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177-21

Approval Report – Application A1190

2'-FL in infant formula and other products

Food Standards Australia New Zealand (FSANZ) has assessed an application by Chr. Hansen A/S¹. The Application is seeking to permit the voluntary addition of 2'-fucosyllactose (2'-FL), produced via new genetically modified *Escherichia coli* BL21 strains, in infant formula products (which includes infant formula, follow-on formula and infant formula products for special dietary uses) and formulated supplementary foods for young children.

On 22 July 2021, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received 10 submissions.

FSANZ approved the draft variation on 27 October 2021. The Food Ministers' Meeting² was notified of FSANZ's decision on 8 November 2021.

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

¹ The application was originally submitted by Jennewein Biotechnologie GmbH. Chr. Hansen A/S acquired Jennewein Biotechnologie GmbH following acceptance of the Application by FSANZ. The applicant is now Chr. Hansen A/S.

² Formerly the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and safety assessment report (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application by Chr. Hansen A/S³ to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of '2'-fucosyllactose' (2'-FL) produced via microbial fermentation of new genetically modified (GM) *Escherichia coli* (*E. coli*) BL21 production strains in infant formula products (IFP) and formulated supplementary foods for young children (FSFYC).

2'-FL is a non-digestible carbohydrate (oligosaccharide) found naturally in human milk. The application's stated purpose for 2'-FL is to provide an infant formula product that more closely aligns with the composition of human milk. According to the applicant, the benefits of 2'-FL are hypothesised to extend past infancy into toddlerhood and thus 2'-FL will be beneficial in FSFYC. Permission was sought for a concentration use of not more than 2.0 g/L of 2'-FL, as consumed, in both liquid and powdered form.

The Code currently permits the voluntary addition of a specific source of 2'-FL to IFP subject to certain conditions. However, this permission does not apply to the applicant's 2'-FL which has a different GM source and specifications. As such, a pre-market assessment of the applicant's 2'-FL was required and the 2'-FL is eligible for an exclusivity period of 15 months.

FSANZ's safety and risk assessment found the applicant's 2'-FL is chemically and structurally identical to those in human milk. Given there is a history of safe exposure to 2'-FL from human milk, FSANZ concluded there are no safety concerns with the addition of the applicant's 2'-FL produced by microbial fermentation to both IFP and FSFYC:

- at the level requested by the applicant, and
- at the higher level permitted for 2'-FL sourced from *E. coli* K-12 in the Code (2.4 g/L - consistent with a range of levels found in mature human milk).

FSANZ undertook an assessment of beneficial health outcomes proposed in the application in accordance with relevant Ministerial Policy Guidelines⁴. That assessment concluded there is evidence to support a role for 2'-FL in promoting a bifidogenic effect and limiting infection by pathogenic strains of *Campylobacter jejuni* (*C. jejuni*) in infants and young children, although the evidence base for these effects in young children was fairly limited. The application provided information suggesting that 2'-FL can mediate changes in the function of the immune response, the intestinal barrier, learning and memory and gut motility. There was limited evidence demonstrating these effects in humans. FSANZ concluded that for these stated health effects, the claims are not adequately supported by the evidence.

Following assessment and preparation of the draft variation, FSANZ called for submissions regarding the draft variation from 22 July 2021 to 19 August 2021. Ten submissions were received, all of which FSANZ had regard to (see Section 2.1 of this report for details of submissions made).

Noting the decision made by the Food Ministers' Meeting in November 2020 regarding the review for A1155⁵, and to support the assessment of all available evidence for application A1190, FSANZ requested additional evidence from the applicant supporting a beneficial health outcome in young children for the addition of 2'-FL in FSFYC. No additional evidence was available from the applicant and FSANZ did not identify any new scientific literature independently. Under section 30 of the FSANZ Act, FSANZ notified the applicant that a permission for the addition of 2'-FL in FSFYC was not proposed in the call for submissions. Before public release, the applicant accepted this variation and agreed to proceed. Additional studies were provided during the CFS from industry stakeholders, however these were of low

³ The application was originally submitted by Jennewein Biotechnologie GmbH. Chr. Hansen A/S acquired Jennewein Biotechnologie GmbH following acceptance of the application by FSANZ. The applicant is now Chr. Hansen A/S.

⁴ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>

⁵ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27>

quality and limited relevance, and therefore did not change FSANZ's conclusions (see SD1 and Section 2.1 and 2.2 of this report).

Based on the information above and other relevant considerations set out in this report, FSANZ has decided to approve the draft variation proposed following assessment with three editorial amendments made to correct typographical errors. The approved draft variation will permit the voluntary addition of the applicant's 2'-FL to IFP, subject to the following Code requirements and conditions:

- It may be added up to a maximum level of 2.4 g/L for 2'-FL, as consumed (i.e. in powder or liquid form).
- The existing prohibition for the use of 2'-FL with galacto-oligosaccharides and inulin-type fructans will apply to IFP that contain the applicants 2'-FL.
- The existing prohibition for the use of the words 'human milk identical 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 IFP that contain the applicant's 2'-FL.
- An exclusive permission to use the applicant's 2'-FL will apply for a period of 15 months, linked to the applicant's brand name 'CHR. HANSEN™ 2'-FL', commencing on the date of gazettal of the variation.
- Schedule 3 of the Code will set a new specification for the applicant's 2'-FL, with which it must comply.
- The permission is subject to the outcome of the five year review⁶ (to be completed by March 2026) which will reassess the evidence of a substantiated beneficial role of 2'-FL in the normal growth and development of infants.

⁶ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27>

1 Introduction

1.1 The Applicant

The application was originally submitted by Jennewein Biotechnologies GmbH in September 2019. On 9 October 2020, Chr. Hansen A/S (Chr. Hansen) acquired Jennewein Biotechnologie GmbH. FSANZ received formal notification that Chr. Hansen was now the applicant for A1190, however other details remained unchanged i.e. its legal entity (including same company identification number); manufacturing premises; manufacturing processes and quality systems and certifications.

Chr. Hansen is a global bioscience company that develops natural ingredient solutions for the food, nutritional, pharmaceutical and agricultural industries.

1.2 The Application

The application sought to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of 2'-fucosyllactose (2'-FL), in infant formula products (IFP)⁷ and formulated supplementary foods for young children (FSFYC)⁸. 2'-FL is a non-digestible carbohydrate (oligosaccharide) found naturally in human milk. The application is specifically for 2'-FL⁹ produced by microbial fermentation from genetically modified (GM) *Escherichia coli* (*E.coli*) BL21 strains. The application claims the 2'-FL is structurally and chemically identical to 2'-FL found in human milk.

This is the second application FSANZ has assessed for 2'-FL. The first was application A1155 - 2'-FL and Lacto-N-neotetraose (LNnT) in infant formula and other products. While permission exists in the Code for 2'-FL from A1155, the source and specifications of the A1190 2'-FL are different. It therefore required a pre-market assessment and was eligible for an exclusivity period of 15 months.

The applicant proposed an intended use level for 2'-FL in IFP of 2 g/L, as consumed, in both liquid and powdered form. The applicant's stated purpose for adding 2'-FL to IFP is that it will result in higher quality products that more closely align with the composition of human milk. The applicant justified the addition of their 2'-FL to FSFYC by stating the benefits of 2'-FL are hypothesised to extend past infancy.

1.3 The current Standards

1.3.1 Australia and New Zealand

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

1.3.1.1 Permitted use

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*.

⁷ Including infant formula, follow-on formula and infant formula products for special dietary use.

⁸ 'Toddler milk' is the main type of FSFYC currently available.

⁹ 2'-FL exists naturally in human milk and can be synthesised chemically or through microbial fermentation. The A1190 SD1 refers to 2'-FL_{human} / 2'-FL_{chem} / 2'-FL_{micro} (respectively), as studies have been done on the different forms, however for the purposes of this report '2'-FL' refers only to the applicant's 2'-FL_{micro} as the other forms are not referenced.

The applicant's 2'-FL is *food produced using gene technology* (as defined in Section 1.1.2—2) as it is derived from an organism modified using gene technology (i.e. sourced from GM *E. coli* BL21 strains). Consequently, express permission for the applicant's 2'-FL is required in accordance with Standard 1.5.2 (i.e. listed in Schedule 26 and comply with any corresponding conditions).

In addition, 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 is *used as a nutritive substance* because its addition to food is intended to achieve specific nutritional purposes. Therefore, express permission for the applicant's 2'-FL to be *used as a nutritive substance* is required in accordance with Standard 2.9.1 (i.e. be listed in the table to Section S29—5; and be in a permitted form at up to the maximum amount per 100 kJ specified in that table). This permission is separate and in addition to the permission required as a *food produced using gene technology* above.

In addition, 2'-FL is currently permitted in Standard 2.9.1 to be *used as a nutritive substance* in IFP either alone; or in combination with Lacto-N-neotetraose (LNnT). This permission will apply to the applicant's 2'-FL.

1.3.1.2 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.

1.3.1.3 Infant formula products

The composition of infant formula is regulated in Standard 2.9.1 and Schedule 29. This Standard (and associated Schedule) sets out specific compositional and labelling requirements for the following IFP:

- infant formula (for infants aged 0 to <12 months)
- follow-on formula (for infants aged from 6 to <12 months)
- infant formula products for special dietary use (for infants aged 0 to <12 months).

1.3.1.4 Formulated Supplementary Food for Young Children

Specific compositional and labelling requirements for FSFYC (for children aged from 1 to <4 years) are set out in Division 4 of Standard 2.9.3, and in Schedules 17 and 29.

1.3.1.5 Labelling requirements

Paragraph 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food. In addition to specific labelling requirements in Standards 2.9.1 and 2.9.3 (Division 4), the following general labelling requirements also apply.

Standard 1.2.4 generally requires food products to be labelled with a statement of ingredients.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food (FSFYC only). The Standard prohibits claims to be made about an infant formula product.

Standard 1.2.8 generally requires food products to be labelled with nutrition information. This Standard does not apply to infant formula products (specific nutrition labelling requirements are set out in Standard 2.9.1).

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*. A *genetically modified food* is defined in subsection 1.5.2—4(5) as a *food produced using gene technology* that contains novel DNA or novel protein or is listed in Section S26—3.

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

1.3.1.6 Current oligosaccharide permissions and restrictions

The ingredient assessed is a non-digestible oligosaccharide. The current permissions and restrictions in the Code relating to oligosaccharides are summarised in this section.

The Code currently regulates the addition of galacto-oligosaccharides (GOS) and inulin-type fructans (ITF) (both are defined in subsection 1.1.2—2) to IFP and FSFYC (see Sections 2.9.1—7 and 2.9.3—7, respectively). GOS and ITF are also permitted in general foods by their specific exclusion from the definition of *used as a nutritive substance* in Sections 1.1.2—12 and general provisions in Section 1.1.1—10. ITF includes substances such as fructo-oligosaccharides (FOS), short-chain FOS (scFOS), oligofructose and inulin (FSANZ 2013). Unlike 2'-FL, ITF are not present in human milk and GOS is found only in trace amounts (FSANZ 2008).

For IFP, Section 2.9.1—7 sets out restrictions on addition of ITF and GOS to IFP. Subsection 2.9.1—7(1) permits the addition of ITF alone (up to 110 mg/100 kJ), GOS alone (up to 290 mg/100 kJ), or ITF and GOS combined (up to 290 mg/100 kJ, with no more than 110 mg/kJ of ITF). These amounts were converted to the respective mg/100 kJ units for Code purposes from 8 g/L of GOS (alone or combined with ITF) and 3 g/L of ITF. Subsection 2.9.1—7(2) prohibits the use of ITF and/or GOS in IFP with 2'-FL either alone; or in combination with LNnT.

For FSFYC, the total amount of ITF or GOS must not be more than 1.6 g/serving (converted from 8 g/L). The permitted maximum amounts take into account both the added and naturally occurring substances.

1.3.2 International Standards

In developing food regulatory measures, 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 are permitted for use in IFP, FSFYC (toddler milks) and many other foods in at least 37 overseas countries at a range of levels. Table 1 outlines some international permissions for 2'-FL alone¹⁰.

Table 1: International permissions for use of 2'-FL in Infant formula*

Country	Max use level
United States	2.4 g/L

¹⁰ When permitted for use with lacto-N-neotetraose (LNnT), these levels are reduced.

Country	Max use level
Canada [#]	1.2 g/L
Singapore	1.2 g/L
European Union	1.2 g/L
Israel	2 g/L
Korea	2 g/L
Philippines	1.2 g/L

Notes to table:

*Infant formula categories vary between countries

[#] permission as novel food with support for use in infant formula

Labelling permissions and restrictions differ across countries, some specify the terminology that must be used for the ingredients on labels while others do not. Some countries permit claims on IFP while other countries do not.

1.3.2.1 Codex Alimentarius (Codex)

The current Codex Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Standard 72-1981), and for Follow-up Formula¹¹ (Codex Standard 156-1987), do not contain specific provisions for 2'-FL. However, the standards contain provisions for 'optional ingredients' which would apply to the addition of substances such as 2'-FL. FSANZ noted that the Follow-up Formula Standard is currently under review¹².

1.3.2.2 Countries with permissions for the applicant's 2'-fucosyllactose

United States

The United States Food and Drug Administration (USFDA) issued 'no questions'¹³ responses to the applicant's self-assessed Generally Recognized as Safe (GRAS) notifications for 2'-FL synthesised chemically and through microbial fermentation for use in various general and special purpose foods (USFDA 2015, 2016a). The maximum intended use level in 'term infant formula' and 'toddler formula' (terms used in the US) is 2 g/L of formula, as consumed. The USFDA also issued 'no questions' responses to applications of other 2'-FL manufacturers who use different GM production sources (Glycom (USFDA, 2016a), FrieslandCampina (USFDA, 2018a) and Dupont (USFDA, 2018b). There are permissions in the US for 2'-FL to be used alone, or in combination with LNnT.

European Union

2'-FL is permitted as a novel food in the European Union (EU) for use in a range of general foods (e.g. milk-based products, cereal bars, bread and pasta products) and special purpose foods (NFU, 2016). In the EU permissions also exist for 2'-FL to be used alone, or in

¹¹ 'Follow-up Formula' is currently defined by Codex as a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children (12-36 months) (Section 1.1.2—3).

¹² Currently under review by CCFSDU. For further information, search on the [Codex Alimentarius website](#).

¹³ 'No questions' response means the USFDA does not question the basis for the notifier's GRAS conclusion (USFDA 2015).

combination with LNnT. The relevant requirements for infant formula products and milk-based drinks for young children¹⁴ are:

- For infant formula and follow-on formula, a maximum level of 1.2 g/L of 2'-FL alone or in combination with up to 0.6 g/L of LNnT at a ratio of 2:1 in the final ready-to-use product.
- For milk-based drinks for young children, a maximum of 1.2 g/L of 2'-FL alone, or 0.6 g/L of LNnT alone, or 1.2 g/L 2'-FL in combination with up to 0.6 g/L LNnT at a ratio of 2:1 in the final ready-to-use product.
- For foods for special medical purposes which includes such foods for infants, the maximum level used must be in accordance with the particular nutritional requirements of the persons for whom the products are intended.

Specifications are currently prescribed in the EU for 2'-FL, which have recently been modified to be generic based on several equivalence notifications to the EU Commission from manufacturers (EU 2018; MEB 2017a, 2017b).

The novel food permissions in Commission Implementing Regulation (EU) 2018/1023 (EU, 2018) designates that labelling of the foodstuffs containing 2'-FL needs to use the term '2'-fucosyllactose'.

Canada

Health Canada issued a Letter of No Objection to the use of 2'-FL for use in formulas for term infants, and toddler formulas. A maximum concentration of 2 g/L 2'-FL is permitted.

Singapore

The Application states that the Agri-Food and Veterinary Authority (now known as the Singapore Food Agency) granted permission for the applicant's 2'-FL (up to 1.2 g/L) in infant formula and follow-on formula in 2017. 2'-FL is permitted at an amount not exceeding 1.20 mg/100 mL (as well as in combination with LNnT) under the Food Regulation 252(6)(g) (SFA 2018).

The regulations also include a prohibition on the use of the terms 'humanised', 'maternalised', or similar terms. There is also a prohibition on comparisons of formula to breastmilk. Guidance documents for industry on labelling provide the following specific examples: "{name of ingredient} sourced/obtained from breastmilk", or "{name of ingredient} similar to breastmilk".

The Philippines

The Application states 2'-FL was permitted by the Food and Drug Administration of the Philippines in May 2017 for use up to 1.2 g/L in infant formula and 'toddler milks'.

Israel

The applicant's 2'-FL is permitted for use in milk-based infant food compounds (infant formula) at a maximum concentration of 2 g/L in the final ready-to-use product. 2'-FL is permitted in baby food and hypoallergenic infant and toddler follow-up compounds at a maximum concentration of 1.2 g/L in the final ready-to-use product. 2'-FL is also permitted in combination with LNnT at reduced levels.

¹⁴ 'Infant formula', 'follow-on formula', 'foods for special medical purposes' and 'young children' are defined in [Regulation \(EU\) No 609/2013](#).

1.3.2.7 Other countries

The applicant also indicated they market 2'-FL in IFP and FSFYC equivalent products in several other countries at a range of 1.0 – 2.0 g/L¹⁵.

1.4 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* (the FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment with three editorial amendments made to correct purely typographical errors (capitalisation of the names of three bacteria) was approved. The variation takes effect on Gazettal. The approved draft variation is at Attachment A.

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

The draft variation on which submissions were sought is at Attachment C.

¹⁵ For a full list of countries or regions where the applicant markets their 2'-FL, please see Table 29 on page 88 of the application.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 22 July 2021 to 19 August 2021. Ten submissions were received, three from government agencies and seven from industry stakeholders. All submissions support a permission for the applicant's 2'-FL product (sourced from *E. coli* BL21 strains) in IFP. Government agencies supported the existing prohibition on the use of the words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO', or any word or words or abbreviations having the same or similar effect on the labels of IFP.

Differing views were received regarding permissions for the applicant's 2'-FL in FSFYC, and are summarised in Table 1 below.

Table 1: Summary of issues

	Issue	Raised by	FSANZ response
	Permission for 2'-FL in FSFYC		
1.	<p>FSANZ received requests to reconsider the current regulation which does not permit the addition of 2'-FL in FSFYC.</p> <p>Further studies were provided for FSANZ's consideration: Fonvig <i>et al</i> (2021); Šuligoj <i>et al</i> (2020); Iribarren <i>et al</i> (2020); Palsson <i>et al</i> (2020); Salli <i>et al</i> (2020); Schluter P <i>et al</i>. (2020); Akkerman, Faas, and de Vos (2019); Kunz <i>et al</i>. (2000).</p>	<p>New Zealand Food Safety (NZFS)</p> <p>Australian Food and Grocery Council (AFGC)</p> <p>New Zealand Food and Grocery</p>	<p>FSANZ's assessment of the evidence on beneficial health outcomes of 2'-FL in infants and young children is at SD1.</p> <p>Noting the decision made by the Food Ministers' Meeting in November 2020 regarding the review for A1155¹⁶, and to support the assessment of all available evidence for application A1190, FSANZ requested additional evidence from the applicant supporting a beneficial health outcome in young children from the addition of 2'-FL in FSFYC. No additional evidence was available from the applicant and FSANZ did not identify any new scientific literature independently.</p> <p>FSANZ reviewed the additional studies submitted during the Call for Submissions (CFS):</p>

¹⁶ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27>

	Issue	Raised by	FSANZ response
		Council (NZFGC) Infant Nutrition Council (INC) Nestlé Dairy Goat Co-operative (NZ) Ltd. (DGC) Nutricia Australia Ltd (Nutricia) Fonterra	<ul style="list-style-type: none"> - One study provided further evidence for 2'-FL having a bifidogenic effect in humans. - Four studies had already been evaluated by FSANZ during the assessment of application A1155. - Several studies assessed mixtures of human milk oligosaccharides, such that the role of 2'-FL alone could not be assessed. - Two studies (Palsson et al. 2020; Fonvig et al. 2021) proposed new health effects that were out of scope for the assessment of the applicant's 2'-FL, such as management of irritable bowel syndrome or prevention of dental caries. - Several studies were reviews of other studies. <p>The studies above were of low quality and limited relevance, and therefore FSANZ's conclusions of the supplementary evidence provided by submitters did not change FSANZ's assessment conclusions from the CFS.</p> <p>FSANZ's rationale for not permitting 2'-FL in FSFYC is discussed further in Section 3.1 of this report.</p>
2.	<p>Support received for the consideration of the regulation of nutritive substances and novel foods in Proposals P1024 and P1028.</p> <p>Support for premarket assessment of new ingredients focusing on safety. It is proposed that this would remove any ambiguity around a benefit assessment and promote innovation.</p>	Fonterra	<p>FSANZ acknowledges the comments received regarding premarket assessment requirements, however notes consideration of regulatory approaches around nutritive substances and novel foods are out of scope for this application and must be considered through other avenues.</p> <p>FSANZ also notes it must also have regard to relevant ministerial policy guidelines, as part of its consideration of the FSANZ Act requirements.</p>

	Issue	Raised by	FSANZ response
	Permission for 2'-FL as a therapeutic good		
3.	The Therapeutic Goods Administration (TGA) permits use of 2'FL in supplements for young children from age one through to senior adults (ARTG IDs: 362438, 320165, 320164, 320162).	INC AFGC Fonterra Nutricia	FSANZ notes the comments received regarding current permissions for products on the Australian Register of Therapeutic Goods (ARTG). However, FSANZ and TGA are separate Commonwealth agencies with different statutory functions, powers and obligations. As such, FSANZ must assess application A1190 in accordance with the FSANZ Act and the assessment criteria and processes prescribed by that Act.
	Cost-benefit considerations		
4.	<p>It was noted that FSANZ's cost benefit consideration highlighted that "...the importance of ensuring caregivers are not confused around the purpose or intent of FSFYC and do not buy foods that are not needed" (CFS p18) and that permitting the voluntary addition of the applicant's 2'-FL in FSFYC may not be beneficial for all consumers.</p> <p>Some submitters did not agree that consumers are confused around the purpose or intent of FSFYC, providing consumer data from an unknown source to support this.</p> <p>It was further stated that any broader concerns relating to the presentation of FSFYC and consumers' understanding of the purpose and intent of FSFYC should be addressed through a separate process and should not be the reason to not allow the voluntary addition of the applicant's 2'-FL to FSFYC.</p>	NZFS INC	<p>FSANZ notes this comment. For the reasons stated in this report, FSANZ decided not to permit the voluntary addition of the applicant's 2'-FL to FSFYC. See in particular Section 3 of this report. Providing choice to consumers is one aspect of a cost-benefit analysis. However, it is also important to ensure the composition of the product aligns with the intended purpose of that product; and, in this regard, the evidence supporting beneficial health outcomes in young children from the consumption of FSFYC containing 2'-FL is limited.</p> <p>FSANZ assessed A1190 in accordance with requirements in the FSANZ Act and its decision not to permit 2'-FL in FSFYC is in line with current permissions for 2'-FL in the Code..</p> <p>This issue has been addressed further in Section 5.1.1 of this report.</p>

	Issue	Raised by	FSANZ response
	Nutritional value of all foods suitable for young children		
5.	<p>It was highlighted that there is no prohibition in the Code for foods or food ingredients that are fed to young children but lack good nutritional value or benefit overall (e.g. highly processed snack foods).</p>	Nutricia	<p>FSANZ notes this comment.</p> <p>However, FSANZ notes the scope of this application specifically relates to special purpose foods designed to supplement the diets of young children where intakes of energy and nutrients may not be adequate to meet a child's requirements, and therefore assessment is required.</p> <p>As such, issues regarding food or food ingredients that are fed to young children ,which lack good nutritional value or benefit overall (e.g. highly processed snack foods) are outside the scope of this application.</p>
	Permissions for GOS and Inulin-Type Fructans		
6.	<p>Concerns were raised regarding inconsistencies in the Code for IFP and FSFYC.</p> <p>There are voluntary permissions to add other non-digestible oligosaccharides (GOS and ITF) to FSFYC with the intent to provide some of the beneficial effects provided by HMOs in human milk but they cannot substitute all HMO functions (Akkerman, Faas, and de Vos 2019).</p> <p>It was also stated that the existing prohibition regarding the use of 2'-FL with GOS and ITF in IFP inhibits innovation and does not harmonise with permissions in other countries.</p>	<p>NZFS</p> <p>INC</p> <p>DGC</p> <p>Fonterra</p> <p>Nutricia</p>	<p>FSANZ notes this concern.</p> <p>However, issues regarding the addition of 2'-FL to IFP and FSFYC in combination with GOS and/or ITF are outside the scope of Application A1190.</p> <p>This is because FSANZ's assessment of an application is limited by the scope of the application, which did not seek permission to use 2'-FL in combination with GOS and/or ITF.</p> <p>If permissions for the use of 2'-FL in combination with other non-digestible oligosaccharides is sought, then an application can be made to FSANZ.</p>

	Issue	Raised by	FSANZ response
	Impacts on international harmonisation and trade		
7.	<p>Several submitters noted that 2'FL is permitted in FSFYC (toddler milks) in many other countries. Harmonisation with international standards, that are based on relevant science and scientific expert opinion, is essential.</p> <p>It was stated that Australia and New Zealand industry will be at a competitive disadvantage with its international competitors, leading to substantial, negative flow-on effects in trade.</p>	<p>Nestlé NZFS INC DGC Fonterra Nutricia AFGC</p>	<p>FSANZ notes this comment.</p> <p>In making its decision, FSANZ had regard to international standards and to the question of consistency between domestic and international food standards. See Section 5.3 of this report.</p> <p>FSANZ's decision is deregulatory in nature and does not impose any new requirements on industry compared to the status quo.</p> <p>Within the domestic market, FSANZ notes that FSFYC will continue to be traded as they are currently. The addition of 2'-FL will be permitted in IFP, which will promote a competitive food industry for relevant products.</p>
	Impacts on innovation		
8.	<p>Concern that not permitting 2'-FL in FSFYC will stifle innovation as there is no incentive for industry in Australia and New Zealand to invest in new products.</p>	<p>INC Nutricia Fonterra NZFGC</p>	<p>FSANZ notes this comment.</p> <p>As stated above, FSANZ assessed A1190 in accordance with requirements in the FSANZ Act and its decision not to permit 2'-FL in FSFYC is in line with current permissions for 2'-FL in the Code.</p> <p>However, incentives to industry in Australia and New Zealand to invest in new products is a broader issue which is outside the scope of A1190.</p>

	Issue	Raised by	FSANZ response
	Ministerial Policy Guideline Part 2.9 – Special Purpose Foods		
9.	<p>It was suggested that where oligosaccharides are approved for use in IFP, these permissions should be extended to FSFYC.</p>	Nestlé	<p>FSANZ notes this comment.</p> <p>Substances used as a nutritive substance must (among other things) be added to food to achieve a nutritional purpose.</p> <p>The intended nutritional purposes for IFP and FSFYC are different. IFP are used as the sole or principal source of nutrition up to 12 months of age. FSFYC are suitable for supplementing the diets of young children where intakes of energy and nutrients may not be adequate to meet a child's requirements.</p> <p>As such, the consumer groups, dietary needs and related risks for IFP and FSFYC are different. Therefore, under FSANZ's regulatory framework, FSANZ considers it is not appropriate to <i>automatically</i> extend permissions as suggested in the submission.</p>
10.	<p>It was the views of some submitters that for an ingredient to align with current ministerial policy guidelines there must be 1) a risk of dietary inadequacy and 2) physiological need.</p> <p>Based on this, references were provided to suggest there is evidence of increasing risk of dietary inadequacy in young children in Australia and New Zealand. Those young children at risk would benefit from FSFYC with 2'-FL added.</p> <p>It was also highlighted that oligosaccharides are found in a wide variety of mammalian milk.</p>	INC Nestlé	<p>FSANZ notes the comments.</p> <p>As stated above, FSANZ assessed A1190 in accordance with requirements in the FSANZ Act and its decision not to permit 2'-FL in FSFYC is in line with current permissions for 2'-FL in the Code.</p> <p>FSANZ acknowledges that oligosaccharides are found in mammalian milk and not just human milk, however this application refers to 2'-FL which FSANZ understands from the application (Page 33) is most abundant in human milk, and only found in small or trace amounts in other mammalian milks (hence the desire to add it to IFP and FSFYC). Amendments have been made to Section 3.1. of this report to clarify this issue.</p>

	Issue	Raised by	FSANZ response
	Schedule 3 - Identity and purity		
11.	<p>Advice was sought on how FSANZ decides what parameters to include in Schedule 3. There is currently an inconsistent approach in Schedule 3 for parameters for microbes, individual nucleotides and heavy metals.</p> <p>It was suggested that microbiological criteria and limits for heavy metals should not be included in the specifications in Schedule 3 unless there is a compelling reason for inclusion for specific substances.</p> <p>It was further stated that the onus should be placed on manufacturers to assess microbiological suitability for their particular product.</p>	<p>AFGC INC Fonterra DGC</p>	<p>FSANZ acknowledges there are differences in some microbiological criteria in Schedule 3.</p> <p>However, the broader issue of parameters in Schedule 3 is out of scope for this application.</p> <p>Specifications are usually provided by applicants and are based on their proprietary manufacturing process, for example an appropriate heating step will decrease requirements around microbial reporting.</p> <p>Therefore, the differences between the 2'-FL specifications currently in the Code for source K-12 (permitted through A1155), and this applicant's 2'-FL specifications from BL21, relate to the unique proprietary manufacturing processes.</p>
12.	<p>It was suggested that FSANZ adopts a specification for 2'-FL in Schedule 3 which aligns with the EU novel food list (EU2017/2470 consolidated to 16.05.21).</p> <p>It is preferred that there is one entry for "2'-Fucosyllactose" (microbial source), a definition including chemical name, chemical formula, CAS No. and molecular weight.</p> <p>Separate descriptions and purity provisions could then be included for the two microbial sources approved for use in specific applications.</p>	<p>AFGC INC Fonterra DGC</p>	<p>FSANZ notes this suggestion, and acknowledges that the EU lists one generic specification with individual permissions at the source level.</p> <p>In the Code, specifications are usually provided by applicants and are based on their proprietary manufacturing process.</p> <p>As noted above, changing how existing specifications for all 2'-FL are set out in Schedule 3 is outside the scope of A1190.</p> <p>FSANZ may consider consolidating existing permissions into one set of generic permissions once substantial equivalence of all types of 2'-FL can be demonstrated.</p>
13.	<p>It was stated that S3—45 (u)(i) should capitalise '<i>Salmonella</i>' and (u)(iv) should capitalise '<i>Cronobacter sakazakii</i>'.</p>	<p>INC</p>	<p>FSANZ thanks the submitter for bringing this to our attention. These typographical errors have been rectified in the approved draft variation in Attachment A to this report.</p>

	Issue	Raised by	FSANZ response
	International permitted use level error		
14.	<p>It was noted that there was an error on page 10 of the CFS relating to EU permissions: "(less if combined with LNnT)".</p> <p>It was clarified that the limit in the EU Regulation (EU) 2017/2470 of 20 December 2017 is the same for 2'-FL whether with or without LNnT so long as a ratio of 2:1 is maintained. It is not clear that there is evidence to support the statement in the Food Standards Code.</p>	INC	<p>FSANZ thanks the submitter for raising this error in the CFS report. This has been rectified to align with the EU permissions in Section 1.3.2 of this report.</p> <p>In relation to the comment regarding existing permissions in the Code, decisions related to the existing levels of 2'-FL and LNnT in the Code were made in accordance with requirements in the FSANZ Act. For example, undertaking risk analysis using the best available scientific evidence (paragraph 18(2)(a)) and the promotion of consistency between domestic and international food standards (paragraph 18(2)(b)).</p> <p>FSANZ set the existing permitted maximum levels of 2'-FL and LNnT in the Code after undertaking a safety, technical and health effects assessment, including estimated dietary intakes and naturally occurring levels in human milk.</p> <p>It is noted that internationally, the permitted levels of 2'-FL for use in infant formula and follow-on formula range from 1.2 g/L to 2.4 g/L. FSANZ considered that approving a higher level of 2.4 g/L of 2'-FL alone or with 0.6 mg/L LNnT in Australia and New Zealand would therefore provide greater compatibility with a wider range of overseas food standards and allow for a more efficient and internationally competitive food industry given the high level of international interest in these substances.</p>
	Labelling Requirements		
15.	Industry submitters opposed the existing prohibition on the use of the words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and	INC Nestlé	FSANZ notes the comments. The existing prohibition for this terminology is consistent with policy principle (l) of the FMM's Ministerial Policy Guideline on <i>Regulation of Infant Formula</i>

	Issue	Raised by	FSANZ response
	<p>abbreviations 'HMO', 'HiMO', or any word or words or abbreviations having the same or similar effect on the labels of IFP. This view was held for a variety of reasons, including historical use of such terms in scientific literature, consumer understanding and trade issues.</p> <p>Government submitters supported the existing prohibition, with one submitter noting the prohibition should also apply to FSFYC if 2'-FL was permitted for voluntary addition under Option 3.</p>	<p>NZFGC AFGC Nutricia DGC TAS PHS VIC DHHS NZFS</p>	<p><i>Products</i>, which states:</p> <p><i>The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breastmilk.</i></p> <p>In addition, prohibitions for IFP:</p> <ul style="list-style-type: none"> • are consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand • ensure that the products cannot be represented as an equivalent to, or better than, breast milk. <p>FSANZ also notes the Code already contains examples of limitations placed on voluntary representations (for example, restrictions on representations of low alcohol, of the words 'non-intoxicating' and that a food containing alcohol is non-alcoholic).</p> <p>These restrictions are in place to reduce the risk of misleading consumers. When assessing 'risk' FSANZ considers the potential for risk as well as the evidence for risk in the context of the current environment, situation and relevant issues including possible effects on consumers and the community.</p> <p>Further, this labelling approach was an important consideration in the Ministers' decision to allow the addition of 2'-FL and LnNT to IFP.</p>

2.2 Risk and safety assessment

The ingredient under assessment is an oligosaccharide 2'-fucosyllactose¹⁷ (2'-FL), commonly found in human milk. There is already a permission in the Code to add 2'-FL derived from *E. coli* K-12 to IFP to a maximum level of 96 mg/100 kJ or 2.4 g/L. The applicant for A1190 is proposing the addition of 2 g/L. While a permission for 2'-FL exists in the Code, the source and specifications of this particular 2'-FL is different and thus requires a pre-market assessment.

2'-FL is manufactured by fermentation, using a unique GM bacterium. A **microbiological assessment** concluded that the host strain has a recognised safe history of use. It is sourced from *E. coli* BL21, which is commonly used for large-scale production of industrial compounds and human therapeutics. It is neither pathogenic nor toxigenic. A **biotechnology assessment** found the production strains were as stated by the applicant and are safe.

A **biochemical assessment** determined the 2'-FL sourced from the microbial fermentation was shown to be chemically and structurally identical to the naturally occurring 2'-FL in human milk. The final product was shown to be free of fermentation-derived contaminants. The purity and other constituents of the final product have been identified and listed in the specification for the product. The shelf-life and specifications are appropriate for addition to IFP and FSFYC.

A **dietary intake assessment** determined the requested level of 2'-FL is within the normal range of 2'-FL reported in human milk (0.6 – 7.8 g/L). This range is found in the 70-80% of women who have the ability to make 2'-FL. The estimated dietary intakes of 2'-FL for infants up to 12 months ranged between 0.1 – 0.33 g/kg bw/day at the mean and 0.2 – 0.66 g/kg bw/day at the 90th percentile, and for children 2-3 years from 0.077 – 0.15 g/kg bw/day at the mean and 0.15 – 0.31 g/kg bw/day at the 90th percentile.

FSANZ's previous **toxicological assessment** of 2'-FL concluded there are no safety concerns associated with the addition of 2'-FL at concentrations up to 2.4 g/L. Further assessment of new studies as a part of this application did not indicate a reason to change this conclusion. 2'-FL was not genotoxic and no adverse effects were observed in multiple short-term oral toxicity studies in neonatal rats, older rats and neonatal piglets. In human studies, infant formula supplemented with 2'-FL was well tolerated with no significant increases in adverse events. 2'-FL was also well tolerated in studies with children and adults.

Protein was not detected in the 2'-FL product, therefore 2'-FL is unlikely to pose an allergenicity concern.

A **nutritional assessment** concluded the addition of 2'-FL to infant formula is not expected to affect the growth profiles of infants. Combined with the limited gastrointestinal absorption of 2'-FL, there is no evidence to indicate a nutritional concern at concentrations that are typically observed in human milk.

As part of the assessment, FSANZ had regard to the Ministerial Policy Guideline's on the regulation of IFP and special purpose foods (including FSFYC). FSANZ concluded through a **benefit assessment** that there is evidence to support a role for 2'-FL in promoting a bifidogenic effect and limiting infection by pathogenic strains of *C. jejuni* in infants and young children. Of note, the evidence base for these effects in young children is fairly limited. The application provided information suggesting that 2'-FL can mediate changes in the function of the immune response, the intestinal barrier, learning and memory and gut motility. There is limited evidence demonstrating these effects in humans. FSANZ concludes that for these stated health effects, the claims are not adequately supported by the evidence.

¹⁷ 2'-fucosyllactose is also known as 2'-O-fucosyllactose. The O indicates the fucosyl group is attached to an oxygen residue.

In summary, 2'-FL is naturally present in human milk in a range of concentrations, providing a history of safe human exposure. FSANZ concludes there are no safety concerns associated with the addition of 2'-FL derived from *E. coli* BL21 produced by fermentation, to IFP and FSFYC, at the requested level of 2 g/L, or at higher estimated dietary intakes based on the existing permitted level in the Code (2.4 g/L).

3 Risk management

Breastfeeding is the recommended way to feed infants. As infants are a vulnerable population group, a safe and nutritious substitute is necessary when breastfeeding is not possible. Before a change in the composition of IFP is permitted, there must be evidence that the change would not pose a risk to the health and safety of consumers of these products, in this case - infants.

3.1 Consideration of the assessment and final approach

Where an infant is not breastfed or is partially breastfed, commercial infant formulas are the only safe alternative to human milk to be used until 12 months of age (NHMRC 2012; NZ MoH 2012). The purpose of FSFYC is different to IFP; it is for when intakes of energy and nutrients may not be adequate to meet a child's (aged 1 to < 4 years) requirements. Australian Infant Feeding Guidelines state that FSFYC are not required for healthy children as they should be consuming adequate nutrients from regular foods (NHMRC 2012).

Following assessment of the applicant's 2'-FL to IFP and FSFYC, FSANZ concluded that it was appropriate to permit the applicant's 2'-FL in IFP only. In coming to this conclusion, FSANZ had regard to:

- the safety, risk and beneficial health outcomes assessment at SD1 and summarised above in Section 2.2 of this report;
- submissions received at the call for submissions;
- Section 29 and subsection 18 of the FSANZ Act, including costs and benefits at Section 5.1.1;
- the justification for the FSANZ position outlined in the A1155 Approval Report¹⁸ and Review Report¹⁹ to permit 2'-FL in both IFP and FSFYC; and
- the decision and justification by the Food Ministers' Meeting²⁰ in November 2020 to amend the drafting to not permit 2'-FL in FSFYC.

The applicant justified the addition of their 2'-FL product in FSFYC as follows:

- the benefits of 2'-FL are hypothesised to extend past infancy into toddlerhood;
- human milk is given to those toddlers who continue to breastfeed after their first year of life, and therefore the permission would allow FSFYC ingredients to align more closely to human milk for formula-fed babies.

FSANZ understands from the application (Page 33) 2'-FL is most abundant in human milk, and only found in small or trace amounts in other mammalian milks. Noting the decision made by the Food Ministers' Meeting, regarding the review for A1155, to not permit 2'-FL in FSFYC; and to support the assessment of all available evidence for application A1190, FSANZ requested additional evidence from the applicant supporting a beneficial health

¹⁸ For more information, see the [A1155 Approval Report](#)

¹⁹ For more information, see the [A1155 Review Report](#)

²⁰ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation. [See the Australia and New Zealand Ministerial Forum on Food Regulation Communique 27 November 2020.](#)

outcome in young children from the addition of 2'-FL in FSFYC. No additional evidence was available from the applicant and FSANZ did not identify any new scientific literature independently. Additional studies were provided during the CFS from industry stakeholders, however these were of low quality and limited relevance, and therefore did not change FSANZ's conclusions (see SD1 and Section 2.1 and 2.2 of this report).

Under section 30 of the [FSANZ Act](#), the applicant was notified of the proposed draft variation and how it differed to that requested in the application. Of note, the notification outlined that FSANZ was not proposing to permit the addition of 2'-FL in FSFYC. Before public release of the Call for Submissions, the applicant accepted this variation and agreed to proceed.

The five year review for 2'-FL and LNnT in Infant Formula Products.

FSANZ acknowledges Food Ministers agreed to permit 2'-FL (alone or in combination with LNnT) in IFP under the condition that a five year review²¹ (dated from gazettal) of the initial (A1155) permission be undertaken by FSANZ. Any permission granted for 2'-FL is subject to this condition. FSANZ ensures any applicant wishing to submit an application to permit a new source of 2'-FL is aware of this condition prior to lodgement.

3.2 Labelling

Given the risk management approach excludes FSFYC, the application of labelling requirements for the proposed permission for addition of 2'-FL in IFP are discussed below.

3.2.1 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 IFP must contain a statement of ingredients. Should manufacturers choose to add the applicant's 2'-FL alone or combined with LNnT to IFP, then this substance 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, or 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*.

Noting the existing prohibited representations in paragraphs 2.9.1—24(1)(ca) and (cb) (refer Section 3.2.3 below), these existing ingredient naming requirements will apply to 2'-FL, enabling industry to have flexibility in how they declare this ingredient (for example, using the scientific name '2'-fucosyllactose').

3.2.2 Mandatory nutrition information

Section 2.9.1—21 regulates the declaration of nutrition information in a nutrition information statement (NIS) on the label of IFP. The NIS is a single statement and may be in the form of a table, as indicated in Section S29—10 *Guidelines for infant formula products*.

Paragraph 2.9.1—21(1)(iii) requires the average amount of any substance used as a nutritive substance permitted by the Standard to be declared in the NIS. The specific 2'-FL in this application will need to be declared in the NIS when it is voluntarily added to a IFP.

3.2.3 Prohibited representations

Paragraph 2.9.1—24(1)(ca) prohibits the use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar

²¹ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27>

effect. In addition, paragraph 2.9.1—24(1)(cb) prohibits the use of the abbreviations ‘HMO’ or ‘HiMO’ or any abbreviation having the same or similar effect. The words and abbreviations in these provisions cannot be used anywhere on the label of a package of IFP. The applicant’s 2’-FL will be subject to these prohibited representations.

3.2.4 Voluntary representations

Subsection 1.2.7—4(b) of Standard 1.2.7 states that a nutrition content or health claim must not be made about an IFP. The prohibition is also set out in Section 2.9.1—24 (1)(f) of Standard 2.9.1, which prohibits a reference to the presence of a nutrient or substance that may be used as a nutritive substance, except for a statement relating to lactose, in the statement of ingredients or the NIS. This existing prohibition for nutrition content and health claims for IFPs will apply to 2’-FL.

3.2.5 Labelling as ‘genetically modified’

As discussed in the safety and risk assessment report (SD1), the applicant’s 2’-FL is highly unlikely to contain novel protein or novel DNA due to the purification step used in the production of this oligosaccharide. It is therefore highly unlikely that novel protein or novel DNA will be present in an IFP that contains this 2’-FL as an ingredient. However, where novel protein or novel DNA is present, the requirement to label 2’-FL as ‘genetically modified’ will apply in accordance with Section 1.5.2—4 of Standard 1.5.2.

3.3 Permitted use of 2’-FL

FSANZ noted the applicant requested a maximum use level for their 2’-FL of 2 g/L. The risk and safety assessment (see SD1) confirmed 2’-FL is safe at the higher level of 2.4 g/L. 2’-FL derived from *E. coli* K-12 is already permitted in the Code at this higher level and this is within the range of concentrations of 2’-FL found naturally in mature human milk. Additionally, the higher use level promotes a competitive food supply and provides industry with product innovation opportunities.

FSANZ therefore proposed a permission for the higher use level of 2.4 g/L or 96 mg/100 kJ.

FSANZ previously assessed and permitted 2’-FL alone or in combination with LnNT at specific concentrations. FSANZ had no concerns with these existing permissions applying to the applicant’s 2’-FL, noting an exclusive use period for LnNT in the Code is applicable for a specific brand.

3.3.1 GM source permission in schedule 26

The 2’-FL being assessed in this application is produced via fermentation using a production system that includes multiple production strains sourced from *Escherichia coli* BL21(DE3), a common strain for recombinant protein production. FSANZ’s biotechnology assessment found the production strains sourced from *E. coli* BL21(DE3) were as stated by the applicant and are safe. Therefore, the draft variation to the Code gives permission for the use of 2’-FL from *Escherichia coli* BL21 strains so long as they contain the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126 and they meet the specification at Schedule 3. This approach is consistent with existing permissions in the Code for 2’-FL.

3.3.1 2’-FL in combination with LNnT

FSANZ acknowledges that the current permissions in the Code permit 2’-FL from any approved source to be used alone or in combination with LNnT (subject to certain conditions). The assessment undertaken for A1155 concluded that there are no public health and safety concerns associated with the addition of 2’-FL alone or in combination with LNnT

to infant formula products at the proposed levels. Given both the Applicant's 2'-FL and the 2'-FL permitted by the Code are safe, and are chemically and structurally identical to each other and 2'-FL from human milk, FSANZ is satisfied that current permissions in the Code are suitable.

3.4 Common substance names for 2'-FL

FSANZ understands there are at least three possible common substance names for 2'-FL: 2'-fucosyllactose; 2'-O-fucosyllactose; and 2'-fucosyl-D-lactose. In previous application A1155, FSANZ adopted the common name used by the applicant "2'-O-fucosyllactose" in the Code permissions. The applicant for A1190 has requested FSANZ use the common name "2'-fucosyllactose".

During the assessment period for this application, FSANZ consulted with the A1155 applicant on the use of different common substance names to describe the same substance in the Code. The applicant for A1155 had no objections to the proposed change. FSANZ considered it appropriate to amend Schedule 26 to reference a single common substance name "2'-fucosyllactose" to ensure consistency in the Code and international harmonisation.

3.5 Exclusivity

An applicant may request an exclusive use permission to use and sell a food (including a substance) for a certain period of time to recognise the investment made in developing a novel food or ingredient or nutritive substance 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 for a period of 15 months on the basis that they have invested significantly in the technology development and safety studies.

FSANZ decided to provide the applicant with a 15 month exclusive use permission for the applicant's brand of 2'-FL, commencing on the date of gazettal of the approved draft variation.

This means that, during that 15 month period, the permission for the applicant's 2'-FL would apply exclusively to that substance under the brand 'CHR. HANSEN™ 2'-FL' in accordance with the Code. Once the 15 month period ends, the exclusive use permission would revert to a general permission, meaning that the permission would apply to all brands of 2'-FL produced by fermentation and sourced from *E. coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *E. coli* O126, 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.

3.6 Risk management conclusion

Having considered the submissions 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 approved a draft variation to the Code to permit the voluntary addition of the applicant's 2'-FL to IFP.

The addition of the applicant's 2'-FL to IFP will be subject to the following Code requirements and conditions:

- It may be added alone or in combination with LnNT up to a maximum level of 2.4 g/L for 2'-FL, as consumed (i.e. in powder or liquid form).

- The existing prohibition for the use of 2'-FL with GOS and ITF will apply to IFP that contain the applicants 2'-FL.
- The existing prohibition for the use of the words 'human milk identical 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 IFP that contain the applicant's 2'-FL.
- An exclusive permission to use the applicant's 2'-FL will apply for a period of 15 months, linked to the applicant's brand name 'CHR. HANSEN™ 2'-FL', 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.
- The permission is subject to the outcome of the five year review²² (to be completed by March 2026) which will reassess evidence of a substantiated beneficial role of 2'-FL in the normal growth and development of infants.

The approved draft variation is at Attachment A. The explanatory statement for the variation is at Attachment B. The draft variation on which submissions were sought is at Attachment C.

4 Risk communication

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. Subscribers and interested parties were notified about the public consultation period via the FSANZ Standards Notification Circular. A media release, FSANZ's social media tools and Food Standards News were also used to raise awareness in the community regarding the opportunity for comment.

A public consultation paper called for submissions from 22 July 2021 to 19 August 2021. Ten submissions were received. FSANZ had regard to all submissions received for this application as part of its assessment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

5 FSANZ Act assessment requirements

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:

5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for permitting genetically modified foods (OBPR correspondence dated 24 November 2010, reference 12065) and for the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April

²² <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27>

2013, reference 14943).

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 are likely to benefit, on balance, from a move from the status quo (where status quo is Option 1: rejecting the Application). This analysis considered costs and benefits to the community, government, and industry of two other options:

- Option 2 is permitting the use of the applicant's 2'-FL in IFP only, and
- Option 3 is permitting the use of the applicant's 2'-FL in both IFP and FSFYC.

FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of permitting the use of the applicant's 2'-FL in IFP only and then in both IFP and FSFYC.

FSANZ's assessment of the applicant's 2'-FL concluded it is chemically and structurally identical to that naturally present in human milk, and will not propose a health or safety risk for consumers. The applicant's 2'-FL is also chemically and structurally identical to the 2'-FL already permitted in the Code.

As discussed in Section 2.2. of this report, FSANZ concluded that there is evidence of a bifidogenic effect and anti-infective effect against invasive *C. jejuni* in infants and young children, however the evidence is limited in young children.

As discussed in Section 3.1 of this report, in order to assess all available evidence, FSANZ requested additional evidence from the applicant supporting a beneficial health outcome in young children from the addition of 2'-FL in FSFYC. No additional evidence was available from the applicant and FSANZ did not identify any new scientific literature independently; additional studies provided in submissions these were assessed as being of low quality and limited relevance to the permission.

Option 2 Costs and benefits of permitting the use of the applicant's 2'-FL in infant formula products only

As the permission is voluntary, industry will use this new 2'-FL permission only where they believe a net benefit exists for them over use of the existing permitted source of 2'-FL.

Option 2 permits an additional source of 2'-FL for IFPs. This would increase competition in the manufacturing processes. Costs of producing and purchasing IFPs might then reduce and availability might increase, potentially benefitting both industry and consumers.

A potentially greater supply and lower cost of 2'-FL from this proposed permission could also help IFP exporters that want to use 2'-FL in their products to compete internationally. IFP exports are important to Australia and New Zealand. Excluding FSFYC, annual IFP exports are approximately valued at over AU\$ 700 million for Australia and over NZ\$ 1 billion for New Zealand²³.

There is a risk that not permitting further sources of 2'-FL (beyond current permissions) and rejecting this application could constrain product innovation that could be enabled by greater

²³ Sources: ABARES Stats for Australian IFP Exports 2018 "19011000" and New Zealand MPI Stats for New Zealand Exports – Tariff Code HS 10.

supply and lower price of 2'-FL, reduce long-term competitiveness of Australia and New Zealand exports over time and reduce employment opportunities. That is because overseas producers of IFPs can access more sources of 2'-FL than are currently permitted in Australia and New Zealand. Permitting this application will improve harmonisation with international regulations by allowing additional sources of 2'-FL onto the IFP market.

Permitting this additional source of 2'-FL may result in a small but likely inconsequential cost to government in terms of compliance monitoring for an additional 2'-FL source.

Option 3 Costs and benefits of permitting the use of the applicant's 2'-FL in IFP and FSFYC

FSANZ acknowledges that permitting the voluntary addition of 2'-FL in both IFP and FSFYC may have some benefit to industry relative to Option 2 and the Status Quo.

However, FSANZ assessed that Option 3 is not the most beneficial option for the community for the following reasons:

- the Australian Infant Feeding Guidelines state that FSFYC are not required for healthy children over the age of twelve months as they should be consuming adequate nutrients from regular foods (NHMRC 2012). Therefore, most healthy young children have no nutritional requirement for FSFYC and parents and caregivers may spend money and resources on unnecessary foods;
- the evidence supporting beneficial health outcomes in young children from the consumption of FSFYC containing 2'-FL is limited.

Conclusions from cost benefit considerations

Having regard to the best available evidence, FSANZ did not reach a conclusion about Option 3, because it is not currently clear how costs to parents and caregivers who give their young children foods that may not benefit them would compare to any industry benefits.

Option 2 is the preferred Option for the reasons stated above. FSANZ's assessment is that the direct and indirect benefits that would arise from that Option will most likely outweigh the associated costs.

5.1.2 Other measures

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

Any relevant New Zealand standards

Relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

Any other relevant matters

Other relevant matters are considered below.

5.2. Subsection 18(1)

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

- **Protection of public health and safety**

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2 of this report. The assessment concluded that the addition of 2'-FL, in powder or liquid form, to IFP and FSFYC at concentrations up to 2.4 g/L is safe.

For the reasons explained in Section 3 of this report, FSANZ decision was to not permit 2'-FL in FSFYC.

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

Current labelling requirements discussed in Section 3.2 of this report would apply to the applicant's 2'-FL when added to IFP and would provide information to enable consumers to make an informed choice.

- **The prevention of misleading or deceptive conduct**

Current labelling requirements, including prohibited representations described in Sections 3.2.3 and 3.2.4 of this report, which aim to prevent misleading or deceptive conduct, would apply to the applicant's 2'-FL when added to IFP.

5.3 Subsection 18(2)

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 and considered the best available evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the applicant's 2'-FL. The applicant submitted a dossier of scientific studies, and FSANZ was also able to draw on conclusions from previous assessments undertaken for application A1155. Other relevant information including scientific literature was also identified through a literature review and used in assessing the Application. During the assessment FSANZ requested the applicant provide any further additional evidence on the safety or beneficial health effects of their 2'-FL, specifically in the young child population. This ensured the assessment was based on the most current and best available evidence. Further studies provided during the call for submissions have been reviewed. These were not sufficient to change FSANZ's conclusions.

- **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. As discussed in Section 1.3.2 of this report, 2'-FL is permitted in other countries. Permissions are for equivalent IFP and FSFYC (and other foods) for use alone or in combination with LNnT; including at a range of levels and with country-specific labelling requirements.

FSANZ considered that the permission to add the applicant's 2'-FL to IFP would contribute to the consistency between domestic and international food standards. For the reasons explained under Section 3 of this report, FSANZ decided not to permit the addition of the applicant's 2'-FL to FSFYC. This approach is consistent with current permissions in the Code.

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

The permission to add the applicant's 2'-FL to IFP would support an internationally competitive food industry in relation to the addition of 2'-FL to IFP, and is consistent with existing permissions in the Code for 2'-FL.

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

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

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

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

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

FSANZ considered that through the permission for 2'-FL to be added to IFP, these Policy Guidelines have been met.

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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 A1190 – 2'-FL in infant formula and other products) Variation

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

Dated [To be completed by Delegate]

[Insert name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1190 – 2'-FL in infant formula and other 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.

4 Order in which amendments in the Schedule take effect

Amendments in the Schedule take effect in numerical order.

Schedule

[1] **Standard 2.9.1** is varied by omitting “2'-O-fucosyllactose” (wherever occurring) in subsection 2.9.1—7(2), substituting “2'-fucosyllactose”

[2] **Schedule 3** is varied by

[2.1] omitting in the table to subsection S3—2(2)

2'-O-fucosyllactose	section S3—40
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and substituting, in alphabetical order

2'-fucosyllactose sourced from <i>Escherichia coli</i> K-12	section S3—40
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[2.2] inserting in the table to subsection S3—2(2), in alphabetical order

2'-fucosyllactose sourced from <i>Escherichia coli</i> BL21	section S3—45
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[2.3] omitting the heading for section S3—40, substituting

S3—40 Specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12

[2.4] omitting “2'-O-fucosyllactose (2'-FL)” in section S3—40, substituting “2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12”

[2.5] inserting after subsection S3—44

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

For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* BL21, the specifications are the following:

- (a) chemical name— α -L-fucopyranosyl-(1→2)- β -D-galactopyranosyl-(1→4)-D-glucopyranose
- (b) chemical formula— $C_{18}H_{32}O_{15}$
- (c) CAS number—41263-94-9
- (d) description—either a white to ivory powder, or a colourless to slightly yellow liquid
- (e) 2'-FL—not less than 90.0%
- (f) D-lactose—not more than 5.0%
- (g) L-fucose—not more than 3.0%
- (h) 3-fucosyllactose—not more than 5.0%

- (i) difucosyllactose—not more than 5.0%
- (j) fucosyl-galactose—not more than 3.0%
- (k) glucose—not more than 3.0%
- (l) galactose—not more than 3.0%
- (m) water—not more than 9.0% for powder, not applicable for liquid
- (n) solids—45% w/v (\pm 5%) dry matter in water, not applicable for powder
- (o) ash, sulphated—not more than 0.5%
- (p) residual proteins—not more than 0.01%
- (q) lead—not more than 0.02 mg/kg
- (r) arsenic—not more than 0.2 mg/kg
- (s) cadmium—not more than 0.1 mg/kg
- (t) mercury—not more than 0.5 mg/kg
- (u) microbiological:
 - (i) *Salmonella*—absent in 100 g for powder, absent in 200 mL for liquid
 - (ii) total plate count—not more than 10000 cfu/g for powder, not more than 5000 cfu/g for liquid
 - (iii) coliform/Enterobacteriaceae—absent in 11 g for powder, absent in 22 mL for liquid
 - (iv) *Cronobacter sakazakii*—absent in 100 g for powder, absent in 200 mL for liquid
 - (v) yeast and mould—not more than 100 cfu/g for powder, not more than 50 cfu/g for liquid
 - (vi) aflatoxin M1—not more than 0.025 μ g/kg
 - (vii) endotoxins—not more than 10 EU/mg
 - (viii) GMO detection—not detected.

[3] Schedule 26 is varied by

[3.1] omitting item 1 in the table to subsection S26—3(7), substituting

<p>1 2'-fucosyllactose</p>	<p>(a) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i></p>	<ol style="list-style-type: none"> 1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare. 3. For the purposes of condition 2 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.
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(b) *Escherichia coli* BL21
containing the gene for
alpha-1,2-
fucosyltransferase from
Escherichia coli O126

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand CHR. HANSEN™ 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 A1190 – 2'-FL in infant formula and other products) Variation* and ending 15 months after that date.

[3.2] omitting “2'-O-fucosyllactose” in item 2 in the table to subsection S26—3(7), substituting “2'-fucosyllactose”

[4] **Schedule 29** is varied by omitting “2'-O-fucosyllactose” (wherever occurring) in the table to section 2.9.1—5, substituting “2'-fucosyllactose”

Attachment B – Explanatory Statement

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 A1190 which sought to permit the voluntary addition of 2'-fucosyllactose (2'-FL) from a new microbial source, as a nutritive substance, to infant formula products and formulated supplementary foods for young children (FSFYC). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

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

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to the Code to:

- amend Schedule 26 to permit the addition of 2'-FL derived from a new microbial source in infant formula products subject to certain conditions, including an exclusive use period of 15 months for the applicant's brand of 2'-FL; and
- insert prescribed specifications for this 2'-FL into Schedule 3.

The approved draft variation includes consequential amendments to the Code as a result of the above amendments.

3. Documents incorporated by reference

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

However, the approved draft variation will vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of 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) Compendium of Food Additive Specifications (FAO/WHO 2019); the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition); and the Commission Regulation (EU) No 231/2012.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1190 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 22 July 2021 for a four-week consultation period.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption, permitting the voluntary use

of genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065), and the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

5. 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 94 of the FSANZ Act.

6. Variation

The amendments in the Schedule take effect in numerical order i.e. according to item and sub-item numbers.

Item [1]

Item [1] varies Standard 2.9.1 by omitting references to '2'-O-fucosyllactose' wherever occurring in subsection 2.9.1—7(2), and substituting them with references to '2'-fucosyllactose'. The revised reference reflects the preferred substance name for all permitted 2'-FL in the Code.

This amendment is a consequence of the amendments in **items [2]** and **[3]** below.

Item [2]

Item [2] sets out the following amendments to Schedule 3.

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. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Sub-item [2.1] omits references to '2'-O-fucosyllactose' and 'section S3—40' in columns 1 and 2 respectively of the table to subsection S3—2(2), substituting them with, in alphabetical order, references to '2'-fucosyllactose sourced from *Escherichia coli* K-12' and 'section S3—40'.

This amendment reflects the preferred substance name and source; and distinguishes between the specifications for 2'-fucosyllactose from *Escherichia coli* K-12 and specifications for the new substance sought to be permitted by the applicant - 2'-fucosyllactose from *Escherichia coli* BL21 (see sub-items [2.2] and [2.5] below).

Sub-item [2.2] inserts into columns 1 and 2 of the table to subsection S3—2(2), in alphabetical order, new references to '2'-fucosyllactose from *Escherichia coli* BL21' and 'section S3—5' respectively. These new references relate to the new provision that is inserted by sub-item [2.5] below.

Sub-item [2.3] omits the heading for section S3—40, substituting it with '2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12' (see sub-item [2.1] above).

Sub-item [2.4] omits the reference to '2'-O-fucosyllactose (2'-FL)' in section S3—40, substituting it with a reference to '2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12' consistent the new heading for section S3—40 (see sub-items [2.1] and [2.3] above).

The effect of the amendments in sub-items [2.3] and [2.4] is that the specifications in section S3—40 will relate specifically to 2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12.

Sub-item [2.5] inserts new section S3—45 which sets out the specifications relating specifically to 2'-fucosyllactose sourced from *Escherichia coli* BL21, the new substance sought to be permitted by the applicant.

Consequently, the permission for 2'-fucosyllactose sourced from *Escherichia coli* BL21 to be used as a nutritive substance in infant formula products (or sold for such use) will be subject

to the requirement in section 1.1.1—15 that the substance must comply with these specifications.

Item [3]

Item [3] sets out the following amendments to Schedule 26.

Schedule 26 relates to food produced using gene technology. 2'-fucosyllactose sourced from *Escherichia coli* BL21 is a food produced using gene technology (as defined in subsection 1.1.2—2(3)) because it is derived 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.

Sub-item [3.1] omits item 1 in the table to subsection S26—3(7), substituting it with a revised item 1.

Revised item 1 refers to '2'-fucosyllactose' as the substance name in column 1 of the table instead of '2'-O-fucosyllactose' (see sub-item [2.1] above).

Revised item 1 also includes a new source (paragraph (b)) of 2'-fucosyllactose in column 2 of the table - *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126.

Revised item 1 also sets out the following new conditions in column 3 of the table, both of which 2'-fucosyllactose from source (b) must comply with:

- (a) 2'-fucosyllactose from source (b) may only be added to infant formula products; and
- (b) during the 'exclusive use period' (i.e. the period commencing on the date of gazettal of this approved draft variation, and ending 15 months after that date), 2'-fucosyllactose from source (b) may only be sold under the brand name 'CHR. HANSEN™ 2'-FL'.

Condition (b) means that the permission for 2'-FL from source (b) will apply exclusively to that substance under the brand 'CHR. HANSEN™ 2'-FL' in accordance with the Code. Once this period ends, the exclusive use permission will revert to a general permission, meaning that the permission will then apply to all brands of 2'-FL from source (b) in accordance with the Code.

The effect of the amendment in sub-item [3.1] is that 2'-fucosyllactose derived from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126 will be permitted to be used as a nutritive substance in infant formula products:

- in accordance with the Code; and
- subject to the above exclusive use condition.

Sub-item [3.2] omits the reference to '2'-O-fucosyllactose' in item 2 in the table to subsection S26—3(7), substituting it with a reference to '2'-fucosyllactose'. This amendment is a consequence of the amendments in sub-item [3.1] above.

The amendments in **item [3]** do not make any substantive changes to *existing* permissions and other requirements in the Code related to food produced using gene technology.

Item [4]

Item [4] varies Schedule 29 by omitting references to '2'-O-fucosyllactose' wherever occurring in the table to section 2.9.1—5, and substituting them with references to '2'-fucosyllactose'. As stated above, the revised reference reflects the preferred substance name for all permitted 2'-FL.

This amendment is a consequence of the amendments in **items [2]** and **[3]** above.

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



Food Standards (Application A1190 – 2'-FL in infant formula and other products) Variation

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

Dated [To be completed by Delegate]

[Insert name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1190 – 2'-FL in infant formula and other 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.

4 Order in which amendments in the Schedule take effect

Amendments in the Schedule take effect in numerical order.

Schedule

[1] **Standard 2.9.1** is varied by omitting “2'-O-fucosyllactose” (wherever occurring) in subsection 2.9.1—7(2), substituting “2'-fucosyllactose”

[2] **Schedule 3** is varied by

[2.1] omitting in the table to subsection S3—2(2)

2'-O-fucosyllactose	section S3—40
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and substituting, in alphabetical order

2'-fucosyllactose sourced from <i>Escherichia coli</i> K-12	section S3—40
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[2.2] inserting in the table to subsection S3—2(2), in alphabetical order

2'-fucosyllactose sourced from <i>Escherichia coli</i> BL21	section S3—45
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[2.3] omitting the heading for section S3—40, substituting

S3—40 Specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12

[2.4] omitting “2'-O-fucosyllactose (2'-FL)” in section S3—40, substituting “2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12”

[2.5] inserting after subsection S3—44

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

For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* BL21, the specifications are the following:

- (v) chemical name— α -L-fucopyranosyl-(1→2)- β -D-galactopyranosyl-(1→4)-D-glucopyranose
- (w) chemical formula— $C_{18}H_{32}O_{15}$
- (x) CAS number—41263-94-9
- (y) description—either a white to ivory powder, or a colourless to slightly yellow liquid
- (z) 2'-FL—not less than 90.0%
- (aa) D-lactose—not more than 5.0%
- (bb) L-fucose—not more than 3.0%
- (cc) 3-fucosyllactose—not more than 5.0%

- (dd) difucosyllactose—not more than 5.0%
- (ee) fucosyl-galactose—not more than 3.0%
- (ff) glucose—not more than 3.0%
- (gg) galactose—not more than 3.0%
- (hh) water—not more than 9.0% for powder, not applicable for liquid
- (ii) solids—45% w/v (\pm 5%) dry matter in water, not applicable for powder
- (jj) ash, sulphated—not more than 0.5%
- (kk) residual proteins—not more than 0.01%
- (ll) lead—not more than 0.02 mg/kg
- (mm) arsenic—not more than 0.2 mg/kg
- (nn) cadmium—not more than 0.1 mg/kg
- (oo) mercury—not more than 0.5 mg/kg
- (pp) microbiological:
 - (ix) *salmonella*—absent in 100 g for powder, absent in 200 mL for liquid
 - (x) total plate count—not more than 10000 cfu/g for powder, not more than 5000 cfu/g for liquid
 - (xi) coliform/enterobacteriaceae—absent in 11 g for powder, absent in 22 mL for liquid
 - (xii) *cronobacter sakazakii*—absent in 100 g for powder, absent in 200 mL for liquid
 - (xiii) yeast and mould—not more than 100 cfu/g for powder, not more than 50 cfu/g for liquid
 - (xiv) aflatoxin M1—not more than 0.025 μ g/kg
 - (xv) endotoxins—not more than 10 EU/mg
 - (xvi) GMO detection—not detected.

[3] Schedule 26 is varied by

[3.1] omitting item 1 in the table to subsection S26—3(7), substituting

<p>1 2'-fucosyllactose</p>	<p>(a) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i></p>	<ol style="list-style-type: none"> 1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare. 3. For the purposes of condition 2 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.
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(b) *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand CHR. HANSEN™ 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 A1190 – 2'-FL in infant formula and other products) Variation* and ending 15 months after that date

[3.2] omitting “2'-O-fucosyllactose” in item 2 in the table to subsection S26—3(7), substituting “2'-fucosyllactose”

[4] **Schedule 29** is varied by omitting “2'-O-fucosyllactose” (wherever occurring) in the table to section 2.9.1—5, substituting “2'-fucosyllactose”