**22 July 2022**
**209-22**

# Call for submissions – Application A1251

## 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Nutricia Australia Pty Ltd and Chr. Hansen A/S to amend the Australia New Zealand Food Standards Code to permit the voluntary combination of 2'-fucosyllactose (2'-FL) with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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.

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

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link how to make a submission. You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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 3 business days.

**DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 19 August 2022**

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.

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

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

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## Supporting document

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

SD1 Risk and technical assessment

# Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application by Nutricia and Chr. Hansen A/S (the Applicants) to amend the Australia New Zealand Food Standards Code (the Code) to permit 2'-fucosyllactose (2'-FL) to be added to infant formula products (IFP) in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF). The Applicants also requested an exclusive use permission for a period of 15 months for their combination of 2′-FL with GOS and/or ITF.

The Code currently permits 2′-FL, GOS and ITF to be added separately to IFP but prohibits the addition of 2-FL to IFP in combination with GOS and/or ITF.

2′-FL, GOS and ITF are non-digestible carbohydrates (oligosaccharides). Current permissions for their addition exist in the Code from previous applications for 2'-FL (Applications A1155 and A1190) and GOS and/or ITF (Proposal P306 and Application A1055). The Application does not seek changes to the existing permitted use levels of these oligosaccharides.

2'-FL is regulated for use in IFP as a nutritive substance and a food produced using gene technology under the Code. All 2'-FL sources currently permitted by the Code are chemically and structurally identical to that found in human milk. GOS and ITF may be added to IFP in accordance with Standard 2.9.1 of the Code.

FSANZ's risk and technical assessment identified no public health and safety concerns with the combination of 2′-FL with GOS and/or ITF in IFP at current permitted maximum use levels. FSANZ undertook an assessment of potential health effects in accordance with relevant Ministerial Policy Guidelines. The assessment found results from *in vitro* and animal studies of combinations of 2′-FL and GOS and/or ITF are consistent with beneficial health effects observed for the individual components and provide some indication of mechanisms involved. However, they do not allow any conclusions to be drawn on whether there are any additional benefits arising from supplementation with a combination of 2′-FL and GOS and/or ITF.

FSANZ has therefore prepared a draft variation to the Code which, if approved, would amend section 2.9.1—7 of the Code by removing the prohibition against the use of 2′-FL in combination with GOS and/or ITF in IFP and including an exclusive use permission for the Applicants' combination of 2′-FL with GOS and/or ITF for a period of 15 months after gazettal of the draft variation (if approved). If the draft variation is approved, 2′-FL would be permitted to be used in combination with GOS and/or ITF in IFP in accordance with the Code.

FSANZ now seeks comments on the draft variation.

# 1 Introduction

## 1.1 The Applicants

The Applicants are two companies who manufacture and develop ingredients and/or products in the infant formula market.

Nutricia Australia Pty Ltd (Nutricia) is a manufacturer of special dietary use food products, infant formula products, formulated supplementary foods for young children and foods for special medical purposes.

Chr. Hansen A/S is a global bioscience company that develops natural ingredient solutions for food, nutritional, pharmaceutical and agricultural industries, including human milk identical oligosaccharides.

## 1.2 The Application

Nutricia and Chr. Hansen A/S seek to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of 2'-FL in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products (IFP)[1].

2'-FL is regulated for use in infant formula products as a nutritive substance and a food produced using gene technology under the Code. The Applicant's 2'-FL is produced through microbial fermentation from a genetically modified production strain and is permitted for addition to IFP in accordance with the Code. All 2'-FL currently permitted by the Code are chemically and structurally identical to that found in human milk. The Applicant currently adds a GOS/ITF mixture of short-chain GOS (scGOS) and long-chain fructo-oligosaccharide (lcFOS), or scGOS/lcFOS to their IFP at a ratio of 9:1 (levels up to 8 g/L). GOS and ITF are regulated as general ingredients for addition to IFP under Standard 2.9.1 of the Code (see below).

No changes are requested to existing permissions for 2'-FL, GOS and/or ITF in IFP, which includes maximum permitted use levels. The Applicants intend to combine Chr. Hansen 2′-FL (levels up to 2.4 g/L) with Nutricia IFP containing the scGOS/lcFOS mixture (levels up to 8 g/L).

If the draft variation is approved, the current prohibition on the combination of 2′-FL with GOS and/or ITF under subsection 2.9.1—7(2) of the Code would be removed. The Application does not seek to remove the prohibition under subsection 2.9.1—7(2) against the combination of 2'-FL, GOS and ITF with lacto-N-neotetraose (LNnT) and this combination would continue to be prohibited under the Code.

Noting the above, the Application includes data and information on the safety, tolerance and proposed beneficial health effects of the combination of 2'-FL with GOS and/or ITF in IFP at permitted levels. The Application cites relevant data and information from previous assessments undertaken for Proposal P306 (FSANZ 2008) and Applications A1190 (FSANZ 2021) and A1055 (FSANZ 2013).

[1] Includes infant formula, follow-on formula and infant formula products for special dietary uses.

## 1.3 The current standard

### 1.3.1 Australia and New Zealand

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

#### *1.3.1.1 Permitted use*

*2′-fucosyllactose and Lacto-N-neotetraose*

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*.

Each form of 2′-FL currently permitted by the Code is a *food produced using gene technology* (as defined in section 1.1.2—2) as each is derived from organisms modified using gene technology. For this reason, their use has been permitted in accordance with Standard 1.5.2 and Schedule 26 of the Code, with the permitted forms of 2′-FL being listed in the table to subsection S26—3(7).

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).

Each form of 2′-FL currently permitted by the Code is permitted to be used as a nutritive substance because its addition to food is intended to achieve specific nutritional purposes. For this reason, their use has been permitted in accordance with Standard 2.9.1 and Schedule 29 of the Code, with the forms of 2′-FL permitted for use as a nutritive substance being listed in in the table to section S29—5.

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 LNnT.

*Galacto-oligosaccharides and inulin-type fructans*

Section 2.9.1—7 of the Code currently regulates the addition of GOS and ITF (as defined in subsection 1.1.2—2) to IFP. GOS and ITF are 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-oligosaccharide (FOS), short-chain FOS, lcFOS, 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/100 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 GOS and/or ITF in IFP with 2′-FL either alone or in combination with LNnT. The permitted maximum amounts consider both the added and naturally occurring substances.

#### *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. Schedule 3

currently lists specifications for different forms of 2′-FL. There is no requirement for a specification for the generally permitted ingredients, GOS and ITF in Schedule 3.

#### *1.3.1.3 Infant formula products*

The composition and labelling of IFP is regulated in Standard 2.9.1 and Schedule 29. They set 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 Labelling requirements*

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

Section 1.2.4—2 requires food products to be labelled with a statement of ingredients. Section 1.2.4—4 requires ingredients to be declared using a name by which they are commonly known, or a name that describes their true nature, or a generic ingredient name if one is specified in Schedule 10.

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

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*[2] (GM food).

Subparagraph 2.9.1—21(1)(a)(iii) requires the average amount of any substance used as a nutritive substance permitted by Standard 2.9.1 to be declared in the nutrition information statement (NIS), expressed in weight/100 mL. Subparagraph 2.9.1—21(1)(iv) states that, if added, the average amount of ITF, GOS or a combination of ITF and GOS must be declared in the NIS, expressed in weight/100 mL. Paragraphs 2.9.1—24(1)(ca) and (cb) prohibit the use of the words ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ and the abbreviations ‘HMO’ or ‘HiMO’ or any words and abbreviations having the same or similar effect. Paragraph 2.9.1—24(1)(f) of Standard 2.9.1 prohibits a reference to the presence of a nutrient or substance that may be used as a nutritive substance, except for a reference in: a statement relating to lactose under subsection 2.9.1—14(6); a statement of ingredients; or in the NIS.

### 1.3.2 Regulation in other countries

2′-FL produced through microbial fermentation and by chemical synthesis is permitted for use in infant formula equivalent products and many general foods overseas, at a range of levels and combined with other oligosaccharides, including GOS and/or ITF.

Some regions, such as the European Union (the EU), indicate no restriction on the combination of 2′-FL with GOS and/or ITF to infant formula equivalent products, if

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

permissions for individual ingredients are adhered to.

The combination of 2′-FL with GOS and/or ITF is specifically approved for use in the United States and Brazil. In the United States, the inclusion of 2′-FL and/or GOS in infant formula and other products has received GRAS (Generally Recognized as Safe) 'no questions' notification. In Brazil, 2′-FL is permitted for use alone or in combination with GOS and/or ITF in infant formula and follow-on formula (ANVISA 2022).

## 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); and
- 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 Summary of the assessment

## 2.1 Risk assessment

The safety, technological aspects, nutritional impact and beneficial health effects from individual addition of these ingredients to infant formula products have previously been considered (A1155, A1190 and A1233 for 2′-FL; P306 for GOS/ITF and A1055 for scFOS). The purpose of this assessment was to consider the combination of these ingredients. Previous assessment found that 2′-FL is stable, structurally and chemically identical to naturally occurring 2′-FL and free from fermentation derived contaminants (FSANZ 2019). Information has been provided to assess the stability of the blended ingredients with FSANZ confirming that the ingredients provide an adequate shelf-life and stability.

FSANZ has previously determined there are no safety concerns associated with the addition of 2′-FL, GOS and/or ITF to IFP at concentrations up to 2.4 g/L for 2′-FL, 3 g/L for ITF and 8 g/L for GOS alone or in combination with ITF (up to a maximum of 3 g/L ITF). These conclusions were supported by toxicological studies in laboratory animals and clinical studies in infants which found no adverse effects from the use of these substances.

FSANZ has previously concluded that 2′-FL added to IFP should not affect infant growth at levels normally found in human milk. In addition, FSANZ has previously assessed the addition of a total level of 8 g/L of GOS and ITF, alone or combined at any ratio, in IFP. It was concluded that a maximum of 8 g/L in IFP is unlikely to pose a risk to the growth and development of infants from birth onwards.

A newly available clinical study reviewed by FSANZ for the present assessment found that consumption of infant formula containing 2′-FL (1 g/L) in combination with a 9:1 ratio of scGOS and lcFOS (8 g/L) was safe, well tolerated and did not affect growth, although some limitations in study design in terms of assessment of growth were noted.

Taken together, the available evidence supports the conclusion that no difference in growth is likely to occur in infants fed IFP that contains 2′-FL, GOS and/or ITF at previously permitted levels.

The limited evidence available from human intervention studies raised no potential microbiological safety concerns from a combination of 2'-FL with GOS and/or ITF in IFP at the levels proposed by the applicant.

Dietary intakes of 2′-FL in combination with GOS and/or ITF from IFP were estimated for infants using a model diet approach. Assuming the addition of 2′-FL with GOS and/or ITF at the maximum permitted levels in the Code (96 mg/100 kJ and 290 mg/100 kJ respectively), the estimated mean and 90th percentile (P90) dietary intakes of 2′-FL combined with GOS and/or ITF from infant and follow-on formula ranged between 5 and 17 g/day. These intakes were lower than the estimated mean and P90 intakes of human milk oligosaccharides from human milk.

Given the absence of any identifiable hazard in toxicological and clinical studies with 2′-FL, GOS and/or ITF, alone or in combination, and noting that estimated exposures are lower than those of human milk oligosaccharides from human milk, there are no safety concerns from the addition of 2′-FL in combination with GOS and/or ITF to IFP at the proposed levels.

No human intervention studies investigating a bifidogenic or anti-pathogenic health effect of the combination of 2′-FL with GOS and/or ITF were provided by the applicant or identified by FSANZ. Results from *in vitro* and animal studies of combinations of 2′-FL and GOS and/or ITF are consistent with beneficial health effects observed for the individual components and provide some indication of mechanisms involved. However, they do not allow any conclusions to be drawn on whether there are any additional benefits arising from supplementation with a combination of 2′-FL and GOS and/or ITF.

## 2.2 Risk management

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

FSANZ has had regard to the requirements of the FSANZ Act (see Section 2.4 below) in developing the proposed regulatory measure. Since the safety and health effects assessment (SD1) concluded that there are no public health and safety concerns associated with the combination of 2′-FL with GOS and/or ITF in IFP, FSANZ is proposing to remove the current prohibition of this combination in the Code.

### 2.2.1 Scope of the A1251 assessment

Individual permissions for 2′-FL, GOS and ITF were not considered in this Application, as each has been assessed and is currently permitted in the Code. Relevant information and assessments from past applications were noted as part of the assessment as follows:

- Applications A1155 - 2'-FL and LNnT in infant formula and other products, A1190 - 2'-FL in infant formula and other products and A1233 - 2′-FL from new GM source for infant formula assessed 2'-FL;
- Proposal P306 - Addition of Inulin / FOS & GOS to Food and Application A1055 - Short-chain Fructo-oligosaccharides assessed GOS and/or ITF.

As the first application to permit a source of 2′-FL, A1155 did not seek to combine 2′-FL with GOS and/or ITF. FSANZ did however consider the available evidence for this potential combined use, noting no adverse effects were reported in infant studies which tested formula supplemented with 2′-FL in combination with scFOS or GOS. The maximum amounts of scFOS or GOS permitted in the Code however were not tested in these studies. Additionally,

no evidence was provided which investigated the use of 2′-FL with both GOS and scFOS. It was also noted that this combination does not occur naturally in human milk. Consequently, the tolerance of infants to this total combination could not be established. On this basis, and noting the combination of 2′-FL with GOS and/or ITF in IFP was not being sought, FSANZ prohibited their use and concluded an application with appropriate supporting evidence would be required to change the Code to allow such combinations.

Additionally, Proposal P1028 – *Infant formula review* has not identified any issues with the individual permissions for oligosaccharides permitted in IFP (FSANZ 2021b; pp 48-50). Though currently under consultation, submitters did not raise any issues in response to FSANZ's proposed approach, which had the primary objective of aligning the Code's regulation of IFP with international regulations (unless safety or other concerns did not support alignment).

### 2.2.2 Long-chain fructo-oligosaccharides as a proxy for inulin-type fructans

Standard 1.1.2—2 defines that inulin-type fructans means mixtures of saccharide chains that have β-D-(2→1) fructosyl-fructose linkages with or without a terminal α-D-(1→2) glucosyl-fructose linked glucose unit. ITF includes substances such as FOS, scFOS, lcFOS, oligofructose and inulin (FSANZ 2013).

The Applicants have presented data and information to support the removal of the Code prohibition of the combination of 2′-FL with GOS and/or ITF based on their specific mixture of scGOS/lcFOS. FSANZ has previously assessed data containing scFOS.

Noting that lcFOS and scFOS are both considered ITF, and no specific individual permissions exist for substances recognised as an ITF, FSANZ has assessed the data and information available to support the amendment to the Code to allow the combination of 2′-FL with GOS and/or any form of ITF.

### 2.2.3 Proposed removal of prohibition against the combination of 2'-fucosyllactose with galacto-oligosaccharides and/or inulin-type fructans

As explained in Supporting Document 1 (see also Section 2.1 above), FSANZ found no evidence indicating concerns with safety, tolerance and/or growth from infants consuming this combination of oligosaccharides. The assessment on potential health effects found those observed from the combination of 2′-FL and GOS and/or ITF are consistent with beneficial health effects observed for the individual components and provide some indication of mechanisms involved. FSANZ notes conclusions could not be drawn on whether there are any additional benefits arising from supplementation with a combination of 2′-FL and GOS and/or ITF compared to those of the individual components.

Based on a review of current international permissions, FSANZ considers the removal of the prohibition would harmonise the Code with international regulations and result in consistency between domestic and international food standards and support an efficient and internationally competitive food industry.

FSANZ has therefore prepared a draft variation to remove the prohibition on 2′-FL being added to IFP in combination with GOS and/or ITF.

### 2.2.4 Exclusivity

An applicant may request exclusive permission to use and sell a food (including a substance) for a certain period to recognise the investment made in developing the food, ingredient or nutritive substance and the need to achieve return on this investment, thereby supporting innovation. The Applicants have requested an exclusive use permission for their specific

brand of 2′-FL with GOS and/or ITF.

The Applicants have advised that they have made significant investments to develop their respective ingredients as part of this application process, which will result in a permission in the Code that benefits other manufacturers of permitted forms of 2′-FL and GOS and/or ITF. This includes research and investment on ingredients and processes, development of patented technology, manufacturing capital expenditure and trials, and conducting sensory, shelf-life and clinical trials (on the individual ingredients and a combination of both ingredients).

FSANZ decided to provide the Applicant with a 15 month exclusive use permission for the combination of 2′-FL with GOS and/or ITF, commencing on the date of gazettal of the draft variation, if approved. This will mean in effect that, during the 15 month period, IFP may not be sold containing 2′-FL together with added ITF, GOS or both unless: the IFP is manufactured by Nutricia Australia Pty Ltd; and the 2′-FL in question is the 2′-FL developed by Chr. Hansen A/S and permitted as a result of Application A1190. Once the 15 month period ends, the exclusive use permission would revert to a general permission and any permitted forms of 2′-FL may be added to IFP in combination with GOS and/or ITF (subject to any conditions imposed by the Code). An exclusive use permission in the Code does not, and cannot, prevent approval of second or subsequent applications either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken.

### 2.2.5 Labelling

The removal of the prohibition would allow 2′-FL to be added with ITF and/or GOS as ingredients to IFP. Existing labelling requirements for ingredient declarations and nutrition information, as well as prohibited representations, would apply to IFP containing added 2′-FL with GOS and/or ITF. Existing GM labelling requirements would also apply (see Section 1.3.1.4 of this report).

### 2.2.6 The five-year review for 2'-fucosyllactose in infant formula products

FSANZ is committed to reviewing any new evidence on the beneficial role of 2′-FL (alone, or in combination with LNnT) in the normal growth and development of infants.

At the request of Food Ministers, FSANZ will carry out a five-year review (to be completed by March 2026) of the evidence of a substantiated beneficial role of 2′-FL in the normal growth and development of infants. This process will include consultation with a range of stakeholders including experts, industry and government agencies and will be independently peer reviewed.

FSANZ has started the review by defining the research questions, reviewing existing evidence and seeking out the relevant data needed, including from industry and recently published studies. Details on the review process will be made available on the FSANZ website.

### 2.2.7 Risk Management conclusion

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines[3], FSANZ is proposing to approve a draft variation to the Code to remove the prohibition on the combination of 2′-FL with GOS and/or

[3] Policy guideline on infant formula products and Policy guideline on intent of Part 2.9 of the food standards code - special purpose foods.

ITF in IFP.

If the draft variation is approved, 2′-FL may be added to IFP in combination with GOS and/or ITF subject to the following Code requirements or conditions:

- An exclusive use permission would apply for a period of 15 months, commencing on the date of gazettal of the variation. During that period, IFP may not be sold containing 2′-FL together with added ITF and/or GOS unless: the IFP is manufactured by Nutricia Australia Pty Ltd; and the 2′-FL in question is the 2′-FL developed by Chr. Hansen A/S and permitted as a result of Application A1190.
- The current maximum permitted use levels for 2′-FL, GOS and/or ITF in Standard 2.9.1—7 and Schedule 29 would apply.
- The combination of 2'-FL and LNnT with GOS and/or ITF remains prohibited.
- The existing prohibition applies 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.
- Existing labelling requirements in Standard 2.9.1 would apply.

## 2.3 Risk communication

### 2.3.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ’s social media tools and Food Standards News.

Subscribers and interested parties are also notified about the availability of reports for public comment. The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received on this call for submissions.

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

### 2.3.2 World Trade Organization (WTO)

As 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 international standards and amending the Code to remove the prohibition against the voluntary combination of 2′-FL with GOS and/or ITF in IFP is unlikely to have a significant effect on international trade as the individual ingredients are permitted in similar products without prohibition of the combination, or the combination is expressly permitted 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.

## 2.4 FSANZ Act assessment requirements

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

### 2.4.1 Section 29

#### *2.4.1.1 Consideration of costs and benefits*

As explained above, Application A1251 seeks an amendment of the Code require to allow the addition of 2FL to IFP in combination with GOS and /or ITF, relying on existing genetically modified food and nutritive substance permissions for 2FL. 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). The OBPR also advised in this case that a RIS was not required as: FSANZ will be ensuring the safety of any fortification permitted; and the proposed change allows business to voluntarily combine ingredients for fortification, rather than making it mandatory (OBPR advice to FSANZ, dated 9 November 2021; OBPR Reference: OBPR21-01118).

FSANZ, however, has considered 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 the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application would outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the Application). This analysis considers the costs and benefits of approving this Application, namely:

- removing the current prohibition on the combination of 2′-FL with GOS and/or ITF under paragraph 2.9.1—7(2)(a) of the Code;
- granting a 15 month exclusive use period (from the date of gazettal) for the combination based on the applicant's brand of 2′-FL, 'CHR HANSEN 2′-FL' combined with Nutricia IFP.

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 and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo if this Application is approved.

*Consumers*

Domestic consumers may benefit from increased variety of IFP for sale, if the combination of 2′-FL with GOS and/or ITF is added to one or more IFP for sale domestically. That assumes there are perceived or actual benefits for consumers' infants.

FSANZ's risk assessment concluded there are no safety concerns from the addition of 2′-FL in combination with GOS and/or ITF to IFP at the proposed levels.

Caregiver understanding and behaviour is not expected to be significantly impacted by the combination of 2′-FL with GOS and/or ITF. A literature search did not identify any studies investigating the impact on caregiver understanding and behaviour from this, or other

combinations of ingredients in IFP. A literature review of studies between 2003 and 2019 undertaken by FSANZ to inform P1028 (review of IFP regulatory requirements) highlighted caregivers often lack knowledge about the contents of ingredient lists and nutritional information statements, particularly what different nutrients are and the benefits they have (FSANZ 2022). This suggests that most caregivers are unlikely to be aware of, or alter their behaviours, due to a minor change like the combination of ingredients that were previously allowed separately. Where caregivers are aware of the change, the literature review supports the applicant's assessment that some may prefer IFP containing the combination of ingredients, finding that some caregivers preferred longer ingredient lists, as they were perceived to be more nutritionally complete (FSANZ, 2022b).

*Industry*

Industry may benefit from increased choice of ingredients for domestically sold and imported IFP. Industry will voluntarily use the combination of 2′-FL with GOS and/or ITF or buy and sell IFP containing that combination, where a net benefit exists for them.

Given the combination of 2′-FL with GOS and/or ITF in IFP is already approved in some overseas countries, granting the permission requested by the Application would favour trade and any growth of overseas markets for domestic IFP exporters. Approving the requested permission may also promote and support innovation in IFP.

Domestic IFP producers, may however face greater competition in the domestic IFP market from international IFP producers that can sooner import IFP containing the combination of 2′-FL with GOS and/or ITF. Any such impacts to domestic producers are assumed to be outweighed by benefits to consumers from greater industry competition.

Greater industry competition is generally assumed to lead to IFP producers competing more on variety and price of IFP, leading to consumers accessing a higher variety and/or lower prices of IFP. If producer A sells a similar product to producer B at a lower price, consumers would likely buy from producer A to save money. Consumers would also likely buy from producer A if their product were the same price as producer B's but is a more appealing variety.

*Government*

The approval of this Application may result in a small but likely inconsequential cost to government from an additional combination of IFP ingredients that is monitored for compliance with individual ingredient maximum limits. That assumes an increase in IFP containing 2′-FL GOS, and/or ITF.

Conversely, other costs would be lower from no longer needing to enforce the current prohibition of the combination of 2'-FL with GOS and/or ITF.

*Conclusion*

FSANZ's current assessment is that the direct and indirect benefits that would arise from approving this Application most likely outweigh the associated costs. Information received, however, from this Call for Submissions, may result in FSANZ arriving at a different conclusion.

#### *2.4.1.2 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.

#### *2.4.1.3 Any relevant New Zealand standards*

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

#### *2.4.1.4 Any other relevant matters*

Other relevant matters are considered below.

### 2.4.2 Subsection 18(1)

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

#### *2.4.2.1 Protection of public health and safety*

FSANZ completed a safety and risk assessment (Supporting Document 1) which is summarised in Section 2.1 of this report. The assessment concluded that the combination of 2′-FL with GOS and/or ITF to IFP is safe, noting current permissions exist for the individual addition of these oligosaccharides and no changes are requested to maximum permitted levels.

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

Current labelling requirements outlined in Section 1.3.1.4 of this report would apply to IFP containing added 2′-FLwith GOS and/or ITF and would provide information to enable consumers to make an informed choice.

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

Current labelling requirements, including prohibited representations which aim to prevent misleading or deceptive conduct, would apply to IFP containing added 2′-FL with GOS and/or ITF (see Section 1.3.1.4 above).

### 2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

Using risk analysis, FSANZ has considered the best available evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the combination of 2′-FL with GOS and/or ITF in IFP.

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

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. 2′-FL, GOS and ITF are permitted both individually and combined in similar products in some countries overseas. Other countries do not regulate for the combination. The proposed permission would promote consistency between domestic and international food standards.

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

The proposed permission would support an internationally competitive food industry in aligning IFP containing the combination of 2′-FL with GOS and/or ITF and is consistent with existing permissions in the Code for 2′-FL, GOS and ITF as individual ingredients.

- **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**

FSANZ has 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.

Noting the assessment in SD1, and the assessment above of FSANZ Act requirements, FSANZ considers these Policy Guidelines have been met.

# 3 Draft variation

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

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

# 4 References

ANVISA (2022) Novos Alimentos, Novos Ingredientes, Probióticos e Enzymas Aprovidos https://app.powerbi.com/view?r=eyJrIjoiNTA3ZDQxOGEtYzg0NC00NTI1LTg0MzYtOGEzMWU4MThlNjAwIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9 Accessed 7 June 2022

FSANZ (2008) First Review Report Proposal P306 Addition of Inulin/FOS and GOS to food. Food Standards Australia New Zealand, Canberra, Australia. https://www.foodstandards.gov.au/code/applications/Documents/A1155%20Review%20Report.pdf Accessed 7June 2022

FSANZ (2013) A1055: Short-chain fructo-oligosaccharides. Supporting Document 1. Risk and technical assessment (at approval). Food Standards Australia New Zealand, Canberra, Australia. https://www.foodstandards.gov.au/code/applications/Documents/A1055%20Addition%20of%20scFOS%20AppR%20SD1%20Risk%20Assess.pdf Accessed 7 June 2022

FSANZ (2021b), P1028 First Call for Submissions – Consultation paper 4: Nutrient Composition. Available at: https://www.foodstandards.gov.au/code/applications/Documents/CP2%20P1028.pdf Accessed 6 June 2022

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D3%20-%20Consumer%20research%20on%20infant%20formula%20labelling.pdf Accessed 22 April 2022

# Attachments

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

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

**Food Standards (Application A1251 – 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products) Variation**

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

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

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

**1 Name**

This instrument is the *Food Standards (Application A1251 – 2′-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products) Variation*.

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

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

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**Standard 2.9.1—Infant formula products**

**[1] Subsection 2.9.1—7(2)**

Repeal the subsection, substitute:

(2) An infant formula product to which an inulin-type fructan and/or a galacto-oligosaccharides is added must not contain lacto-N-neotetraose as an added substance.

(3) During the exclusive use period, an infant formula product which contains the following added substances may only be sold if the infant formula product is a prescribed infant formula product:

(a) 2′- fucosyllactose; and

(b) an inulin-type fructan, a galacto-oligosaccharides, or both.

(4) For the purposes of subsection (3):

(a) **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1251 – 2′-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products) Variation* and ending 15 months after that date; and

(b) **prescribed infant formula product** means an infant formula product that:

(i) is manufactured by Nutricia Australia Pty. Ltd.; and

(ii) contains, as a nutritive substance, 2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126.

# 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 A1251 which sought to amend the Code to:

- remove the prohibition on the addition of 2'-fucosyllactose (2′-FL) to infant formula products in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF); and

- thereby allow forms of 2′-FL that are currently permitted by the Code to be added to IFP to be added to IFP in combination with GOS and/or ITF in accordance with applicable limits and conditions currently set by the Code.

The Application also sought a 15 month exclusive use permission. That is an amendment to the Code to provide that IFP may not be sold containing 2′-FL together with added ITF and/or GOS unless: the IFP is manufactured by Nutricia Australia Pty Ltd; and the 2′-FL in question is the 2′-FL developed and owned by Chr. Hansen A/S.

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

## 2. Variation will be a legislative instrument

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

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

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

FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

## 3. Purpose

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

- amend section 2.9.1—7, to remove the prohibition on the addition of 2′-FL to IFP in combination with GOS and/or ITF; and.
- provide the exclusive use permission requested by Application A1251.

## 4. Documents incorporated by reference

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

## 5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1251 will include one round of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this Application (OBPR correspondence dated 9 November 2021; OBPR Reference: OBPR21-01118). This exemption was provided as FSANZ would ensure the safety of any fortification permitted, and the proposed change allows business to voluntarily combine ingredients for fortification, rather than making it mandatory.

## 6. Statement of compatibility with human rights

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

## 7. Variation

Item [1] of the Schedule to the draft variation will amend subsection 2.9.1—7(2) of the Code.

Subsection 2.9.1—7(2) prohibits an IFP to which an ITF and/or a GOS is added from also containing either 2′-FL or a combination of 2′-FL and lacto-N-neotetraose.

Item [1] will replace and replace subsection 2.9.1—7(2) with new subsections 2.9.1—7(2), (3) and (4).

New subsection 2.9.1—7(2) will provide that an IFP to which an ITF and/or a GOS is added must not contain lacto-N-neotetraose as an added substance. Subsection 2.9.1—7(2) will no longer prohibit an IFP to which an ITF or a GOS is added from also containing 2′-FL. The removal of that prohibition will in effect allow those forms of 2′-FL that are currently permitted by the Code to be added to IFP to be added to IFP in combination with GOS and/or ITF in accordance with applicable limits and conditions currently set by the Code.

New subsections 2.9.1—7(3) and (4) will provide the exclusive use permission requested by Application A1251. The new subsections will impose a condition of use on the addition of 2′-FL to IFP in combination with GOS and/or ITF. This condition will be that, during the exclusive use period, IFP may not be sold containing 2′-FL together with added ITF and/or GOS unless the IFP: is manufactured by Nutricia Australia Pty Ltd; and contains, as a nutritive substance,

2′-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126. That is, the 2′-FL in question is the 2′-FL developed by Chr. Hansen A/S and permitted as a result of Application A1190.

New subsection 2.9.1—7(4) will provide that, for the purposes of the above, the exclusive use period will be the period commencing on the date of gazettal of the *Food Standards (Application A1251 – 2′-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products) Variation* and ending 15 months after that date. On the expiry of this 15 month period, the condition of use will lapse and IFP may be sold containing any form of 2′-FL permitted by the Code in combination with GOS and/or ITF (subject to applicable limits and conditions set by the Code).

The proposed amendments made by item [1] will not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology and nutritive substances.