escherichia coli* BL21 applies to 2′-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* (the applicant's donor organism) or *Escherichia coli* O126 (donor organism for which an existing permission exists)
  - remove the criterion for 'GMO detection—not detected' in subparagraph S3—45(u)(viii) from the specification in Schedule 3 of the Code for 2′-FL sourced from *E. coli* BL21 (section S3—45) – a criterion assessed by FSANZ as being not necessary.

4. Documents incorporated by reference

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

However, the approved draft variation will vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of Standard 1.1.1 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 A1340 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 15 January 2026 for a 4-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

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

6. Statement of compatibility with human rights

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

7. Variation

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1340 – 2′-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) for use 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.

7.1 Items [1] and [2]

Items [1] and **[2]** of the Schedule to the variation amend Schedule 3 of the Code.

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

Item [1] amends the table to subsection S3—2(2) by repealing the table item dealing with '2′-fucosyllactose sourced from *Escherichia coli* BL21' and substituting the repealed table item with an amended item: '2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126' and a corresponding reference to section S3—45 (see **item [2]** below).

This amendment is consequential to the amendment in **item [2]** below.

Item [2] amends section S3—45, which sets out the specification for 2′-FL sourced from *Escherichia coli* BL21. 2′-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126 was the only 2′-FL sourced from *Escherichia coli* BL21 listed in the table to subsection S26—3(7) as a permitted GM food of microbial origin, i.e. permitted to be sold and used as a GM food in accordance with the Code. Consequently, the existing specification only applied to that 2′-FL for the purposes of the Code.

Item [2] amends section S3—45 by repealing the section and substituting the repealed section with an amended section S3—45 setting out a specification for '2′-fucosyllactose sourced from *Escherichia coli* BL21' with the following two changes.

First, the text 'For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* BL21' is amended

to ‘For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126’. The new text refers to 2′-FL sourced from *Escherichia coli* BL21 containing the alpha-1,2-fucosyltransferase from donor organisms approved under Application A1190 and Application A1340.

Second, the criterion for ‘GMO detection—not detected’ in subparagraph S3—45(u)(viii) is removed.

The effects of the amendments in **items [1]** and **[2]** are that:

- the amended specification applies specifically to 2′-FL produced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126
- 2′-FL produced from either of those source organisms will have to comply with the amended specification set out in section S3—45 when added to infant formula products for use as a nutritive substance in accordance with the Code (or sold for such use)
- as the criterion for ‘GMO detection—not detected’ in subparagraph S3—45(u)(viii) is removed from that specification - food businesses no longer have to comply with that criterion.

7.2 Item [3]

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

Schedule 26 relates to GM food.

2′-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila* is a GM food (as defined in section 1.1.2—16 of the Code) because it is a food derived from an organism that contains novel DNA and does not fall within any of the exceptions listed in that section.

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

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

The table to subsection S26—3(7) lists permitted GM food of microbial origin. Item 1 of this table sets out various sources of 2′-FL and their corresponding conditions of use.

Item [3] amends item 1 of the table to subsection S26—3(7) by inserting a new entry consisting of the applicant’s 2′-FL and associated conditions of use into columns 3 and 4 of that table respectively. This new entry is listed as paragraph (h) and consists of the following:

- the new permitted source of 2′-FL is:

  ‘Escherichia coli BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila’*

- associated conditions of use for 2′-FL from this new source are:
  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 Synbilac; and
  3. for the purposes of condition 2,’exclusive use period’ means the period commencing on the date of gazettal of the *Food Standards (Application A1340 -*

2′-FL from GM Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) for use as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.

Condition 2 means that 2′-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila* may only be sold under the brand 'Synbilac' during the exclusive use period. 'Exclusive use period' is defined in condition 3 as the period commencing on the date of gazettal of the variation and ending 15 months after that date.

Once the exclusive use period ends, the exclusive use permission will revert to a general permission, meaning that 2′-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila* may be sold under any brand.

The effect of the amendment in **item [3]** is to permit the sale and use of the substance, *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila* as a GM food in accordance with the Code, subject to the above conditions of use for the substance.

Permission for the substance to be used as a nutritive substance in infant formula products

Standard 2.9.1 and Schedule 29 already permit '2′-fucosyllactose permitted for use by Standard 1.5.2' to be used as a nutritive substance in infant formula products at an amount no greater than 96 mg/100 kJ.

Consequently, the effect of the amendment in **item [3]** is to also permit 2′-FL from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Akkermansia muciniphila* to be used as a nutritive substance in infant formula products at an amount no greater than 96 mg/100 kJ.

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

Food Standards (Application A1340 – 2′-FL from GM *Escherichia coli* BL21 (gene donor: *Akkermansia muciniphila*) for use as a nutritive substance in infant formula products) Variation

---

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

Dated [To be completed by Delegate]

[Insert name 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 A1340 – 2'-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) for use 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 item dealing with 2′-fucosyllactose sourced from *Escherichia coli* BL21)

Repeal the item, substitute:

2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126	section S3—45

[2] Section S3—45

Repeal the section, substitute:

S3—45 Specification for 2′-fucosyllactose sourced from *Escherichia coli* BL21

For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from either *Akkermansia muciniphila* or *Escherichia coli* O126*,* the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

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

(c) CAS number—41263-94-9;

(d) description—either a white to ivory powder, or a colourless to slightly yellow liquid;

(e) 2′-FL—not less than 90.0%;

(f) D-lactose—not more than 5.0%;

(g) L-fucose—not more than 3.0%;

(h) 3-fucosyllactose—not more than 5.0%;

(i) difucosyllactose—not more than 5.0%;

(j) fucosyl-galactose—not more than 3.0%;

(k) glucose—not more than 3.0%;

(l) galactose—not more than 3.0%;

(m) water—not more than 9.0% for powder, not applicable for liquid;

(n) solids—45% w/v (± 5%) dry matter in water, not applicable for powder;

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

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

(q) lead—not more than 0.02 mg/kg;

(r) arsenic—not more than 0.2 mg/kg;

(s) cadmium—not more than 0.1 mg/kg;

(t) mercury—not more than 0.5 mg/kg;

(u) microbiological:

(i) *Salmonella*—absent in 100 g for powder, absent in 200 mL for liquid

(ii) total plate count—not more than 10000 cfu/g for powder, not more than 5000 cfu/g for liquid;

(iii) coliform/Enterobacteriaceae—absent in 11 g for powder, absent in 22 mL for liquid;

(iv) *Cronobacter sakazakii*—absent in 100 g for powder, absent in 200 mL for liquid;

(v) yeast and mould—not more than 100 cfu/g for powder, not more than 50 cfu/g for liquid;

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

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

Schedule 26— Genetically modified food

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

Insert:

(h) Escherichia coli BL21 containing the gene for alpha-1,2-fucosyl-transferase from *Akkermansia muciniphila*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand Synbilac. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing *Food Standards (Application A1340 – 2'-FL from GM* Escherichia coli *BL21 (gene donor:* Akkermansia muciniphila*) Variation* and ending 15 months after that date.