21 October 2025
363–25

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

Submissions on this application need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

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

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

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

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

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 18 November 2025

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

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

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

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

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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:

SD1 Risk and technical assessment – Application A1334

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, the Code does not currently permit the use of 2′-FL sourced from GM *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* for that 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 current maximum permitted amount in the Code. The applicant's 2′-FL is chemically, structurally and functionally identical to the naturally occurring substance present in human milk. It is also chemically, structurally and functionally identical to 2′-FL already assessed by FSANZ and permitted in the Code. The associated health benefits from the addition of 2′-FL to 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.

Following assessment and for reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit the use of 2′-FL produced from a GM source as a nutritive substance in infant formula products in accordance with the Code.

The table to section S29—7 of the Code lists permitted nutritive substances in infant formula and special medical purpose product for infants, 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".

If approved, the draft variation would:

- 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) – this amendment would permit the sale and use of the applicant's 2′-FL as a genetically modified food in infant formula products subject to certain conditions, including an exclusive use period of 15 months linked to the applicant's brand name 'XINFU 2′-FL', and
- 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* (proposed new permission) 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 would provide clarity, and consistency with existing permissions for 2′-FL in the Code.

The proposed permission would be subject to existing labelling requirements.

If approved, the effect of the draft variation would be that the applicant's 2′-FL produced from this new GM source would be permitted to be used as a nutritive substance in infant formula

products manufactured and/or sold in Australia in accordance with the Code.

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

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 seeks 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[1]. 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[2].

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

[1] Includes infant formula, follow-on formula and special medical purpose product for infants.
[2] For further information on any relevant New Zealand standard see section 2.4.1.3 of this report.

1.3.2.2 Nutritive substances

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

The applicant's 2′-FL would 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 would not be a mandatory requirement in the Code.

Subsection 2.9.1—9(1) and section 2.9.1—37 provide for the use of optional nutritive substances in infant formula and in 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 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 levels of up to 96 mg/100 kJ (equivalent to 2.4 g/L).

If the applicant's 2′-FL is permitted for use by Standard 1.5.2, the applicant's 2′-FL would 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. This existing specification is relevant to the only 2′-FL sourced from *C. glutamicum*

listed in the table to section S26—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.

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

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

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 genetically modified food.

Division 3 of Standard 2.9.1 contains the labelling and packaging requirements for infant formula and follow-on formula. This includes (among other things) an optional format for the statement of ingredients where a vitamin or mineral is added to the formula in accordance with section 2.9.1—8, and a mandated Nutrition Information Statement (NIS) which must contain specific information and be declared in a prescribed format.

Division 3 of Standard 2.9.1 also sets out what representations are prohibited for infant formula and follow-on formula. Paragraph 2.9.1—28(1)(i) prohibits the label on a package of infant formula or follow-on formula to contain (among other things) information relating to the presence of certain substances, including a substance used as a nutritive substance, except for a reference in a statement of ingredients, or in a declaration or statement expressly permitted or required by the Code, such as in the NIS.

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

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

1.4 Regulation in other countries

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 levels. Table 1 outlines some international permissions for 2′-FL.

It is noted that internationally, the permitted levels of 2′-FL for use in infant formula range from 1.2 g/L to 2.4 g/L. FSANZ set the existing permitted maximum levels 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	2.4
Canada#	1.2
Singapore	2.4
European Union (EU)	3.0
Israel	2.0
Korea	1.1
Philippines	1.2

Notes to table:
* Infant formula categories vary between countries
# Permission as a novel food with support for use in infant formula

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 is being assessed under the General Procedure in accordance with the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

The Code already permits 2′-FL from several source organisms to be used as a nutritive substance in infant formula products. The maximum permitted 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 2′-FL produced by microbial fermentation using a strain of *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum.*

The applicant's 2′-FL is chemically, structurally and functionally identical to the naturally occurring substance present in human milk. It is chemically, structurally and functionally identical to 2′-FL previously assessed and permitted by FSANZ. FSANZ's assessment indicates the substance meets the currently approved specification for 2′-FL from *C. glutamicum*. 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 genetically modified 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 HMOs 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 that estimated mean and 90th percentile dietary intakes of 2′-FL from infant formula products at the maximum permitted amount 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 previous microbiological assessments, given the identical chemical structure and noting the applicant has not requested any change in the maximum permitted amount of 2′-FL added to infant formula products, 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 permitted amount in the Code.

2.2 Risk management

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

2.2.1 Risk management options

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

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

For the reasons set out in this report, FSANZ decided to prepare a draft variation to the Code to 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 proposed permission and associated proposed 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.

2.2.2 Proposed 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 table to section S26—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 other than *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* as permitted GM food.

The draft variation would list *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *C. urealyticum* as a source of 2′-FL in the table to subsection S26—3(7). This would have the effect that 2′-FL from that source would be a permitted GM food for the purposes of Standard 1.5.2.

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 proposed draft variation would 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 under Standard 1.5.2, and
- for reasons set out at sections 1.3.2.1 and 1.3.2.2 of this report, 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.

2.2.3 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 draft variation would amend section S3—51 and the table to subsection S3—2(2) to include the identity of the permitted gene (alpha-1,2-fucosyltransferase) and donor organism (*C. urealyticum*). The applicant's 2′-FL would 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 draft variation also proposes to list *Pseudopedobacter saltans* as an additional donor organism in section S3—51 and table to subsection S3—2(2). This consequential amendment reflects the existing permission in the Code for 2′-FL sourced from *C. glutamicum* (approved under Application A1283), and ensures clarity and consistency in the identification of the gene and donor organism for 2′-FL permissions in the Code. The proposed amendment would have no impact on existing 2′-FL permissions in the Code.

2.2.4 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[3].

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

FSANZ is proposing to provide the applicant with a 15-month exclusive use permission for this 2′-FL commencing on the date of gazettal of the draft variation (if approved).

If the draft variation is approved, this means that, during the 15-month exclusive use period, this 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 would 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 undertaken.

2.2.5 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 HiMOs in the normal growth and development of infants. At the request of Food Ministers[4], FSANZ is

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

undertaking a five-year review of the initial permission gazetted under Application A1155. This will review the evidence of a substantiated beneficial role of 2′-FL and Lacto-N-neotetraose (LNnT) in the normal growth and development of infants. The review is to be completed by March 2026.

2.2.6 Labelling

Division 3 of Standard 2.9.1 provides specific labelling requirements for infant formula and follow-on formula. Labelling requirements that apply to SMPPi are set out in Division 4 of the same Standard. FSANZ refers to the relevant requirements below that would apply to the applicant's 2′-FL if it was added to an infant formula product.

2.2.6.1 Statement of ingredients

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

Infant formula and follow-on formula

The label on a package of infant formula or follow-on formula must contain a statement of ingredients in accordance with Standard 1.2.4. Should manufacturers choose to add the applicant's 2′-FL to infant formula or follow-on formula in accordance with the Code, then the 2′-FL would have to be declared in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require that, subject to Division 3 of Standard 1.2.3, ingredients be identified using:

- a name by which they are commonly known
- a name that describes its true nature, or
- a generic ingredient name if one is specified in Schedule 10 - *Generic names of ingredients and conditions for their use* in accordance with any conditions specified in that Schedule.

A generic ingredient name for 2′-FL has not been specified in Schedule 10.

These ingredient naming requirements would apply to the applicant's 2′-FL, enabling industry to have flexibility in how they declare this ingredient (e.g. using the name '2′-fucosyllactose'). Existing prohibited representations for infant formula and follow-on formula in paragraphs 2.9.1—28(1)(e) and (f) would also apply to the ingredient name (refer to section 2.2.6.3 below).

SMPPi

Section 2.9.1—51 sets the requirement for information relating to ingredients in SMPPi. This section specifies that ingredient information may be provided on the label of a package of SMPPi in a statement of ingredients (in accordance with the Code), or ingredient information that complies with either the EU or US regulations. These labelling requirements are intended to facilitate the importation of highly specialised SMPPi that are manufactured in low volumes in the EU and in the US. Therefore, for the use of the applicant's 2′-FL in SMPPi, the ingredient naming requirements of the Code or the EU or US could apply.

2.2.6.2 Mandatory nutrition information

Infant formula and follow-on formula

Section 2.9.1—24 regulates the declaration of nutrition information in a NIS on the label of a package of infant formula or follow-on formula. The NIS is a single statement in which certain

information is declared in accordance with section 2.9.1—24. It must be in the form of a table, as specified in the table to section S29—10 in accordance with section 2.9.1—25.

Subparagraph 2.9.1—24(3)(e)(i) requires the average quantity of any substance used as a nutritive substance (including any naturally-occurring amount) in infant formula and follow-on formula to be declared in the NIS expressed in grams, micrograms or milligrams per 100 mL of formula. Therefore, the applicant's 2′-FL would have to be declared accordingly in the NIS when it is used in infant formula or follow-on formula. Subsection 2.9.1—25(3) requires the declaration to be made under the heading 'Additional' in the NIS, using the same format as specified in the table to section 29—10.

SMPPi

Paragraph 2.9.1—53(1)(c) requires the declaration of a substance used as a nutritive substance in an SMPPi and added to that product to achieve that product's intended medical purpose, to be expressed per given amount of the product. Should manufacturers choose to add the applicant's 2′-FL to an SMPPi this provision would apply. However, there are no formatting requirements for this nutrition information, as labelling provisions for SMPPi are generally more flexible compared to infant formula and follow-on formula to ensure the importation of SMPPi is not impeded, noting the majority of these products are not manufactured in Australia.

2.2.6.3 Prohibited representations and prohibited claims

Infant formula and follow-on formula

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

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

SMPPi

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

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

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

These prohibitions would apply in relation to the applicant's 2′-FL where it is used as a nutritive substance in SMPPi. However, the prohibitions would not apply in relation to:

- a claim that is expressly permitted by this Code, or

- a declaration that is required by an application Act [5].

2.2.6.4 Voluntary representations

Paragraph 1.2.7—4(b) states that a nutrition content claim or health claim must not be made about an infant formula product. This prohibition would also apply to all infant formula products that contain the applicant's 2′-FL.

Subparagraph 2.9.1—46(2) explicitly states that a nutrition content claim or health claim must not be made about an SMPPi.

2.2.6.5 Labelling as 'genetically modified'

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). Considering the supplied data and previous FSANZ assessments of similar HiMO substances, it is considered highly unlikely that novel DNA or novel protein from the production organism would be present in an infant formula product containing the applicant's 2′-FL as an ingredient. However, under circumstances where novel protein or novel DNA were to remain present, the requirement to label the 2′-FL ingredient as 'genetically modified' would apply in accordance with section 1.5.2—4.

2.2.7 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 prepare 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.

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

2.3 Risk communication

2.3.1 Consultation

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

[5] An Act or Ordinance of the Commonwealth, or of a State or Territory under which the requirements of the Code are applied.

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

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

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

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

2.3.2 World Trade Organization (WTO)

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

There are no relevant international standards and amending the Code to permit the voluntary use of the applicant's 2′-FL as a nutritive substance in infant formula products is unlikely to have a significant effect on international trade as similar sources of 2′-FL are already permitted in similar products in countries overseas. Therefore, a notification to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

2.4.1.1.1 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 if the draft variation concerned is approved. Therefore, FSANZ's assessment is that a RIS is not required for this application.

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

2.4.1.1.2 Consumers

The proposed permission, if approved, would apply in Australia only and therefore any impacts would be on consumers in Australia only (see section 1.3.1 and 2.4.1.3 of this report).

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FLproduced 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 applicant has requested an exclusive use permission for their specific brand of 2′-FL. FSANZ is proposing to provide the applicant with a 15-month exclusive use permission for this 2′-FL commencing on the date of gazettal of the draft variation (if approved).

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.

2.4.1.1.3 Industry

The proposed permissions provided by the draft variation, if approved, would 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 would be permitted to sell their products in Australia (where the products fully comply with the Code), subject to the exclusive use permission described above. 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.

Granting an exclusive use permission as proposed would 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.

2.4.1.1.4 Government

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

2.4.1.1.5 Conclusion

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

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

New Zealand opt-out from joint infant formula standard

Paragraph 29(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[6] 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.

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

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

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, if approved, the draft variation would 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, if the draft variation is approved, 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.

If approved, the draft variation would 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 (*Pseudopedobacter 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. If the draft variation is approved, the application of the amended specification in the approved draft variation in New Zealand remains a matter for the New Zealand Government.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2.1 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 proposed

maximum amount of 96 mg/100 kJ.

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

Current labelling requirements outlined in Section 2.2.5 of this report would apply to infant formula products containing the applicant's 2′-FL and would provide adequate information to enable consumers to make an informed choice.

2.4.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in Section 2.2.5.3, which aim to prevent misleading or deceptive conduct, would apply to infant formula products containing the applicant's 2′-FL.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the risk analysis framework[7] 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 Forum on Food Regulation**

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

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

Noting the food technology aspects, safety, nutritional impact and beneficial health effects assessed in SD1 and Section 2.1 of this report, FSANZ considers that these Ministerial Policy Guidelines have been met.

3 Draft variation

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

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

4 References

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). Rome, Italy: Codex Alimentarius Commission. Available at: 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

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. Rome, Italy: Codex Alimentarius Commission. 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

EFSA (2025) Novel Food Application: EFSA-Q-2025-00169. https://open.efsa.europa.eu/question/EFSA-Q-2025-00169. Accessed 25 August 2025

FDA (2025) GRAS Notices, GRN No. 1238: 2′-fucosyllactose. https://www.hfpappexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=1238. Accessed 9 October 2025

FSANZ (2019) Application A1155 - 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Second Call for Submissions. Report prepared by 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. Report prepared by 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. Report prepared by Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/2024-02/A1283%20SD1.pdf

Attachments

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

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

Food Standards (Application 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 – Draft Explanatory Statement

DRAFT 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 Authority accepted Application A1334 which seeks 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 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 prepared a draft variation - the *Food Standards (Application A1334 – 2'-FL from GM* Corynebacterium glutamicum *(gene donor:* Corynebacterium urealyticum*) in infant formula products) Variation* (the draft variation).

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

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

instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the draft variation to:

- Amend Schedule 26 of the Code to permit 2′-FL produced from a new GM source, *Corynebacterium glutamicum* containing 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 would 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 is for 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from either *Corynebacterium urealyticum* (proposed new permission) or *Pseudopedobacter saltans* (existing permitted donor organism).

4. Documents incorporated by reference

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

However, if approved, the draft variation would vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 4-week 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

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

7. Variation

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application 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.

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

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

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

Item [1] would amend the table to subsection S3—2(2) by 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 would be consequential to the amendment in **item [3]** below.

Item [2] would amend 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] would amend 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* which is listed in the table to section S26—7 i.e., 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*.

Item [3] would amend 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 would apply to 2′-FL produced from both *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Corynebacterium urealyticum* and *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter*

saltans. 2′-FL produced from either of those source organisms -would have to 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 draft variation would amend 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] would amend item 1 of that table (2′-FL) by inserting a new paragraph (g) into the column headed 'Source'. If approved, the new paragraph (g) would refer 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 would be 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 would mean 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' would be defined in condition 3 as the period commencing on gazettal of the draft variation and ending 15 months after that date.

If the draft variation is approved, the effect of the amendment in **item [4]** would be 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.

Once the exclusive use period ends, the exclusive use permission would 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 proposed amendment made by **item [4]** would not 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 at an amount no greater than 96 mg/100 kJ.

Consequently, if the draft variation is approved, the effect of the amendment in **item [4]** would be 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 at an amount no greater than 96 mg/100 kJ.