14 May 2025
340-25

Approval report – Application A1308

A1308 - 2′-FL from GM *Escherichia coli* W in infant formula products

---

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Kyowa Hakko Bio Co., Ltd to amend the Australia New Zealand Food Standards Code to permit the use of 2′-fucosyllactose produced from a genetically modified *Escherichia coli* W as a nutritive substance in infant formula products.

On 26 November 2024, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 30 April 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 14 May 2025.

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 is available on the A1308 page on the FSANZ website:

SD1 Supporting document 1 – Risk and technical assessment (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Kyowa Hakko Bio Co., Ltd to amend the Australia New Zealand Food Standards Code (the Code) to permit 2′-fucosyllactose (2′-FL) produced from genetically modified (GM) *Escherichia coli* (*E. coli*) W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae (H. mustelae)* to be used as a nutritive substance in infant formula products.

The Code already permits 2′-FL from other GM sources to be used as a nutritive substance in infant formula products. However, the Code does not currently permit the use of 2′-FL produced from GM *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae* for that purpose.

The applicant also requested an exclusive use permission under the brand name '2′-FL Kyowa' 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 synthesised from the applicant's source organism to infant formula products at levels up to the current maximum permitted amount in the Code. The applicant's 2′-FL is chemically and structurally identical to the naturally occurring substance present in human milk. It is also chemically and structurally identical to 2′-FL already assessed by FSANZ and permitted in the Code. Given this, 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 preparation of a draft variation, FSANZ called for submissions from 26 November 2024 to 24 December 2024. Four submissions were received. 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 with minor numbering and formatting amendments. The purpose of the approved draft variation is to permit the use of 2′-FL produced from GM *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae* as a nutritive substance in infant formula products in accordance with the Code.

The approved draft variation will:

- amend Schedule 26 of the Code to list the applicant's 2′-FL as a food produced using gene technology permitted to be used in infant formula products for sale subject to certain conditions, including an exclusive use period of 15 months linked to the applicant's brand name '2′-FL Kyowa', and
- insert a new specification for the applicant's 2′-FL into Schedule 3 of the Code, with which the applicant's 2′-FL will have to comply when used as a nutritive substance in infant formula products (or sold for such use).

The effect of those amendments is that the applicant's 2′-FL will be permitted to be used as a nutritive substance in infant formula products in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant, Kyowa Hakko Bio Co., Ltd is a manufacturer of biotechnology and fermentation products. The applicant brings to market chemical substances produced via fermentation technologies.

1.2 The application

On 29 June 2024, Kyowa Hakko Bio Co., Ltd applied to amend Standard 2.9.1 and Schedules 3, 26 and 29 of the Australia New Zealand Food Standards Code (the Code) to permit a new genetically modified (GM) source organism *Escherichia coli* W (*E. coli* W) containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae (H. mustelae)* for the production of 2′-fucosyllactose (2′-FL) to be used as a nutritive substance in infant formula products.

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 (from birth).

1.3.2 Permitted use

1.3.2.1 Food produced using gene technology

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

2′-FL produced from various sources is already permitted in the Code as a *food produced using gene technology of microbiological origin* for use in infant formula products, however not from *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae.*

The applicant's 2′-FL is a *food produced using gene technology* (section 1.1.2—2) as it is produced from an organism modified using gene technology i.e. produced from GM *E. coli* W. Consequently, express permission for the applicant's 2′-FL is required in accordance with paragraph 1.5.2—3(a) (i.e. to be listed in Schedule 26 and to comply with any corresponding conditions).

[2] For further information on any relevant New Zealand standard see section 2.5.1.3.

1.3.2.2 Nutritive substances

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance* (as defined in section 1.1.2—12). The applicant's 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.

2′-FL is a non-digestible oligosaccharide that is a component of human milk. 2′-FL is currently permitted to be *used as a nutritive substance* in infant formula products at levels up to 96 mg/100 kJ (equivalent to 2.4 g/L) in accordance with section 2.9.1—9 (i.e. if, among other things, it is listed in the tables to sections S29—7 or S29—8 and is in a permitted form at up to the maximum amount per 100 kJ specified in that table). The tables to sections S29—7 and S29—8 list 2′-fucosyllactose *permitted for use by Standard 1.5.2* (see section 1.3.2.1 of this report above).

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

1.3.3 Identity and purity

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. The application provided a proposed specification for the applicant's 2′-FL for this purpose.

1.3.4 Labelling requirements

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

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

Standard 1.2.4 generally requires food products to be labelled with a statement of ingredients and provides requirements for ingredient names.

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

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

Standard 2.9.1 sets out the specific requirements for declaring nutrition information and includes provisions for prohibited representations on infant formula product labels.

---

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

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).

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)	1.2
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 2020) and for 'Follow-up formula for Older Infants and Product for Young Children' (Codex Alimentarius 2023) contain provisions for 'optional ingredients' which are applicable to 2′-FL.

In the United States (US), Kyowa Hakko Bio Co., Ltd has received a letter of 'no questions' from the US Food and Drug Administration (FDA) regarding the Generally Recognised as Safe (GRAS) status of their 2′-FL produced by fermentation using a modified strain of *E. coli* W (GRAS Notice (GRN) 1051) (U.S. FDA 2023a).

1.5 Reasons for accepting application

The application was accepted for assessment because:

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

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve the draft variation proposed at the call for submissions with minor numbering and formatting amendments. The approved draft variation will amend the Code to permit the applicant's 2′-FL produced from GM *E.coli* W to be used as a nutritive substance in infant formula products in accordance with the Code.

The approved draft variation takes effect on gazettal and 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 called for submissions on the draft variation to the Code from 26 November 2024 to 24 December 2024.

Four submissions were received, two from industry, one from a non-government organisation and one from a government agency. Three submitters supported the regulatory decision and one submitter did not support. Submitters provided comments on FSANZ's assessment and/or the draft regulatory measure which FSANZ has addressed in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
The submitter did not support the application and requested FSANZ reject A1308 and withdraw earlier approvals for A1155, A1190, A1233, A1251, A1265, A1277 and A1283.	Gene Ethics Ltd	For the reasons detailed in this report, FSANZ does not agree that rejection of the draft regulatory measures is warranted. The amendments made as a result of A1155, A1190, A1233, A1251, A1265, A1277 and A1283 are out of scope. Responses to specific issues raised by the submitter are below.
The submitter stated the evidence presented is flawed and incomplete. FSANZ must give all carers evidence of the hazards, risks and costs of formula composition and supplements, including synthetic 2′-FL and other industrial human oligosaccharides it has approved.	Gene Ethics Ltd	FSANZ's risk assessment concluded 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. The assessment also concluded the addition of 2′-FL to infant formula products would have associated health benefits. The assessment and those conclusions was based on the best available scientific evidence. See Supporting Document 1. The submission does not identify how or why the evidence was flawed or incomplete.
The submitter requested the application be considered in the context of an ultra-processed food and further development of a program to reduce ultra processed food consumption and promote fresh foods for the Australian population.	Gene Ethics Ltd	Infant formula products are the only safe and nutritious substitute for breast milk for infants who are not breast fed. Infant formula is a formulated food with the most prescriptive regulation in the Code. This is because it provides the sole source of nutrition to a vulnerable population. As detailed above, FSANZ's risk assessment concluded 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. The assessment also concluded the addition of 2′-FL to infant formula products would have associated health benefits. The assessment and those conclusions was based on the best available scientific evidence. See Supporting Document 1. A food consumption program targeted at the broader Australian population is out of scope for this application.

Issue	Raised by	FSANZ response
The submitter stated the assessment documents do not mention whether the applicant's 2′-FL functions identically to the same substance in human breast milk, only that it is chemically and structurally identical.	Gene Ethics Ltd	FSANZ has not assessed the functional effects of this specific 2′-FL compared to the same substance in human breast milk. However this has been assessed in A1155 where there were found to be no differences. In addition, in Proposal P1055 FSANZ's safety assessment on substances derived from a GM source found that a refined ingredient, such as 2′-FL from a GM microorganism, that is identical to the conventional food, such as human breast milk 2′-FL, in terms of the structural or chemical characteristics is unlikely to be functionally different. 2′-FL (microbial) is chemically identical to 2′-FL (human milk) and 2′-FL (synthesised) and they have physiological effects in the gut which are indistinguishable i.e. they are the same. There is no *a priori* reason to anticipate any unique physiological effects of 2′-FL from a new GM-microbial source which is added at a level consistent with human milk.
The submitter noted it was disappointing but not surprising that 10 of the 13 appendices were labelled 'confidential and proprietary'.	Gene Ethics Ltd	The information in question met the definition of confidential commercial information (CCI) set by the FSANZ Act. As such, disclosure of that information is restricted by and under that Act and other Australian laws. FSANZ conducted a full and independent evidence-based assessment of the application and was satisfied approval of the proposed draft variation was warranted.
The submitter noted the application is similar to application A1265 and anticipates that this kind of duplication will be reduced once Proposal P1055 – Definitions for gene technology and new breeding techniques including a new definition for genetically modified food is finalised.	Qld Health	Proposal P1055 is a current proposal being assessed by FSANZ. The outcomes of P1055 and any potential implications for application A1308 or future similar applications cannot be pre-empted.

Issue	Raised by	FSANZ response
A1308 is the first application where the proposed exclusive use permission will likely extend beyond the application A1155 – 2′-FL and LNnT in infant formula and other products review date of March 2026. Suggest that clarification is added that the exclusive use permission would be subject to any decision arising from the A1155 review.	Qld Health	On 27 November 2020, the Food Ministers' Meeting (FMM)[4] agreed to permit the voluntary addition of 2′-fucosyllactose (2′-FL) alone or in combination with Lacto-N-neotetraose (LNnT) in infant formula products in the Code. In conjunction with this decision[5], the FMM requested a review of the permission within five years from gazettal (26 March 2021) to determine whether there continues to be sufficient evidence of a 'substantiated beneficial role in the normal growth and development of infants, or a technological role', as per the Ministerial Policy Guideline[6]. FSANZ cannot pre-empt the actions the FMM may take as a result of the A1155 review. However, if a decision by the FMM resulted in the need for a change to existing permissions, this would then require a proposal to change the Code.
In relation to the costs and benefits – the submitter stated a larger range and supply of infant formula products for sale containing the applicant's 2′-FL may not necessarily be a benefit and may cause confusion at the consumer level.	Qld Health	The intended meaning of the paragraph in the CFS assessment summary referred to by the submitter was that there may be health benefits for formula-fed infants if the range and supply of infant formula products with 2′-FL (irrespective of source) increases as a result of the permission. FSANZ has amended the text in section 2.5.1.1 of this report for clarity. It is not clear how an additional source of 2′-FL would cause additional confusion for consumers, relative to the status quo due to the prescribed labelling requirements set out in Section 2.3.5. Labelling requirements for infant formula products were reviewed in the recent comprehensive review of infant formula product regulations (Proposal P1028).

[4] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation
[5] Australia and New Zealand Ministerial Forum communiqué – 27 November 2020
[6] Ministerial policy guideline on the regulation of infant formula products

Issue	Raised by	FSANZ response
The submitter noted new substances must be of benefit to the growth and development of infants given that FSANZ's safety assessment is based on well-controlled short term studies with well children. The submitter noted the ESPGHAN (European Society for Pediatric Gastroenterology, Hepatology and Nutrition) consideration that the inclusion of unnecessary substances in infant formula may place a burden on the infant's system, particularly if they are unwell or under stress. The ESPGHAN Position paper was provided.	Qld Health	FSANZ has used the same assessment procedure for application A1308 as was used for the previous seven human identical milk oligosaccharide applications. This included assessment of both safety and benefit. In addition, FSANZ has adhered to the *Policy Guideline for the Regulation of Infant Formula Products*[7] which requires consideration of the composition of breast milk. It also notes the greater level of risk to be managed for infants compared to other population groups and states that the regulatory framework should include requirements commensurate with this level of risk. Proposal P1028 introduced a regulatory framework consisting of a new category of infant formula products for unhealthy infants. This new category, special medical purpose products for infants (SMPPi), is based on the principle that compositional requirements are compliant with the baseline composition (including voluntary permissions) for infant formula, unless deviation is required for a particular medical purpose. Risk of inappropriate use of SMPPi is mitigated through restricted sale, labelling and use under medical supervision.
The submitter noted support for FSANZ's commitment to reviewing new evidence on the beneficial role of HiMO in the normal growth and development of infants (i.e. the Application A1155 review).	Infant Nutrition Council	Noted. Out of scope for Application A1308.

[7] Policy guideline on infant formula products | Food Regulation

Issue	Raised by	FSANZ response
The submitter noted concern that there was no mention of the New Zealand standard at clause 2.4.1.3 (Any relevant New Zealand standards) of the CFS assessment summary. Standard 2.9.1 as gazetted in 2002 remains the New Zealand standard and any application needs to take into consideration the New Zealand domestic standard, as per the obligations contained in section 29 of the FSANZ Act. This would be irrespective of whether or not the application permission only applies to Australia.	Infant Nutrition Council	See section 2.5.1.3 of this report.
The submitter requested a change to the definition of HETCOR (Section 2.1.1) from “Heteronucleare Correlation Spectroscopy” to “HEteronucleare Correlation Spectroscopy”.	Kyowa Hakko Bio Co., Ltd	No change. Naming convention does not support this change.
The submitter noted that in Section 2.2 of Supporting Document 1 it described the manufacturing method is the same as that in application A1155. The submitter stated the method is not exactly the same and requested amendment - “The method of production for the applicant’s 2′-FL is similar to that of earlier applications”.	Kyowa Hakko Bio Co., Ltd	This change has been made to the text but has not changed the outcomes of the assessment.
The submitter requested a change in Section 3.2.2 of Supporting Document 1 relating to the description of the study by Jochum et al. (2023), so that the concentration of 2′-FL in the test formula be amended to 1 g/L.	Kyowa Hakko Bio Co., Ltd	No change. As per the study, the description currently reads 1.0 g/L 2′-FL.
The submitter requested the notation “et al” be italicized and standardized as “et al.,” in the SD and CFS documents.	Kyowa Hakko Bio Co., Ltd	FSANZ convention is to not italicise or include a comma in ‘et al.’. Changes have been made in some instances for consistency with FSANZ convention.

Issue	Raised by	FSANZ response
The submitter requested changes to Table 1.0-1 relating to the specifications of their 2′-FL as listed in the SD and Appendix A to the CFS: • Change ‘difucosyllactose (difucosyl-d-lactose)’ to ‘difucosyllactose’ • Change ‘Aerobic mesophilic bacteria total count’ to ‘Aerobic plate count’	Kyowa Hakko Bio Co., Ltd	Re: Change ‘difucosyllactose (difucosyl-d-lactose)’ to ‘difucosyllactose’. No change to maintain consistency within the Code and to maintain nomenclature that stakeholders are familiar with. Re: Change ‘Aerobic mesophilic bacteria total count’ to ‘Aerobic plate count’. No change for consistency with other specifications. The methodology between these terms are the same. FSANZ associates the term “aerobic mesophilic bacteria total count” with the methodology ISO 4833 which the applicant has used in their testing.

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 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 therefore to assess the safety of 2′-FL produced by the new production strain.

The applicant's 2′-FL, produced by a microbial fermentation method of production, is chemically and structurally identical to the naturally occurring substance present in human milk. It is also chemically and structurally identical to 2′-FL previously assessed and permitted by FSANZ.

The *E. coli* W host organism has a long history of use for the production of recombinant proteins and other products, and is unlikely to pose a risk to humans. No safety concerns arising from the gene donor were identified. Characterisation of the GM production strain confirmed that the introduced alpha-1,2-fucosyltransferase gene is both genetically stable and functional.

FSANZ has previously determined that there are no safety concerns associated with the addition of 2′-FL to infant formula products at concentrations up to 2.4 g/L. Newly available information did not indicate a reason to change this conclusion.

No treatment-related adverse effects were found in a 90-day oral toxicity study of the applicant's 2′-FL in rats. The NOAEL in this study was 2000 mg/kg bw/day, the highest dose tested. The applicant's 2′-FL was not genotoxic *in vitro* or *in vivo*.

The dietary intake assessment compared the estimated dietary intake of 2′-FL from infant and follow-on formula to that of mature human milk for 3- and 9-month-old infants. As there is no requested change to the current permitted amount of 2′-FL in infant formula products, no extension of use, and no data suggesting a higher concentration in human milk since the most recent FSANZ assessment, estimated dietary intakes of 2′-FL from previous FSANZ assessments were used in this current assessment. These data showed that estimated mean and 90th percentile dietary intakes of 2′-FL at the maximum permitted amount in the Code from infant formula products fall within the range of estimated dietary intakes from mature human milk.

FSANZ has previously concluded that based on the available evidence the addition of 2′-FL to infant formula products is unlikely to pose a risk to normal growth of infants at levels typically found in human milk. No new relevant studies were identified for this assessment and therefore FSANZ maintains this conclusion.

Overall the safety assessment concluded 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.

2.3 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.

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 26 November 2024 to 24 December 2024 (the submission period).

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

- 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 reasons set out in this report, FSANZ has decided to approve the draft variation to the Code proposed at the call for submissions with minor numbering and formatting amendments.

2.3.1 Regulatory approval

The approved draft variation prepared by FSANZ lists *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae* as a source of 2′-FL in the table to subsection S26—3(7).

Application A1308 requested an amendment to the Code to provide a permission for 2′-FL produced from GM *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae* to be used as a nutritive substance in infant formula products.

The approved draft variation will permit:

- infant formula products for sale to consist of, or have as an ingredient, the applicant's 2′-FL as a *food produced using gene technology* 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* with a maximum amount of 96 mg/100 kJ in infant formula products.

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. The approved draft variation will insert a new specification for the applicant's 2′-FL sourced from *E. coli* W, with which this 2′-FL will have to comply when used as a nutritive substance in infant formula products (or sold for such use).

2.3.3 Exclusivity

An applicant may request exclusive permission to use and sell a food (including a substance) for a certain period of time to recognise the investment made in developing that food, and the need to achieve return on this investment, thereby supporting innovation.

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 that 15 month period, the permission will apply exclusively to those substances under the brand name '2′-FL Kyowa' in accordance with the Code.

Once the 15 month period ends, the exclusive use permission will revert to a general permission, meaning that anyone may use the permitted forms of 2′-FL in accordance with the Code.

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

2.3.4 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 human identical milk oligosaccharides (HiMO) in the normal growth and development of infants. At the request of food ministers[8], FSANZ is carrying out a five-year review (to be completed by March 2026) 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.

2.3.5 Labelling

Division 3 of Standard 2.9.1 provides specific labelling requirements for infant formula and follow-on formula. Labelling requirements that apply to Special Medical Purpose Products for infants (SMPPi) are set out in Division 4 of this Standard. FSANZ refers to the relevant requirements below that will apply to the applicants' 2′-FL if it is added to an infant formula product.

2.3.5.1 Statement of ingredients

Standard 1.2.4 requires food for sale to be labelled with a statement of ingredients unless exempt. The label on a package of infant formula or follow-on formula must contain a statement of ingredients. 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 must be declared in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require ingredients to be identified using: a name by which they are commonly known; a name that describes its true nature; or a generic ingredient name if one is specified in Schedule 10 - Generic names of ingredients and conditions for their use. A generic ingredient name for 2′-FL has not been specified. These ingredient naming requirements will apply to the applicant's 2′-FL, enabling industry to have flexibility in how they declare these ingredients (for example, using the name '2′-fucosyllactose'). However, note that existing prohibited representations in paragraphs 2.9.1—28(1)(e) and (f) will also apply to the ingredient name (refer to section 2.2.5.3 below).

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 SMPPi in a statement of ingredients (in accordance with the Code as mentioned immediately above), or ingredient information that complies with either the EU or US regulations. These regulatory labelling requirements are intended to facilitate the importation of highly specialised SMPPi that are manufactured in low volumes in Europe and in the United States. Therefore, for the use of the applicant's 2′-FL in SMPPi, the ingredient naming requirements of the Code or the EU or US will apply.

2.3.5.2 Mandatory nutrition information

Section 2.9.1—24 regulates the declaration of nutrition information in a Nutrition Information Statement (NIS) on the label of a package of infant formula or follow-on formula. The NIS is a

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

single statement that must be in the form of a table, as indicated in section 2.9.1—25 and in accordance with section S29—10.

Subparagraph 2.9.1—24(3)(e)(i) requires any substance used as a nutritive substance to be declared in the NIS. Therefore, the applicant's 2′-FL will need to be declared in the NIS when it is used voluntarily 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 format specified in section S29—10.

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

2.3.5.3 Prohibited representations and prohibited claims

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. The prohibition on these words and abbreviations also applies to SMPPi as a result of paragraphs 2.9.1—45(c) and (d).

Paragraph 2.9.1—28(1)(i) prohibits information relating to the presence of a nutritive substance except for a reference in a statement of ingredients or in a NIS on the label of a package of infant formula or follow-on formula.

For SMPPi, subsection 2.9.1—46 sets out an explicit prohibition for nutrition content, health claims and claims which represent the product for therapeutic use. This prohibition will apply in relation to the use of the applicant's 2′-FL in SMPPi.

2.3.5.4 Voluntary representations

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

2.3.5.5 Labelling as 'genetically modified'

Based on previous FSANZ assessments of 2'FL, it is considered highly unlikely that the applicant's 2′-FL would contain novel protein or novel DNA due to the purification step used in its production. It is therefore highly unlikely that novel protein or novel DNA will be present in an infant formula product that contains this 2′-FL as an ingredient. However, where novel protein or novel DNA is 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 the draft variation to the Code proposed at the call for submissions with minor numbering and formatting amendments. The purpose of

the approved draft variation is to permit the use of 2′-FL from *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae* 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 the following:

- It may be added alone, or in combination with Lacto-N-neotetraose (LNnT), or in combination with inulin-type fructans (ITF) and/or galacto-oligosaccharides (GOS) to infant formula products up to a maximum level of 2.4 g/L for 2′-FL, as consumed.
- The existing prohibition for the use of the words 'human identical milk oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO' or any word or words or abbreviations having the same or similar effect, will apply to infant formula products that contain the applicant's 2′-FL.
- An exclusive use permission to use 2′-FL produced using *E. coli* W containing the gene for alpha-1,2-fucosyltransferase from *H. mustelae* will apply for a period of 15 months, linked to the applicant's brand name '2′-FL Kyowa', commencing on the date of gazettal of the approved draft variation.
- Schedule 3 of the Code will set a specific specification for the applicant's 2′-FL, with which it must comply when used as a nutritive substance in infant formula products (or sold for such use).

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. 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.

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

2.5.1 Section 29

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

2.5.1.1 Consideration of costs and benefits

For reasons set out below, FSANZ considers that the direct and indirect benefits that will arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, Government or industry that will arise from the development or variation of the food regulatory measure.

Background

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[9]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for the applications relating to nutritive substances OIA Reference: OIA23-06224. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was 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). This analysis considered the costs and benefits of permitting the proposed use of the applicant's 2′-FL as a nutritive substance in infant formula products.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of the applicant's 2′-FL as a nutritive substance in infant formula products.

Consumers

The permission to add the applicant's 2′-FL to infant formula products has been assessed in Australia only (see section 1.3.1 and 2.5.1.3).

In terms of impacts on the health of infants, FSANZ's risk assessment concluded no safety concerns from the addition of the applicant's 2′-FL to infant formula products at the proposed maximum permitted amounts. Australian formula-fed infants may experience health benefits if the permission results in a larger range and supply of infant formula products for sale that contain 2′-FL, due to the factors discussed in the industry section below.

A new source for an already permitted ingredient, 2′-FL may also lead to overall price reductions in infant formula products containing 2′-FL for consumers. That is if industry passes on any cost efficiencies gained from using 2′-FL from this new source (the applicant's 2′-FL). In the longer term it may also become a more common ingredient that no longer draws any price premium which will provide increased value to all consumers.

The role of granting an exclusive use permission is to encourage industry innovation and allow applicants to achieve commercial rewards through higher returns on their investment. Any commercial reward from this application's exclusive use period could come at the expense of consumers in the short-term, through other businesses not being able to compete to supply the applicant's 2′-FL at lower prices during the exclusivity period. However, without this incentive this innovation may not have taken place. It is assumed that the greater

[9] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

incentive to innovate will lead to greater benefits in the medium to long term for consumers, because innovation encourages more products to come to market that may benefit consumers.

Industry

The permission to add the applicant's 2′-FL to infant formula products has been assessed in Australia only. Manufacturers of infant formula products that contain the applicant's 2′-FL for export to Australia will be permitted to sell their products in Australia (where they fully comply with the Code).

Industry may benefit from increased choice of sources for 2′-FL permitted to be used as nutritive substances in infant formula products for sale. That may reduce costs of sourcing 2′-FL. Industry may voluntarily use 2′-FL from this new source or buy and sell infant formula products containing 2′-FL from this new source, where they believe a commercial net benefit exists for them.

Given the applicant's 2′-FL is already approved in some overseas countries, approving the applicant's 2′-FL will favour trade and any growth of overseas markets for exports of Australian infant formula products. The proposed permission may also support innovation in infant formula products.

Producers of infant formula products in Australia, may however face greater competition in the domestic infant formula products market from overseas-based producers that can also supply Australia with infant formula products containing the applicant's 2′-FL. Any such impacts to domestic producers are assumed to be outweighed by benefits to consumers from greater industry competition.

Granting the exclusive use permission requested by the applicant, will prevent other businesses from producing 2′-FL from this additional source in the short-term. There may also be short-term restrictions on numbers of businesses that can access the applicant's 2′-FL, relative to if the exclusive use period had not been granted. 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. Therefore, the market for this additional source of 2′-FL could be opened during the 15 months' exclusivity for any other companies willing to make an application.

Government

The approval of this application may result in a small but likely inconsequential cost to Australian governments in terms of an addition to the current range of 2′-FL from various sources which are monitored for compliance.

Conclusion

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

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

New Zealand opted-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 of the Code is an Australian only standard[10]. Schedule 29 of the Code lists the permissions, limits, calculations, permitted forms etc for the purposes of that Australia only Standard 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, 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's amendment of Schedules 3 and 26 of the joint Code

As explained in section 1.3, Standard 2.9.1 and Schedule 29 currently permit 2′-FL to be used as a nutritive substance in infant formula products. 2′-FL that are food produced using gene technology must also be permitted by Standard 1.5.2 and Schedule 26 in order to be used as a nutritive substance in infant formula products. For this reason, the approved draft variation will amend Schedule 26 of the Code to list the applicant's 2′-FL as a food produced using gene technology subject to conditions of use that provide that it may only be added to infant formula products.

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

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

The draft approved variation will also amend Schedule 3 of the Code to insert a new specification for the applicant's 2′-FL. If this amendment is approved, the applicant's 2′-FL must comply with this specification when used as a nutritive substance in infant formula products (or sold for such use).

---

[10] 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*.

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

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

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

The application of the specification in the approved draft variation to and in New Zealand remains a matter for the New Zealand Government.

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

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ completed a risk and technical assessment (SD1) which is summarised in Section 2.2 of this report. Previous assessments found no safety concerns associated with the use of 2′-FL in infant formula products. New information provided did not change this conclusion.

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 2.3.5 of this report will apply to infant formula products containing the applicant's 2′-FL, and will provide 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 2.3.5.3, 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[11] 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 will support an internationally competitive food industry in relation to the use of 2′-FL as a nutritive substance in infant formula products, and is consistent with existing permissions in the Code for 2′-FL.

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

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

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

As part of A1308, FSANZ had regard to both high order and specific policy principles in the following Ministerial Policy Guidelines:

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

Noting the food technology aspects, safety, associated health benefits and nutritional impact assessed in SD1 and section 2.2 of this report, FSANZ considers these Ministerial Policy Guidelines have been met.

3 References

Codex Alimentarius (2020) 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 and 2020, 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

FSANZ (2008) First Review Report Proposal P306 Addition of Inulin/FOS and GOS to food. Food Standards Australia New Zealand, Canberra, Australia.

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

https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P306%20FOS%20_%20GOS%20FRR%20FINAL.pdf

FSANZ (2013) A1055: Short-chain fructo-oligosaccharides. Supporting Document 1. Risk and technical assessment (at approval). Food Standards Australia New Zealand, Canberra, Australia.
https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1055%20Addition%20of%20scFOS%20AppR%20SD1%20Risk%20Assess.pdf

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

U.S. FDA (2023a). Agency Response Letter GRAS Notice No. GRN 1051 [2′-fucosyllactose, Tokyo, Japan: Kyowa Hakka Bio Co., Ltd.] Silver Spring (MD): U.S. Food and Drug Administration (U.S FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety. Available at :
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=1051
[Nov. 21, 2023 – FDA response – no questions]

Attachments

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

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

Food Standards (Application A1308 – 2′-FL from GM *Escherichia coli* W in infant formula products) Variation

---

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

Dated [To be completed by 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 A1308 – 2'-FL from GM* Escherichia coli *W in infant formula products) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

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

Insert:

2′-fucosyllactose sourced from *Escherichia coli* W	section S3—54

[2] After section S3—53

Insert:

S3—54 Specification for 2′-fucosyllactose sourced from *Escherichia coli* W

For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*, the specifications are the following:

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

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

(c) molecular weight—488.44 g/mol;

(d) CAS number—41263-94-9;

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

(f) 2′-FL—not less than 82% (water free);

(g) D-lactose—not more than 5.0% (water free);

(h) L-fucose—not more than 1.0% (water free);

(i) fucosylgalactose—not more than 3.0% (water free);

(j) difucosyllactose (difucosyl-d-lactose)—not more than 3.0% (water free);

(k) glucose and galactose—not more than 1.0% (water free);

(l) water—not more than 9.0%;

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

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

(o) lead—not more than 0.1 mg/kg;

(p) arsenic—not more than 0.1 mg/kg;

(q) cadmium—not more than 0.1 mg/kg;

(r) mercury—not more than 0.1 mg/kg;

(s) microbiological:

  (i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;

  (ii) yeasts and moulds—not more than 100 cfu/g;

  (iii) *Enterobacteriaceae*—absent in 10 g;

  (iv) residual endotoxins—not more than 10 EU/g.

Schedule 26—Food produced using gene technology

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

Insert:

(f)	*Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand 2′-FL Kyowa. 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 A1308 - 2′-FL from GM* Escherichia coli *W 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 A1308 – 2'-FL from GM* Escherichia coli *W 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 A1308 which sought to amend the Code to permit the use of 2′-fucosyllactose (2′-FL) produced from genetically modified *Escherichia coli* W to be used as a nutritive substance in infant formula products. The application also sought a 15 month exclusive use permission. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1308 – 2'-FL from GM* Escherichia coli *W 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. 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 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 approved the draft variation to the Code to:

- Amend Schedule 26 of the Code to permit 2′-FL produced from a new genetically modified source, *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*, to be used as a nutritive substance in infant formula products subject to certain conditions, including an exclusive use permission for a period of 15 months linked to the applicant's brand name '2′-FL Kyowa'.
- Insert a new specification for this 2′-FL into Schedule 3 with which this 2′-FL will have to comply when used as a nutritive substance in infant formula products (or sold for such use).

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 varies Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3.

Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances 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 A1308 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 26 November 2024 for a four-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.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[12]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement was not required for applications relating to nutritive substances OIA Reference: OIA23-06224. This is

[12] Formerly known as the Office of Best Practice Regulation (OBPR)

because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1308 - 2′-FL from GM* Escherichia coli *W in infant formula products) Variation.*

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

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

Schedule to the variation

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

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, 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] inserts into columns 1 and 2 of the table to subsection S3—2(2), in alphabetical order, new references to '2′-fucosyllactose sourced from *Escherichia Coli* W' and 'section S3—54' respectively. These new references relate to the new provision inserted by **item [2]** below.

Item [2] inserts a new section S3—54 which sets out the specifications relating specifically to 2′-fucosyllactose sourced from *Escherichia coli* W, the new substance sought to be permitted by the applicant.

Consequently, the permission for 2′-fucosyllactose sourced from *Escherichia coli* W to be used as a nutritive substance in infant formula products (or sold for such use) is subject to the requirement in section 1.1.1—15 that the substance must comply with these specifications.

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

Schedule 26 relates to food produced using gene technology. 2′-FL sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae* is a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is produced from an organism modified using gene technology.

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

The table to subsection S26—3(7) lists food produced using gene technology of microbial origin. **Item [3]** amends item 1 of that table (2′-FL) by inserting new paragraph (f) into the column headed 'Source'. New paragraph (f) refers to:

'*Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae'*.

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 2′-FL Kyowa; and;
3. for the purposes of condition 2, 'exclusive use period' means the period commencing on the date of gazettal of the *Food Standards (A1308 - 2′-FL from GM* Escherichia Coli *W in infant formula products) Variation* and ending 15 months after that date.

Condition 2 means that 2′-FL sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae* may only be sold under the brand 2′-FL Kyowa 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.

The effect of the amendment in **item [3]** is to permit the sale and use of the substance, 2′-FL from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae* as a food produced using gene technology, subject to the above conditions of use for the substance.

Once the exclusive use period ends, the permission will revert to a general permission, meaning that the proposed permission will then permit the sale and use of 2′-FL sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae* under any brand.

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

The effect of the amendment in **item [3]** is to permit 2′-FL from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae* to be used as a nutritive substance in infant formula products in accordance with the Code.

This is because subsection 2.9.1—9(1) and 2.9.1—9(2) and section S29—7 and S29—8 permit a '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.

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

Food Standards (Application A1308 – 2′-FL from GM *Escherichia coli W* in infant formula products) Variation

---

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

Dated [To be completed by 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 A1308 – 2'-FL from GM* Escherichia coli W *in infant formula products) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

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

Insert:

2′-fucosyllactose sourced from *Escherichia coli* W	section S3—52

[2] After section S3—51

Insert:

S3—52 Specification for 2′-fucosyllactose sourced from *Escherichia coli W*

For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*, the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;
(b) chemical formula—$C_{18}H_{32}O_{15}$;
(c) molecular weight—488.44 g/mol;
(d) CAS number—41263-94-9;
(e) description—white to off-white powder;
(f) 2′-FL—not less than 82% (water free);
(g) D-lactose—not more than 5.0% (water free);
(h) L-fucose—not more than 1.0% (water free);
(i) fucosylgalactose—not more than 3.0% (water free);
(j) difucosyllactose (difucosyl-d-lactose)—not more than 3.0% (water free);
(k) glucose and galactose—not more than 1.0% (water free);
(l) water—not more than 9.0%;
(m) ash, sulphated—not more than 0.5%;
(n) residual proteins—not more than 0.01%;
(o) lead—not more than 0.1 mg/kg;
(p) arsenic—not more than 0.1 mg/kg;
(q) cadmium—not more than 0.1 mg/kg;
(r) mercury—not more than 0.1 mg/kg;
(s) microbiological:
    (i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;
    (ii) yeasts and moulds—not more than 100 cfu/g;
    (iii) *Enterobacteriaceae*—absent in 10 g;
    (iv) residual endotoxins—not more than 10 EU/g.

Schedule 26—Food produced using gene technology

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

Insert:

(f)	*Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand 2′-FL Kyowa. 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 A1308 - 2'-FL from GM* Escherichia coli W *in infant formula products) Variation* and ending 15 months after that date.