

**22 July 2021**  
**163-21**

## **Call for submissions – Application A1190**

### **2'-FL in infant formula and other products**

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Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measure it has prepared in response to an application originally submitted by Jennewein Biotechnologies GHmb<sup>1</sup>. The application is seeking to permit the voluntary addition of 2'-fucosyllactose (2'-FL), produced via a new genetically modified *Escherichia coli* strain, 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.

For information about making a submission, visit the FSANZ website and see [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within three business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 19 August 2021**

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

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<sup>1</sup> Chr. Hansen A/S acquired Jennewein Biotechnologie GmbH following acceptance of the application by FSANZ. The applicant is now Chr. Hansen.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand  
PO Box 5423  
KINGSTON ACT 2604  
AUSTRALIA  
Tel +61 2 6271 2222

Food Standards Australia New Zealand  
PO Box 10559  
The Terrace WELLINGTON 6143  
NEW ZEALAND  
Tel +64 4 978 5630

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## Supporting documents

The following document informed the assessment of this Application and is available on the FSANZ website:

SD1 Risk and safety assessment report

## Executive summary

FSANZ has assessed an application by Chr. Hansen A/S to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of '2'-fucosyllactose' (2'-FL) produced via a new genetically modified (GM) *Escherichia coli* (*E.coli*) strain 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 applicant's 2'-FL product is produced by microbial fermentation using GM production strains. 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 type 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 source and specifications. As such, a pre-market assessment of that 2'-FL was required.

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 in accordance with relevant Ministerial Policy Guidelines. That assessment concluded that there is evidence to support a role for 2'-FL in promoting a bifidogenic effect in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children. However, the evidence base for such effects in young children is fairly limited.

After assessing the application, and for the reasons stated in this report, FSANZ has prepared a draft variation to permit the voluntary addition of the applicant's 2'-FL to IFP. The Code currently permits 2'-FL to be used alone or in combination with Lacto-N-neotetraose (LNnT). FSANZ has previously assessed this combination and confirmed its safety so it will apply to the applicant's 2'-FL (noting LNnT currently has an exclusive use period for a specific brand). As explained in this report, the draft variation will not permit the addition of the applicant's 2'-FL to FSFYC.

The addition of the applicant's 2'-FL to IFP will be subject to the following Code requirements or 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 would 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, would apply to IFP that contain the applicant's 2'-FL.
- An exclusive permission to use the applicant's 2'-FL would 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 specific specification for the applicant's 2'-FL, with which it must comply.

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

# 1 Introduction

## 1.1 The Applicant

The application was originally submitted by Jennewein Biotechnologies GmbH in September 2019. On the 9<sup>th</sup> of October 2020, Chr. Hansen A/S (Chr. Hansen) acquired Jennewein Biotechnologie GmbH. FSANZ has since received formal notification that Chr. Hansen is now the applicant for A1190, however other details remain 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 is seeking 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)<sup>2</sup> and formulated supplementary foods for young children (FSFYC)<sup>3</sup>. 2'-FL is a non-digestible carbohydrate (oligosaccharide) found naturally in human milk. The application is specifically for 2'-FL<sup>4</sup> 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 and therefore it 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 justifies 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 relevant standards

### 1.3.1 Australia and New Zealand Food Standards Code (the Code)

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

#### 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*.

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<sup>2</sup> Including infant formula, follow-on formula and infant formula products for special dietary use.

<sup>3</sup> 'Toddler milk' is the main type of FSFYC currently available.

<sup>4</sup> 2'-FL exists naturally in human milk and can be synthesised chemically or through microbial fermentation. The A1190 SD1 refers to 2'-FL<sub>human</sub> / 2'-FL<sub>chem</sub> / 2'-FL<sub>micro</sub> (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<sub>micro</sub> as the other forms are not referenced.

The applicant's 2'-FL is *food produced using gene technology* (section 1.1.2—2) as it is derived from an organism modified using gene technology (i.e. derived from GM *E.coli* strains). If approved, 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 substance that was *used as a nutritive substance* (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, if approved, 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 would be in addition to the permission as *food produced using gene technology* above.

In addition, if approved, the applicant's 2'-FL would be permitted by Standard 2.9.1 to be *used as a nutritive substance* in IFP either alone; or in combination with Lacto-N-neotetraose (LNnT).

#### **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 under assessment is a non-digestible oligosaccharide. This section summarises the current permissions and restrictions in the Code relating to oligosaccharides.

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 section 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 Regulations for 2'-FL in other countries**

2'-FL produced by microbial fermentation and by chemical synthesis are permitted for use in IFP, FSFYC and many other foods in at least 37 overseas countries at a range of levels. Table 1 outlines some international permissions for 2'-FL alone<sup>5</sup>.

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<sup>5</sup> When permitted for use with lacto-N-neotetraose (LNnT), these levels are reduced.



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

<b>Country</b>	<b>Max use level</b>
United States	2.4 g/L
Canada <sup>#</sup>	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

<sup>#</sup> 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 standards**

The current Codex Alimentarius Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Standard 72-1981), and for Follow-up Formula<sup>6</sup> (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 notes that the Follow-up Formula Standard is currently under review<sup>7</sup>.

### **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'<sup>8</sup> 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 strains (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.

<sup>6</sup> '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 6<sup>th</sup> month on and for young children (12-36 months)*.

<sup>7</sup> Currently under review by CCNFSDU. For further information, search on the [Codex Alimentarius website](#).

<sup>8</sup> 'No questions' response means the USFDA does not question the basis for the notifier's GRAS conclusion (USFDA 2015).

## *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 combination with LNnT. The relevant requirements for infant formula products and milk-based drinks for young children<sup>9</sup> are:

- For infant formula and follow-on formula, a maximum level of 1.2 g/L of 2'-FL in the final ready-to-use product (less if combined with LNnT).
- For milk-based drinks for young children, a maximum of 1.2 g/L of 2'-FL in the final ready-to-use product (less if combined with LNnT).
- 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 (see Appendix C to the application) 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

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<sup>9</sup> 'Infant formula', 'follow-on formula', 'foods for special medical purposes' and 'young children' are defined in [Regulation \(EU\) No 609/2013](#).

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.

### 1.3.2.7 Other countries

The application indicates they market 2'-FL in IFP and FSFYC equivalent products in several countries at a range of 1.0 – 2.0 g/L<sup>10</sup>.

## 1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- It complied with the procedural requirements under subsection 22(2)
- It related to a matter that warranted the variation of a food regulatory measure.

## 1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

# 2 Risk and safety assessment

The ingredient under assessment is an oligosaccharide 2'-fucosyllactose<sup>11</sup> (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 genetically modified bacterium. A **microbiological assessment** concluded that the host strain has a recognised safe history of use. It is derived from *E. coli* BL21, which is commonly used for large-scale production of industrial compounds and human therapeutics. It is also 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 90<sup>th</sup> 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 90<sup>th</sup> percentile.

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<sup>10</sup> 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.

<sup>11</sup> 2'-fucosyllactose is also known as 2'-O-fucosyllactose. The O indicates the fucosyl group is attached to an oxygen residue.

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 must have 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 in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children. Of note, the evidence base for these effects in young children is fairly limited.

**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 and produced by microbial 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. Any changes to the composition of infant formula products must be established as safe and suitable prior to being permitted.

#### 3.1 FSANZ's approach and consideration of the policy guidelines

The application seeks permission for the voluntary addition of 2'-FL to both IFP and FSFYC. FSANZ's safety assessment indicated no concerns with the addition of 2'-FL produced by microbial fermentation to IFP and FSFYC at the highest permitted use level of 2.4 g/L. It also concluded that there are plausible beneficial health outcomes for infants and young children in consuming 2'-FL (though the evidence is weaker in young children).

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, in that it is to ensure nutritional adequacy in children aged 1 to <4 years. 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).

As the safety assessment concluded that the addition of the applicant's 2'-FL to IFP at the requested levels, or at higher estimated levels of dietary intakes based on 2.4 g/L 2'-FL, and for the reasons stated in this report (including under section 5), FSANZ is proposing to permit that 2'-FL to IFP.

FSANZ's is proposing to not permit the applicant's 2'-FL in FSFYC. In assessing the addition of the applicant's 2'-FL in FSFYC, FSANZ had regard to:

- the safety, risk and beneficial health outcomes assessment at SD1 and summarised above in section 2;
- section 29 and subsection 18 of the FSANZ Act and relevant ministerial policy guidelines, including costs and benefits at section 5.1.1;
- the justification for the FSANZ position outlined in the A1155 Approval Report<sup>12</sup> and Review Report<sup>13</sup> to permit 2'-FL in both IFP and FSFYC;
- the March 2020 review request and associated rationale made by jurisdictions; and
- the decision and justification by the Food Ministers' Meeting<sup>14</sup> to amend the drafting to not permit 2'-FL in FSFYC and their associated concerns that FSFYC are not intended to be human milk substitutes.

FSANZ considered the applicant's justification for permitting their 2'-FL product in FSFYC and note the application states:

- the benefits of 2'-FL are hypothesised to extend past infancy into toddlerhood; and
- thus Jennewein (now Chr. Hansen) 2'-FL will be beneficial in 'toddler formula'; and
- that 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 acknowledges that the evidence to support beneficial health effects from the consumption of 2'-FL in young children is weak. FSANZ also notes the applicant cannot, at this time, provide additional data or information to support or strengthen the plausible beneficial health effects of 2'-FL in young children, nor has FSANZ been able to identify any in the scientific literature.

FSANZ also noted the applicant's justification for 2'-FL addition in FSFYC does not *directly* align with the intention of FSFYC (i.e. because 2'-FL is naturally found in human milk only, and FSFYC is not a human milk substitute).

In light of the above, including the position taken by the Food Ministers' Meeting on this issue, and noting the absence of any new data or information on the beneficial health effects for 2'-FL in young children, FSANZ assessment was not to permit the applicant's 2'-FL in FSFYC.

## 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.

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<sup>12</sup> For more information, see the [A1155 Approval Report](#)

<sup>13</sup> For more information, see the [A1155 Review Report](#)

<sup>14</sup> [See the Australia and New Zealand Ministerial Forum on Food Regulation Communique 27 November 2020](#)

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 would 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 on the label of IFP. The nutrition information statement (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 would 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 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.

### **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 would 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 DNA due to the purification step used in the production of this oligosaccharide. It is therefore highly unlikely that novel protein or DNA will be present in an IFP that contains this 2'-FL as an ingredient. However, where novel protein is present, the requirement to label 2'-FL as 'genetically modified' would apply in accordance with section 1.5.2—4 of Standard 1.5.2.

## **3.3 Permitted use of 2'-FL**

FSANZ notes the applicant has 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 FSANZ highlights 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 will provide industry with product innovation opportunities.

FSANZ is therefore proposing a permission for the higher use level of 2.4 g/L or (for the purposes of the draft variation in the Code) 96 mg/100 kJ.

FSANZ has previously assessed and permitted 2'-FL alone or in combination with LnNT at specific concentrations. FSANZ has no concerns with these existing permissions applying to the A1190 applicant's 2'-FL, noting exclusive use of LnNT in the Code applies at this time for a specific brand.

### **3.4 Common substance names for 2'-FL**

FSANZ understands there are at least three possible common substance names for 2'-FL: "2'-fucosyllactose" and "2'-O-fucosyllactose" and "2'-fucosyl-D-lactose". In previous application A1155 (which also included a permission for 2'-FL), 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 A1190 assessment period, FSANZ consulted with the A1155 applicant on the use of different common substance names to describe the same substance in the Code. FSANZ considers it appropriate to amend Schedule 26 to reference a single common substance name "2'-fucosyllactose".

### **3.5 Exclusivity**

An applicant may request exclusive permission for a period of 15 months to recognise the investment made in developing the food or ingredient or nutritive substance and the need to achieve return on this investment, thereby supporting innovation. The applicant has requested exclusivity for their specific brand of 2'-FL on the basis that they have invested significantly in the technology development and safety studies.

Following the 15 month period, the permission would revert to a general approval for the class of food. An exclusivity 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.

FSANZ's proposed approach is to provide 15 months exclusivity from the date of gazettal for the applicant's brand of 2'-FL, linked to the specific gene-gene donor information.

### **3.6 Risk management conclusion**

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has prepared a draft variation 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 or 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 galacto-oligosaccharides and inulin-type fructans would 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, would apply to IFP that contain the applicant’s 2’-FL.
- An exclusive permission to use the applicant’s 2’-FL would 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 specific specification for the applicant’s 2’-FL, with which it must comply.

The draft variation reflecting this option is at Attachment A. The draft explanatory statement for the variation is in Attachment B.

## **4 Risk communication**

### **4.1 Consultation**

Consultation is a key part of FSANZ’s standards development process. FSANZ developed a communication strategy for this application. Subscribers and interested parties were notified about public consultation periods via the FSANZ Notification Circular, media release, Food Standards News and through FSANZ’s social media tools.

FSANZ welcomes submissions from individuals and organisations on this application and FSANZ’s assessment. All comments are valued and contribute to the rigour of our assessment.

### **4.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant overseas standards and amending the Code to permit the voluntary addition of the applicant’s 2’-FL to IFP as proposed is unlikely to have a significant effect on international trade as this substance is already permitted in similar products in some countries overseas. Therefore, a notification to the WTO under Australia’s and New Zealand’s obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **5 FSANZ Act assessment requirements**

### **5.1 Section 29**

When assessing this application and the subsequent development of food regulatory measures, FSANZ has 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



2013, reference 14943).

FSANZ, however, has given 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 is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is Option 1: rejecting the application). This analysis considers 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, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks 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 2.3. of this report, FSANZ concludes that the bifidogenic effect and anti-infective effect against invasive *C. jejuni* are biologically plausible in both infants and young children, though the evidence is weaker in young children.

If the draft variation is approved, during an 'exclusive use period' (the period commencing on the date of gazettal of the draft variation and ending 15 months after that date), the applicant's 2'-FL could only be sold under the brand CHR. HANSEN™ 2'-FL. Once this period ends, the exclusive use permission would revert to a general permission, meaning that the permission to add the applicant's 2'-FL to IFP would apply to all brands of this 2'-FL that meet the specific source and associated specifications in Schedule 3.

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

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

Option 2 would permit 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 Zealand<sup>15</sup>.

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 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 multiple brands of 2'-FL than are currently permitted in Australia and New Zealand. Permitting this application would improve harmonisation with international regulations by allowing additional sources of 2'-FL onto the market.

Permitting this additional brand 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 voluntary addition of 2'-FL in both IFP and FSFYC may further benefit industry relative to Option 2 and the Status Quo and further promote trade with other countries. Consumers might also benefit from a greater choice of foods.

That said, 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. FSANZ acknowledges the importance of ensuring caregivers are not confused around the purpose or intent of FSFYC and do not buy foods that are not needed. FSANZ also acknowledges that the evidence supporting beneficial health outcomes in young children from the consumption of FSFYC containing 2'-FL is weak. For this reason, Option 3 may not be the most beneficial option for all consumers.

### ***Conclusions from cost benefit considerations***

FSANZ's assessment is that the direct and indirect benefits that would arise from both Options 2 and 3, most likely outweigh the associated costs.

Option 3 gives more flexibility for industry and international consistency. That said, any benefits of Option 3 above Option 2 would depend on the extent that consumers understand the purpose of FSFYC and purchase FSFYC according to their young children's needs.

#### **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.

#### **2.5.1.3 Any relevant New Zealand standards**

Relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards at the time of writing.

#### **2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

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<sup>15</sup> Sources: ABARES Stats for Australian IFP Exports 2018 "19011000" and New Zealand MPI Stats for New Zealand Exports – Tariff Code HS 10.

## **5.2. Subsection 18(1)**

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

### **5.2.1 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, FSANZ's assessment was not to permit 2'-FL in FSFYC.

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

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

### **5.2.3 The prevention of misleading or deceptive conduct**

Current labelling requirements, including prohibited representations described in section 3.2.3, 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 has 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 as part A1190, and FSANZ was 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 the applicant was asked to provide any additional evidence on the safety or beneficial health effects of their 2'-FL. This was to ensure the assessment was based on the most current and best available evidence. No further information was provided.

- **the promotion of consistency between domestic and international food standards**

FSANZ has 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, 2'-FL is permitted for use alone or in combination with LNnT around the world, in equivalent IFP and FSFYC, at a range of levels and with country-specific labelling requirements.

FSANZ considers 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 above, FSANZ assessment was not to permit the addition of that 2'-FL to FSFYC. The latter is consistent with current permissions in the Code.

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

The proposed permission 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. FSANZ assessment was not to permit the addition of that 2'-FL to FSFYC.

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

No negative impact is anticipated on fair trading.

- **any written policy guidelines formulated by the Forum on Food Regulation**

As part of A1190, FSANZ has had regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. Two Ministerial Policy Guidelines specifically apply to this application:

- Regulation of Infant Formula Products
- Intent of Part 2.9 – Special Purpose Foods.

FSANZ considers that through the proposed permission for 2'-FL to be added to IFP, these policy guidelines have been met.

## 6 Draft variation

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

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

## 7 References

EU (2016) [Commission Delegated Regulation](#) (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Accessed 12 February 2020

EU (2017) [Commission Implementing Decision](#) (EU) 2017/2201 of 27 November 2017 authorising the placing on the market of 2'-fucosyllactose produced with Escherichia coli strain BL21 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2017) 7662). Accessed 17 September 2018.

EU (2018) [Commission Implementing Regulation](#) (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. Accessed 17 February 2020.

MEB (2017a) 2'-Fucosyllactose (2), Assessment of substantial equivalence for a notification, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients. Novel Foods Unit, Medicines Evaluation Board (MEB).

MEB (2017b) 2'-Fucosyllactose (3), Assessment of substantial equivalence for a notification, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients. Novel Foods Unit, MEB.

National Health and Medical Research Council (NHMRC) (2012) Infant Feeding Guidelines. Available at <https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers>.

New Zealand Ministry of Health (NZ MoH) (2012) Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2). Available at <https://www.health.govt.nz/publication/food-and-nutritionguidelines-healthy-infants-and-toddlers-aged-0-2-background-paper-partially>.

NFU (2016) 2'-Fucosyllactose: Assessment of safety for the consumer, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients. Novel Foods Unit, Medicines Evaluation Board, Netherlands.

SFA (2018) [Sale of Food Act](#) (Chapter 283, Section 56(1)): Food regulations Rg1 G.N. No. S264/1988 (revised edition 2005). Singapore Food Authority.

USFDA (2015) GRAS notice [GRN No. 571](#), 2'-Fucosyllactose, Jennewein Biotechnologies, GmgH.

USFDA (2016a) GRAS notice [GRN No. 650](#), 2'-O-Fucosyllactose Produced by Fermentation, Glycom A/S.

USFDA (2016b) Guidance for Industry: Labeling of Infant Formula. Office of Nutrition and Food Labeling. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-infant-formula>. Accessed 17 January 2020

USFDA (2018a) GRAS notice [GRN No. 735](#), 2'-Fucosyllactose, Glycosyn, LLC and Friesland Campina Domo B.V. Accessed 17 January 2020

USFDA (2018b) GRAS notice [GRN No. 749](#), 2'-O-Fucosyllactose, DuPont Nutrition & Health. Accessed 17 January 2020

## **Attachments**

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

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



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

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

Dated [To be completed by 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— $\alpha$ -L-fucopyranosyl-(1→2)- $\beta$ -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  $\mu$ 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><b>1 2'-fucosyllactose</b></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"> <li>1. May only be added to infant formula products.</li> <li>2. During the exclusive use period, may only be sold under the brand GlyCare.</li> <li>3. For the purposes of condition 2 above, <b>exclusive use period</b> 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.</li> </ol>
	<p>(b) <i>Escherichia coli</i> BL21 containing the gene for alpha-1,2-fucosyltransferase from <i>Escherichia coli</i> O126</p>	<ol style="list-style-type: none"> <li>1. May only be added to infant formula products.</li> <li>2. During the exclusive use period, may only be sold under the brand CHR. HANSEN™ 2'-FL.</li> <li>3. For the purposes of condition 2 above, <b>exclusive use period</b> means the period commencing on the date of gazettal of the <i>Food Standards (Application A1190 – 2'-FL in infant formula and other products) Variation</i> and ending 15 months after that date</li> </ol>

[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 – Draft 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 application 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 prepared a draft variation to the Code.

### **2. Purpose**

The Authority has prepared 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 draft variation includes consequential amendments to the Code as a result of the above amendments.

### **3. Documents incorporated by reference**

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

However, the 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 2017); the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th 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 will include one round of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted FSANZ 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 proposed amendments in the Schedule would take effect in numerical order i.e. according to item and sub-item numbers.

### Item [1]

**Item [1]** would vary 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 proposed amendment is a consequence of the proposed amendments in **items [2]** and **[3]** below.

### Item [2]

**Item [2]** sets out the following proposed 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] would omit 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] would insert 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 would be inserted by sub-item [2.5] below.

Sub-item [2.3] would omit 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] would omit 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 proposed amendments in sub-items [2.3] and [2.4] is that the specifications in section S3—40 would relate specifically to 2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12.

Sub-item [2.5] would insert 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 proposed 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) would 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 proposed 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] would omit 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 draft variation (if approved), 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 proposed permission for 2'-FL from source (b) would 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 would revert to a general permission, meaning that the proposed permission would apply to all brands of 2'-FL from source (b) in accordance with the Code.

The effect of the proposed 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 would 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] would omit 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 proposed amendment is a consequence of the proposed amendments in sub-item [3.1] above.

The proposed amendments in **item [3]** would 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]** would vary Schedule 29 by omitting references to '2'-O-fucosyllactose' wherever occurring in 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 proposed amendment is a consequence of the proposed amendments in items [2] and [3] above.