24 March 2026
385-26

Approval report – Application A1334

A1334 – 2′-FL from GM *Corynebacterium glutamicum* (gene donor: *Corynebacterium urealyticum)* in infant formula products

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Cataya Bio (Shanghai) Company Limited to amend the Australia New Zealand Food Standards Code to permit the use of 2′-fucosyllactose produced from a genetically modified source organism, *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum*, as a nutritive substance in infant formula products.

On 21 October 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 5 submissions.

FSANZ approved the draft variation on 10 March 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 24 March 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 A1334 page on the FSANZ website:

Supporting Document 1 (SD1) Risk and technical assessment – Application A1334 (at Approval)

The published submissions from the call for submissions can be found on the A1334 Consultation Hub page.

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Cataya Bio (Shanghai) Company Limited to amend the Australia New Zealand Food Standards Code (the Code) to permit their 2′-fucosyllactose (2′-FL) produced from a new genetically modified (GM) source organism for use as a nutritive substance in infant formula products. The applicant's 2′-FL is sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum.* The Code already permits 2′-FL sourced from other GM organisms for use in infant formula products, however, it does not currently permit the applicant's 2′-FL for this purpose. The applicant has also requested an exclusive use permission under the brand name 'XINFU 2′-FL' for a period of 15 months after gazettal.

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FL sourced from the applicant's GM organism to infant formula products at the maximum amount permitted 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 a specification for 2′-FL from *C. glutamicum* in the Code, which is relevant to the applicant's 2′-FL and with which the applicant's 2′-FL will have to comply when it is added to food for sale i.e. infant formula products, 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 anti-pathogenic effect; (2) immunomodulation; and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 21 October 2025 to 18 November 2025. Five submissions were received, and each was considered as part of our assessment.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions without change. The approved draft variation will permit 2′-FL produced from this new GM source for use as a nutritive substance in infant formula products in accordance with the Code.

The approved draft variation will:

- amend Schedule 26 of the Code by listing a new entry for the applicant's 2′-FL and associated conditions of use in the table to subsection S26—3(7), including an exclusive use period of 15 months linked to the applicant's brand name 'XINFU 2′-FL'
- amend the existing specification for 2′-FL sourced from *C. glutamicum* in Schedule 3 of the Code (section S3—51) to specify that the source may contain the gene for alpha-1,2-fucosyltransferase from either *C. urealyticum* (new permitted donor organism) or *Pseudopedobacter saltans* (existing permitted donor organism). It is intended that inclusion of the identity of the permitted gene and donor organisms in the amended specification will provide clarity and consistency with existing permissions for 2′-FL in the Code.

The approved permission would be subject to relevant maximum amount and labelling requirements in the Code.

The effect of the approved draft variation will be 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, Cataya Bio (Shanghai) Company Limited is a manufacturer of chemical and biochemical products.

1.2 The application

Application A1334 sought to amend 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 to be used as a nutritive substance in infant formula products[2]. This 2′-FL is sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum.*

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 or have as an ingredient or component a GM food.

2′-FL produced from various sources is already permitted in the Code as a GM food of microbial origin for use in infant formula products, however not 2′-FL from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* (the applicant's 2′-FL).

The applicant's 2′-FL is a GM food (section 1.1.2—16) as it is a food derived from an organism that contains novel DNA and does not fall within any of the exceptions listed in paragraph 1.1.2—16(1)(b). Consequently, express permission for the applicant's 2′-FL to be used in infant formula products in accordance with the Code (or sold for such use) is required

[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.

in accordance with section 1.5.2—3 (i.e. to be listed in Schedule 26 and to comply with any corresponding conditions).

1.3.2.2 Nutritive substances

Paragraph 1.1.1—10(6)(b) requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance* (as defined in section 1.1.2—12). The applicant's 2′-FL will be *used as a nutritive substance* for the purposes of the Code because its use in infant formula products is intended to achieve specific nutritional purposes and it is a substance that would be identified in this Code as a permitted nutritive substance (see section 1.1.2—12(1)).

2′-FL is a non-digestible oligosaccharide that is a component of 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.

The applicant's 2′-FL will be an optional nutritive substance used in infant formula products for the purposes of Standard 2.9.1 as food businesses would be able to decide whether to add the substance to those products. Addition of the applicant's 2′-FL to infant formula products will not be a mandatory requirement in the Code.

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

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

A substance used as a nutritive substance in infant formula, follow-on formula or SMPPi must be added to the formula or product in a permitted form. For nutritive substances that are not vitamins, minerals or electrolytes, paragraphs 2.9.1—10(b) (infant formula and follow-on formula) and 2.9.1—38(b) (SMPPi) provide that the permitted forms are listed in the table to section S29—9. The permitted form for 2′-FL permitted for use by Standard 1.5.2 is "2′-fucosyllactose".

The applicant is not requesting any changes to the existing permissions for 2′-FL in the tables to sections S29—7, S29—8 and S29—9.

2′-FL permitted for use by Standard 1.5.2 (see section 1.3.2.1 of this report above) is currently listed in the tables to section S29—7 and section S29—8 as being permitted for use as a nutritive substance in infant formula products at amounts of up to 96 mg/100 kJ (equivalent to 2.4 g/L)[4].

[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 A1334 is based on the current requirements in the Code.

As the applicant's 2′-FL will be permitted for use by Standard 1.5.2, the applicant's 2′-FL will also be permitted to be used as a nutritive substance in infant formula products for the purposes of Standard 2.9.1 and Schedule 29.

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 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 *C. glutamicum* under section S3—51. In addition to the applicant's 2′-FL, this existing specification is relevant to the only other 2′-FL sourced from *C. glutamicum* listed in the table to subsection S26—3(7) i.e., 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*.

1.3.4 Labelling requirements

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

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

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

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

Standard 1.2.7 sets out the restrictions, requirements and conditions for making voluntary nutrition, health and related claims about food. Paragraph 1.2.7—4(b) states a nutrition content claim or health claim must not be made about an infant formula product.

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

- contains, or consists of, a GM food that is listed in Schedule 26, and
- the GM food:
  - contains novel DNA or novel protein, or
  - is listed in section S26—3 as being subject to a condition that its labelling must comply with section 1.5.2—4 (these foods are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not a GM food), and

- is not any of these foods:

  - a food for sale that contains a GM food that is:
    - unintentionally present in the food for sale; and
    - present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient,

  - a food for sale that is:

- intended for immediate consumption; and
- prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).

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

- requirements that a package of infant formula or follow-on formula must not contain (among other things):
  - information relating to the presence of certain substances, including a substance used as a nutritive substance, except for a reference in a statement of ingredients, or in a declaration or statement expressly permitted or required by the Code, such as in the Nutrition Information Statement (NIS) (paragraph 2.9.1—28(1)(i)),
  - representations relating to 'human milk oligosaccharide' (HMO) and 'human identical milk oligosaccharide' (HiMO) (both words and abbreviations) or other words or abbreviations having the same or similar effect (paragraphs 2.9.1—28(1)(e) and (f)),

- a mandated NIS which must contain specific information and be declared in a prescribed format (sections 2.9.1—24 and 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.

It is noted that 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 amounts of 2′-FL in the Code after undertaking a safety, technical and health effects assessment, 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 European Union (EU), Cataya Bio (Shanghai) Company Limited has applied for authorisation of 2′-FL produced by a derivative strain (CGMCC 7.559) of *C.glutamicum* ATCC 13032 as an already approved novel food. The application is currently undergoing risk assessment by the European Food Safety Authority (EFSA) (EFSA 2025).

In the United States (US), Cataya Bio (Shanghai) Company Limited achieved self-Generally Recognized as Safe (GRAS) status and has notified the Food and Drug Administration (FDA) and has received a response of 'no questions' (FDA 2025).

1.5 Reasons for accepting application

The application was accepted for assessment because:

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

1.6 Procedure for assessment

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

1.7 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. 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 5 submissions to the CFS (see Table 2 below). The submissions are publicly available on the FSANZ A1334 Consultation Hub page.

One industry and one individual submitter supported FSANZ's assessment and/or draft regulatory measure and 2 submitters (individuals) did not. One submitter (individual) listed their response as 'other'. Submitters provided comments on FSANZ's assessment and/or the draft regulatory measure. FSANZ's responses to submitter comments are provided in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
There is limited long-term clinical evidence on HiMO safety, with most studies addressing short-term tolerance rather than developmental or metabolic outcomes.	Individual	FSANZ considers that longer-term toxicity or clinical studies of 2′-FL are not required. This conclusion is based on the following considerations: • 2′-FL is identical to that found in human milk, and estimated dietary intakes at the proposed maximum amount are within the range of estimated dietary intakes of naturally occurring 2′-FL from human milk. This provides a history of safe use by human infants. • Intestinal absorption of 2′-FL is very limited. • No adverse effects were observed at very high doses in 90-day oral toxicity studies with neonatal rats or in older rats, and there were no adverse effects in neonatal piglets given formula containing 2′-FL. • The 90-day exposure period used in the rat studies is equivalent to approximately 9 human years (Sengupta 2013[5]). • The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has concluded that safety studies in very young animals are critical for substances used in infant formula. These studies provide a more complete evaluation of safety than human clinical studies. This is because they include detailed investigations that cannot be done in human studies, such as microscopic examination of organs and tissues. In addition, neonatal rats are likely to be substantially more sensitive to any adverse health effects due to their relative gut immaturity compared to newborn human infants. • Clinical studies in human infants have also found no adverse effects.
There is limited evidence for safety of GMO pertaining to feeding infants.	Individual	FSANZ has conducted a comprehensive safety assessment of the GM strain of *C. glutamicum* used to produce the 2′-FL intended for use in infant formula products. This assessment included a detailed evaluation of the genetic modifications to the production organism, including their stability. The safety assessment concluded there are no safety concerns associated with the use of the GM *C. glutamicum* as the production organism. Please refer to section 3.1.2 of the SD1. In addition, FSANZ notes that 2′-FL is highly purified, and analysis of the final preparation demonstrated neither viable cells nor DNA from the production organism were detectable in the final product. Refer to section 3.1.1 of the SD1.

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

Issue	Raised by	FSANZ response (including any amendments to drafting)
The dossier lacks sufficient detail on genetic modifications, fermentation substrates and purification steps, making it difficult to assess residuals, by-products or allergenic risks.	Individual	As noted in section 3 of the SD1, some information relevant to the safety assessment was deemed Confidential Commercial Information (CCI) under Section 114 of the *Food Standards Australia New Zealand Act (1991)* meaning it cannot be disclosed. However, FSANZ evaluated this information as part of its safety assessment. The data provided on the genetic modification was sufficient to enable a comprehensive safety assessment to be completed. With respect to allergenicity, batch analysis of the applicant's 2′-FL indicates a lack of detectable proteins. The specification for 2′-FL from *C. glutamicum* at section S3—51 of the Code lists a protein content of not more than 0.005%, while batch analyses provided with the present application found protein levels to be < 0.0016%, the limit of detection. Therefore, 2′-FL is unlikely to pose an allergenicity concern. Consistent with this conclusion, a study by Nowak-Wegrzyn et al. (2019[6]), reviewed by FSANZ as part of the A1155 Review[7], found infant formula containing 1.0 g/L 2′-FL (source unspecified) was hypoallergenic in infants with cow's milk protein allergy.
Introducing a new HiMO source raises concerns about variability in purity and contamination, requiring strict specifications and independent verification. The term "human-identical" may be misleading unless molecular identity and stereochemistry are fully confirmed.	Individual	The applicant's 2′-FL must comply with the specification set out in section S3—51 when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use). That specification includes parameters for identity and purity. Independent verification may be required for enforcement purposes to ensure this 2′-FL meets those parameters. FSANZ has assessed information provided by the applicant regarding chemical identity and structure and is satisfied the applicant's 2'-FL is identical to that found in human milk. FSANZ has also assessed data provided for sample batches of the applicant's 2′-FL from the new source to confirm it can meet the relevant specification for 2′-FL from *C. glutamicum*.

[6] Nowak-Wegrzyn A, Czerkies L, Reyes K, Collins B, Heine RG (2019) Confirmed hypoallergenicity of a novel whey-based extensively hydrolyzed infant formula containing two human milk oligosaccharides. Nutrients 11:1447

[7] Application A1155 Review. Supporting Document 1 – Safety and Growth Assessment (5 October 2020 [137-20]).

Issue	Raised by	FSANZ response (including any amendments to drafting)
The statement that 2'-FL is chemically, structurally, and functionally the same as the naturally occurring substance found in human milk and other 2'-FL previously assessed and permitted by FSANZ needs to be supported by robust evidence. Functional benefits of this source have not been independently replicated, and extrapolation from other HiMO is not scientifically justified.	Individuals (2)	FSANZ has assessed the functional effects of 2′-FL compared to the same substance in human milk in application A1155, where no differences were identified. 2'-FL naturally present in human milk is chemically and structurally identical to 2'-FL produced from microbial or synthetic processes. Both forms demonstrate indistinguishable physiological effects in the gut. Therefore, there is no reason to expect unique effects from 2′-FL produced by a new GM-microbial source when used at amounts consistent with human milk.
The inclusion of synthetic “human-identical” ingredients in infant formula raises ethical concerns, as marketing claims may blur the distinction between infant formula and breast milk.	Individual	Noted. Provisions in the Code related to infant formula products prohibit the making of certain claims and representations in relation to those products. These provisions aim to protect carers of infants who consume infant formula products (for example, parents of those infants) from misleading and deceptive conduct and enable those carers to make informed choices about those products. For example: Paragraph 1.2.7—4(b) of the Code states a nutrition content claim or health claim must not be made about an infant formula product. Further, paragraphs 2.9.1—28(1)(e) and 2.9.1—28(1)(f) of the Code prohibit the use of the terms ‘human milk identical’ and ‘human identical milk oligosaccharide’, the abbreviations ‘HMO’ or HiMO’, or words or abbreviations of similar effect on the label for infant formula products. See section 1.3.4 of this report.
Comments were received relating to FSANZ assessment of 3-fucosyllactose under Application A1324.	Individual	Those comments are not in scope for this current application.

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. The permitted maximum amount of 2′-FL in infant formula products is 96 mg/100 kJ, equivalent to 2.4 g/L. The purpose of the present assessment was to assess the safety of the applicant's 2′-FL produced by microbial fermentation using a strain of *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum.*

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 present in human milk, similar to 2′-FL previously assessed and permitted by FSANZ. There is a specification for 2′-FL from *C. glutamicum* in the Code, which is relevant to the applicant's 2′-FL and with which the applicant's 2′-FL will have to comply when it is added to food for sale i.e. infant formula products, or sold for such use. The substance is stable under ambient storage conditions.

FSANZ's microbiological risk assessment did not identify any public health and safety concerns associated with the use of *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* as a production organism for 2′-FL. Characterisation of the GM production strain confirmed that all introduced genes were genetically stable and functional.

As the applicant's 2′-FL is identical to naturally occurring 2′-FL, it is not anticipated there will be any significant differences in pharmacokinetics or safety between naturally occurring and manufactured forms of these substances. Intestinal absorption of HMO is limited and a significant proportion reaches the large intestine where they are fermented by the microbiota or excreted unchanged in the faeces.

Toxicity studies previously reviewed by FSANZ demonstrated 2′-FL is not genotoxic and does not produce adverse effects in short-term oral toxicity studies, including studies using neonatal animal models. In human clinical studies, infant formula containing 2′-FL was safe and well tolerated. Newly available toxicity studies of the applicant's 2′-FL were consistent with the previously reviewed data. 2′-FL did not cause acute toxicity and was not genotoxic. In a 90-day oral toxicity study in rats, the NOAEL was 10% in the diet (equal to 7460 mg/kg bw/day), the highest concentration tested. In a prenatal developmental toxicity study in rats, the NOAEL for maternal and fetal toxicity was 10000 mg/kg bw/day, the highest dose tested.

Previous dietary intake assessments performed by FSANZ have shown estimated mean and 90th percentile dietary intakes of 2′-FL from infant formula products at the maximum amount permitted in the Code fall within the range of estimated dietary intakes from mature human milk.

FSANZ previously reviewed 20 clinical trials and cohort studies that measured the effect of infant formula containing 2′-FL on infant growth. It was 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 reviewed for the current assessment reported no significant differences in growth between infants consuming infant formula products with or without 2′-FL or breastfed infants. Therefore, FSANZ maintains its previous conclusion.

Based on microbiological assessments and given that the 2′-FL is chemically, structurally and functionally identical, with no changes to the maximum amount permitted in infant

formula products requested, FSANZ has concluded that there are no microbiological public health and safety concerns. The associated health benefits from the use of 2′-FL as a nutritive substance in infant formula products for infants remain the same: (1) an anti-pathogenic effect; (2) immunomodulation and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Based on the available data, there are no public health and safety concerns associated with the addition of 2′-FL from the new source organism to infant formula products at the maximum amount permitted in the Code.

2.3 Risk management

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

The risk management options available to FSANZ after the submission period were to:

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

For the reasons set out in this report, FSANZ decided to approve the draft variation to the Code proposed at the call for submissions without change. 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 (see Section 2.4 below) in developing the draft variation.

2.3.1 Regulatory approval

Application A1334 requested 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 approved draft variation will amend the Code by listing *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* as a permitted source of 2′-FL in the table to subsection S26—3(7). This will have the effect that infant formula products for sale will be permitted to have as an ingredient or component 2′-FL from that source as a GM food in accordance with the Code for the purposes of Standard 1.5.2.

For reasons set out at Sections 1.3.2.1 and 1.3.2.2 of this report, as the applicant's 2′-FL will be 'permitted for use by Standard 1.5.2', the applicant's 2′-FL will also be permitted to be used as a nutritive substance in infant formula products for sale in accordance with the Code for the purposes of Standard 2.9.1 and Schedule 29.

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 approved draft variation will amend section S3—51 and the table to subsection S3—2(2).

As set out in Section 1.3.3 above, section S3—51 sets out the specification for 2′-FL sourced from *C. glutamicum*. Currently, the only 2′-FL sourced from *C. glutamicum* to which the specification applies is *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* - a substance permitted by the Code to be used as a nutritive substance in infant formula products as a result of Application A1283 (the A1283 2′-FL).

The table to subsection S3—2(2) refers to the name of the substance and its associated provision.

The draft variation will amend section S3—51 and table to subsection S3—2(2) to specify the identity of the gene and donor organisms of the 2′-FL to which that specification will apply, i.e.: '2′-fucosyllactose (2′-FL) sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* or *Pseudopedobacter saltans*'.

The effect of those amendments will be to clarify that the specification applies to 2′-FL sourced from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from the two donor organisms permitted by the Code to be used as nutritive substances in infant formula products – the applicant's 2′-FL and the A1283 2′-FL.

Consequently, the applicant's 2′-FL and the A1283 2′-FL will have to comply with the specification set out in section S3—51 when used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use).

The amendment will have no impact on existing 2′-FL permissions in the Code.

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 to recognise the investment made in developing that food and the need to achieve return on this investment, thereby supporting innovation[8].

The applicant has requested an exclusive use permission for their specific brand of 2′-FL.

FSANZ has decided to grant the applicant with a 15-month exclusive use permission for this 2′-FL commencing on the date of gazettal of the approved draft variation.

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

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

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

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

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[9], FSANZ undertook a Five Year Review of the initial permission gazetted under Application A1155 and findings were considered by Food Ministers in November 2025[10]. The review concluded that 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 to infant formula, follow-on formula or SMPPi.

The applicant states the production organism *C. glutamicum* is removed during the processing and purification steps during the production of 2′-FL (see section 2.3.1 of SD1). Based on the supplied data and previous FSANZ assessments of similar HiMO substances, it is considered highly unlikely that novel DNA or novel protein from the production organism will be present in an infant formula product containing the applicant's 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 to permit the use of 2′-FL sourced from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* as a nutritive substance in infant formula products.

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 *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* will apply for a period of 15 months, linked to the applicant's brand name 'XINFU 2′-FL', commencing on the date of gazettal of the approved draft variation.

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

- The applicant's 2′-FL will have to comply with the specification in section S3—51 for 2′-FL sourced from *C. glutamicum* when used as a nutritive substance in infant formula products for use as a nutritive substance (or sold for such use).

2.4 Risk communication

2.4.1 Consultation

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

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

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

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development 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 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 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. 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 measures are set out below.

2.5.1.1.2 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 2.5.1.3 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 permitted amounts in the Code.[4] 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 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 Industry

Amendments in the approved draft variation will apply to infant formula products manufactured and /or sold in Australia only.

Domestic manufacturers (and exporters to Australia) of the applicant's 2′-FL, and 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.

An exclusive use permission will prevent other businesses from producing the applicant's specific brand of 2′-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 during the exclusive use period providing the usual application process is undertaken.

2.5.1.1.4 Government

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

FSANZ's assessment is that the direct and indirect benefits that will arise from permitting the applicant's specific brand of 2′-FL as proposed are likely to outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than the food regulatory measures 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[11] regulating infant formula products. 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, 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 '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.

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 associated labelling requirements. Schedule 26 lists permitted GM food, including GM food of microbial origin, and any associated conditions of use.

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[11] 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.*

As described in Section 1.3 of this report, Standard 2.9.1 and Schedule 29 currently permit 2′-FL from certain sources to be used as a nutritive substance in infant formula products. As the applicant's 2′-FL is a GM food, its use as a nutritive substance in infant formula products also requires express permission in 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 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 of the Code 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.

Draft variation amendments of Schedule 3 of the joint Code

As described in Section 1.3 of this report, section 1.1.1—15 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—51 to specify the identity of the gene (alpha-1,2-fucosyltransferase); and the donor organism (*C. urealyticum*) of the applicant's 2′-FL; and the donor organism (*P. saltans*) previously approved for the purposes of Application A1283.

The amendments to Schedule 3 aim to ensure consistency and clarity in the Code and would have no impact on existing permissions for 2′-FL in the Code.

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 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2.2 of this report and 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[12] and considered the best available scientific evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the applicant's 2′-FL.

- **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 proposed permission would 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.

- **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.

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

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Attachments

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

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

Food Standards (Application A1334 – 2′-FL from GM *Corynebacterium glutamicum* (gene donor: *Corynebacterium urealyticum*) 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 A1334 – 2′-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) 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 *Corynebacterium glutamicum*)

Repeal the item, substitute:

2′-fucosyllactose sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* or *Pseudopedobacter saltans*	section S3—51

[2] Section S3—51 (Section heading)

Repeal the section heading, substitute:

S3—51 Specification for 2′-fucosyllactose sourced from *Corynebacterium glutamicum*

[3] Section S3—51

Omit *"*sourced from *Corynebacterium glutamicum,"*, substitute:

"sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* or *Pseudopedobacter saltans*,"

Schedule 26—Genetically modified food

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

Insert:

(g)	*Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand XINFU 2′-FL. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1334 – 2′-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) in infant formula products) Variation* and ending 15 months after that date.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1334 – 2'-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) in infant formula products) Variation

1. Authority

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

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

The purpose of Application A1334 was to amend the Code to permit the use of 2′-fucosyllactose (2′-FL), a human-identical milk oligosaccharide (HiMO), produced using a new genetically modified (GM) source organism as a nutritive substance in infant formula products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1334 – 2'-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) 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 2′-FL produced from a new GM source, *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum*, to be used as a GM food for the purposes of Standard 1.5.2 of the Code and, consequently, as a nutritive substance in infant formula products for the purposes of Standard 2.9.1 – these permissions will be subject to certain conditions, including an exclusive use permission for a period of 15 months linked to the applicant's brand name 'XINFU 2′-FL'.
- Amend the current specification in Schedule 3 of the Code for 2′-FL sourced from *Corynebacterium glutamicum* (section S3—51) to specify that this specification applies to 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* (new permitted donor organism) or *Pseudopedobacter saltans* (existing permitted donor organism).

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 A1334 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 21 October 2025 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 Standards Development Committee (SDC) was established with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to the Authority throughout the standard development process. The SDC contributed a broad spectrum of knowledge and expertise covering industry, government, research and consumers

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. 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 draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1334 – 2′-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) 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 variation.

7.1 Items [1], [2] and [3]

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

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

Item [1] amends the table to subsection S3—2(2) by repealing the table item dealing with '2′-fucosyllactose sourced from *Corynebacterium glutamicum*' and replacing the omitted table item with '2′-fucosyllactose sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* or *Pseudopedobacter saltans*. This amendment is consequential to the amendment in **item [3]** below.

Item [2] amends the section heading of section S3—51 by repealing the section heading and substituting the repealed heading with: 'S3—51 Specification for 2′-fucosyllactose sourced from *Corynebacterium glutamicum'* to correct a typographical error in which 'for' had previously been left out of the heading. The inclusion of the word 'for' is consistent with other entries in Schedule 3.

Item [3] amends section S3—51, which sets out the specification for 2′-FL sourced from *Corynebacterium glutamicum*. The existing specification is relevant to the only 2′-FL sourced from *Corynebacterium glutamicum* listed in the table to subsection S26—3(7) prior to the variation coming into effect i.e., 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*.

Item [3] amends that section by omitting 'sourced from *Corynebacterium glutamicum*,' in the

specification, and substituting the omitted words with ‘sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* or *Pseudopedobacter saltans,’*.

The effect of the amendments in **items [1], [2]** and **[3]** is that the amended specification applies to 2′-FL produced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* and to 2′-FL produced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*. 2′-FL produced from either of those source organisms must comply with the amended specification set out in section S3—51 when added to infant formula products for use as a nutritive substance in accordance with the Code (or sold for such use).

7.2 Item [4]

Item [4] of the Schedule to the variation amends Schedule 26 of the Code.

Schedule 26 relates to GM food.

2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* 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 has been genetically modified to contain 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 [4] amends item 1 of that table (2′-FL) by inserting a new paragraph (g) into the column headed ‘Source’. The new paragraph (g) refers to:

‘Corynebacterium glutamicum containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum’.*

Associated conditions of use for 2′-FL from this new source are set out in column 3 of the table 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 XINFU 2′-FL; 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 A1334 – 2′-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) in infant formula products) Variation* and ending 15 months after that date.

Condition 2 means that 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* may only be sold under the brand XINFU 2′-FL during the exclusive use period. ‘Exclusive use period’ is defined in condition 3 as the period commencing on 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 *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* may be sold under any brand.

The effect of the amendment in **item [4]** is to permit the sale and use of the substance, 2′-FL from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* as a GM food, subject to the above conditions of use for the substance.

The amendment made by **item [4]** does make any substantive change to existing permissions and to other requirements in the Code relating to GM food.

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 in accordance with the Code.

Consequently, the effect of the amendment in **item [4]** is to also permit 2′-FL from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* to be used as a nutritive substance in infant formula products in accordance with the Code.