14 December 2022
[223-22]

Approval Report – Application A1251

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

---

Food Standards Australia New Zealand (FSANZ) 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.

On 22 July 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 11 submissions.

FSANZ approved the draft variation on 14 December 2022. The Food Ministers' Meeting was notified of FSANZ's decision on 19 December 2022.

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

Table of contents

Supporting document

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

SD1 Risk and technical assessment (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) assessed an application by Nutricia Australia Pty Ltd 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[1] (IFP) as a nutritive substance in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF). The Applicants also requested an exclusive use permission for their combination of 2′-FL with GOS and/or ITF for a period of 15 months after gazettal of the approved draft variation.

2′-FL, GOS and ITF are non-digestible carbohydrates (oligosaccharides). 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. 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).

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. The Application did not seek changes to the existing maximum permitted amounts of these oligosaccharides.

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 maximum permitted amounts. FSANZ undertook an assessment of potential health effects in accordance with relevant Ministerial Policy Guidelines[2]. The assessment found results from *in vitro* and animal studies of combinations of 2′-FL and GOS and/or ITF were consistent with beneficial health effects observed for the individual components and provided some indication of the mechanisms involved. However, they did not allow any conclusions to be drawn on whether there were any additional benefits arising from supplementation with a combination of 2′-FL and GOS and/or ITF.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 22 July 2022 to 19 August 2022. Eleven submissions were received, all of which FSANZ had regard to (see Section 2.1 of this Report for details of submissions made).

Based on the information above and on other relevant considerations set out in this Report, FSANZ has decided to approve the draft variation proposed following assessment with amendments. The effect of the approved draft variation is that the voluntary addition of 2′-FL in combination with GOS and/or ITF in IFP, will be permitted in accordance with the Code. The approved draft variation will:

- 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
- include an exclusive use permission for the Applicants combination of 2′-FL with GOS and/or ITF in IFP for a period of 15 months after gazettal of the approved draft variation.

[1] Includes infant formula, follow-on formula and infant formula products for special dietary purposes.
[2] Policy guideline on infant formula products and Policy guideline on intent of Part 2.9 of the Food Standards Code - special purpose foods.

1 Introduction

1.1 The Applicants

Nutricia Australia Pty Ltd and Chr. Hansen A/S (the Applicants) 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

The Applicants applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of 2′-fucosyllactose (2′-FL) in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products (IFP).

2′-FL is regulated for use in IFP as a nutritive substance and a food produced using gene technology under the Code. Chr. Hansen A/S'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. Nutricia currently add 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 (amounts 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 were requested to the existing permissions for 2′-FL, GOS and/or ITF in IFP, which include maximum permitted amounts. The Applicants intend to combine Chr. Hansen 2′-FL (amounts up to 2.4 g/L) with Nutricia IFP containing the 9:1 scGOS/lcFOS mixture (amounts up to 8 g/L).

Upon approval, the current prohibition on the combination of 2′-FL with GOS and/or ITF under subsection 2.9.1—7(2) of the Code will be removed. The Application did 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). The safety of the combination of 2′-FL, GOS, ITF and LNnT has not been assessed and will continue to be prohibited under the Code.

Noting the above, the Application included 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 amounts. The Application also cited relevant data and information from previous assessments undertaken for Proposal P306 (FSANZ 2008) and Applications A1190 (FSANZ 2021) and A1055 (FSANZ 2013).

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 (2′-FL)

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 in IFP 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 (GOS) and inulin-type fructans (ITF)

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 (scFOS), 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. The maximum permitted amounts consider both the added and naturally occurring substances.

Combined use

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.

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 sources 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*[3] (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)(a)(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 amounts and combined with other oligosaccharides, including GOS and/or ITF.

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

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 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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments. The amendments made to the draft variation are explained in Section 2 of this Report. The approved draft variation, as varied after consideration of submissions, takes effect on Gazettal. The approved draft variation is at Attachment A.

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

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation to the Code from 22 July 2022 to 19 August 2022. Eleven submissions were received, five from government agencies, five from industry and one from a public health body. The key issues raised in submissions and how they have been addressed are provided in Table 1.

Table 1: Summary of issues

Issue	Raised by:	FSANZ Response
Exclusive Permission		
Support in principle the concept of exclusivity however question possible implications for the broader food industry and future applications. Note specific concerns including the perceived ad hoc nature of FSANZ's decision making.	Australian Food & Grocery Council New Zealand Food & Grocery Council Infant Nutrition Council Fonterra Nestle Victorian Departments of Health and of Jobs, Precincts and Regions New Zealand Food Safety	The Application relates to a special purpose food i.e. infant formula products (IFP) and FSANZ's consideration, and the subsequent granting of exclusivity, has been conferred in part on this basis. Innovation within the infant formula sector has led to the development of a number of ingredients that do not clearly fit as either a novel food or a nutritive substance. In some instances, an ingredient may meet the definitions of both.[4] This can occur when an ingredient is developed using a novel process, but is used as a nutritive substance in the final food. For regulatory clarity i.e. both implementation and enforcement purposes, the Code stipulates that a food cannot be regulated as both a novel food and a nutritive substance.[5] To address this conundrum, FSANZ established the Advisory Committee on Novel Foods (ACNF) to consider and provide advice on regulating these types of ingredients. Typically, if an ingredient is a novel food used as a nutritive substance as defined in paragraph 1.1.2—12 of the Code, it will be regulated as a nutritive substance. The outcome of FSANZ's deliberations and the granting of a limited exclusive use period is not considered to be precedent setting for the broader food supply as the decision specifically relates to the addition of these ingredients to IFP only. It will not be extrapolated to their use in general foods as ITF and GOS are not deemed to be nutritive substances when added to general foods. This recognises their dual functionality to perform a technological and/or nutritional role in general foods and manufacturers who currently use these ingredients can continue to do so without concern. FSANZ is of the view that the investment in a new product justifies a 'first to market advantage' in the specific food category of the Applicant's specific brand of nutritive substance, in this instance IFP. In this regard, a precedent was set in March 2021

[4] Definitions in Standards 1.1.2—8 and 1.1.2—12.
[5] Novel foods are regulated by Standard 1.5.1 and Schedule 25, and nutritive substances by Part 2.9 and Schedules 17 and 29.

		onwards with gazettal of Applications A1155, A1190 and A1233. To minimise any potential confusion as to any real or perceived implications from this decision impacting general food products, FSANZ has amended the drafting so the limited exclusive use permission relates specifically to the Applicants branded ingredients for both 2′-FL and GOS and ITF (at the ratio of 9:1 scGOS/lcFOS).
Justification for exclusivity of the combination is unwarranted as research relied on to demonstrate safety has been funded by other bodies and companies and therefore the justification for exclusivity of the combination is unwarranted.	Tasmanian Department of Health	There is no requirement for applicants seeking exclusive permissions to rely on their own funded data and *at present any manufacturer can submit an application using data generated by others if that data is publicly available*[6]. The dossier provided by the Applicants to support their request has included both research generated 'in-house' and commissioned that encompasses 'in combination' stability, tolerance and sensory trials, together with independent data that is publicly available which FSANZ considers appropriate for application use. Furthermore, if all the supporting studies provided by applicants were self-funded, the evidence may be perceived by stakeholders as introducing bias. See Section 2.3.4 of this Report for further discussion.
Highlight concerns regarding exclusivity including: • the 'novel' aspect of combining existing permissions (especially when one was granted exclusivity) • how exclusivity may be granted to a substance that is neither a novel food or nutritive substance. Suggest because the	New South Wales Food Authority	The limited exclusive use permission relates to the 'in combination' i.e. the Applicants branded ingredients for both 2′-FL and GOS and ITF (at the ratio of 9:1 scGOS/lcFOS). Historically, the condition of exclusivity was introduced into the Code at the request of the Food Ministers. At the time, it was requested that FSANZ consider exclusivity of use for novel foods in Standard 1.5.1 and to limit the period of exclusive permissions for up to 15 months, after which any exclusive permissions revert to a generic permission at the expiration of the approved period of exclusivity. Food Ministers endorsed exclusivity for the former as part of Proposal P305, and extended the permission to nutritive substances under Application A1155. The FSANZ Act allows for FSANZ to provide a limited conditional permission to a particular brand, where FSANZ has adopted a policy position that such limitation periods apply for a maximum of 15 months. Exclusive permissions are currently

[6] Exclusivity of use for novel foods and nutritive substances (foodstandards.gov.au).

proposed exclusivity is not limited to a specific oligosaccharide combination it could be interpreted as applying to any combination of relevant substances within that broad category and limiting any industry innovation of ITF or GOS to one company.		restricted to novel foods and nutritive substances. Where patents on the final ingredient are in place, exclusive use is redundant, for example GM foods. GOS and ITF are not considered nutritive substances when added to general foods. Their exclusion from the definition of a nutritive substance recognises their dual technological and nutritional purpose in general foods. This however applies only to general foods and not to IFP where compositional restrictions are in place. This reflects the intention of adding GOS and ITF to IFP for a nutritive purpose, primarily as a suitable substitute for human milk oligosaccharides. While permissions for GOS, ITF and 2′-FL as individual ingredients in IFP currently exist, a combination of these ingredients in IFP had not been assessed by FSANZ in a premarket approval process, as required by specific policy principle (i) of the ministerial policy guideline on *Regulation of Infant Formula Products*. To reflect this, the Code currently includes an explicit prohibition. To remove the prohibition in the Code, an application was required including a dossier of evidence supporting the safety, stability, and beneficial effects of the oligosaccharide combination in IFP. This is the same requirement as for new single ingredients seeking permission for use in IFP. The Applicants have invested significantly in order to demonstrate that the 'new product' (i.e. combined substances) for use in IFP fulfils FSANZ's regulatory requirements, and sought to bring that product to market. The Policy rationale for exclusivity as recognised by Food Ministers is to secure a return on investment and encourage innovation. FSANZ's assessment is that this rationale applies here. Ensuring that the specific requirements of the Ministerial Policy Guidelines are met is also a critical consideration in FSANZ's decision to afford the exclusivity for the combination of separately permitted ingredients in IFP. Refer to Section 2.3.4 of this Report for further information. Following consultation, FSANZ has amended the drafting so the limited exclusive use permission specifies the Applicants branded ingredients for both 2′-FL and GOS and ITF (at the ratio of 9:1 scGOS/lcFOS). Importantly, the approved draft variation does not prevent another food company seeking approval to use a combination of the same or similar ingredients during the 15 month period, providing an application process is undertaken.

Labelling		
Oppose the existing prohibition for the 'human milk oligosaccharide' terminology (including abbreviations) in paragraphs 2.9.1—24(1)(ca) and (cb) for the following reasons: • scientific names are not consumer friendly; their use is counter to building consumer confidence in, and understanding of, label information. • does not provide adequate information to enable informed choice. • ignores existing protections in the Code and in consumer protection legislation concerning truthfulness of the description of ingredients. • the terms and abbreviations are permitted by other overseas regulations.	Australian Food & Grocery Council New Zealand Food & Grocery Council Infant Nutrition Council	A review of the existing prohibition is not in scope of this Application because the Applicants did not request a change to this prohibition. FSANZ notes that the labelling requirement aligns with the regulatory approach for prohibiting HMO terminology that was described in the Approval Report for A1155 2′-FL and LnNT in infant formula and other products and gazetted in March 2021. FSANZ also notes its more recent published responses to similar concerns from industry submitters. See, for example, Table 1 to Section 2.1 in the Approval Report for A1190 2'-FL in infant formula and other products .The permission sought in A1190 was gazetted in January 2022.
Beneficial Health Effect		

Evidence of an additional beneficial role of the combination of ingredients is required, not just the beneficial role of each ingredient alone. Question whether FSANZ has given sufficient regard to policy principle (j) of the *Ministerial Policy Guideline for the Regulation of Infant Formula Products.* Request for FSANZ to explore further the relevant scientific literature and provide further commentary on the combined health benefit of 2′-FL and GOS/FOS.	New South Wales Food Authority Department of Health Tasmania	As stated in Section 2.5.3 of this Report, in assessing this Application, FSANZ had regard to the following Ministerial policy guidelines related to IFP: - Regulation of Infant Formula Products (including paragraph (j)), and - Intent of Part 2.9 of the Food Standards Code –Special Purpose Foods. In addition to other assessments FSANZ conducted, FSANZ conducted a health effects assessment of the combination of 2′-FL with GOS and/or ITF (see Supporting Document 1 - Risk and technical assessment of the call for submissions for Application A1251). 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 on protective immune responses against infections; on production of branched-chain fatty acids; and on the relative abundance of various bacterial genera. The results imply an additive and/or synergistic effect of a combination of 2′-FL and GOS and/or ITF on some measures. However, it is unclear whether these results are applicable to human infants fed formula supplemented with a combination of 2′-FL and GOS and/or ITF. FSANZ has undertaken a thorough search of the scientific literature post consultation on the potential health effects of the supplementation of infant formula products with 2′-FL and GOS/ITF – either separately or in combination. No new reports of relevance were identified.
There is no evidence for the benefit of permitting the ingredients.	Dietitians Australia	In FSANZ's health effects assessment of the combination of 2′-FL with GOS and/or ITF (see Supporting Document 1 - Risk and technical assessment of the call for submissions for Application A1251), FSANZ noted that both 2′-FL and scGOS/lcFOS have been individually demonstrated to have a bifidogenic effect *in vivo*. FSANZ also notes that although there is no conclusive evidence of *additional* benefits arising from supplementation with *a combination of* 2′-FL and GOS and/or ITF, results from *in vitro* and animal studies of combinations of 2′-FL and GOS and/or ITF are consistent with the beneficial health effects observed for the individual components, i.e. 2′-FL and GOS and/or ITF. See Section 2.2 of this

		Report for further discussion.
Concern that approval is premature and should be deferred pending review of the permission to add 2′-FL to IFP.	Department of Health Tasmania	FSANZ notes this comment. As stated in Section 2.3.7 of this Report, 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. The outcomes of that review may affect provisions in the Code regulating the use of 2'-FL as a nutritive substance. FSANZ reiterates the risk assessment conclusion that the combination of 2′-FL with GOS and/or ITF in IFP presents no safety, tolerance or growth concerns, and can benefit formula-fed infants.
Safety		
Whilst the safety of 2'FL alone has previously been assessed up to 2.4 g/L, FSANZ has not assessed the safety at this higher amount with the combination proposed. Question FSANZ's inference that because human milk can contain higher amounts of (up to 200) total oligosaccharides the proposed maximum permitted amounts are safe. Direct evidence showing the safety and tolerance of	Department of Health Tasmania Victorian Departments of Health and of Jobs, Precincts and Regions	FSANZ has conducted an evidence based safety assessment. Its conclusion based on the best available scientific evidence is that the proposed higher maximum permitted amount of 2′-FL, in combination with GOS and/or ITF, does not pose a public health and safety risk. See the supporting document. FSANZ notes that: - Intestinal absorption of 2′-FL, GOS and/or ITF is very limited, with the majority passing to the large intestine where they are fermented by the intestinal microbiota or excreted intact in the faeces. Data previously reviewed by FSANZ indicated that GOS and ITF are fermented to a similar or greater extent to human milk oligosaccharides. - No adverse effects have been observed in toxicity studies with these substances at high doses that exceed the estimated dietary intakes for infants consuming IFP containing the proposed maximum permitted amounts. Although the concentration of 2′-FL used in the clinical study (1.0 g/L) was lower than the proposed maximum permitted amount (2.4 g/L), studies with neonatal piglets

these ingredients at the proposed maximum amounts is required.		administered formula containing 2′-FL at concentrations up to 4 g/L found no adverse effects. - Clinical studies with these substances, alone or in combination, also found no adverse effects. - Given the limited absorption of 2′-FL, GOS and/or ITF, the absence of any identifiable hazard from both toxicity and clinical studies, as well as the history of safe human exposure to these substances (via human milk or infant formula), there is no plausible basis to suggest that combined exposure to 2′-FL, GOS and/or ITF at the proposed maximum permitted amount in IFP would result in adverse health effects.
Investigator-reported adverse events in the clinical study in infants were higher in the FOS/GOS + 2′-FL group than others.	New South Wales Food Authority	As noted by the submitter, although the overall incidence of adverse events was higher in infants given test formula compared to those consuming control formula or human milk, the difference was not statistically significant and was not considered clinically relevant by the study authors. In addition, all serious adverse events were reported to be not related or unlikely to be related to the study product. The incidence of reported adverse events in this study (24.6% – 39.3%) was also relatively low compared with some other clinical studies with infant formula. For example, Puccio et al (2017) reported 90.8% of infants consuming a control formula and 84.1% of those consuming formula supplemented with 2′-FL and LNnT experienced at least one adverse event. Overall, the results of the clinical study indicate that the formula was safe and well tolerated.
Considered the findings from the Vandenplas study were not fully discussed in the context of other studies.	New Zealand Food Safety	In undertaking the nutrition assessment, FSANZ considered all relevant studies in the body of evidence, which included the study by Vandenplas et al. as well as studies that were described in detail in Applications A1155, A1190 and A1055 and Proposal P306.
Requested FSANZ continue to search literature for	New South Wales Food Authority	FSANZ will continue to monitor the literature. To date, further clinical studies of 2′-FL in combination with GOS and/or ITF have not been identified.

clinical trials for 2'FL and FOS/GOS.		
Consumer awareness and behaviour		
One submitter raised concerns that consumers may be misled if substances that provide no benefit are added to IFP, as consumers perceive longer ingredient lists to be more nutritionally complete.	Department of Health Tasmania	FSANZ is satisfied that the addition of 2′-FL in combination with GOS and/or ITF will provide a benefit. This benefit would therefore negate any concern that consumers may be misled. Refer to response above. Previous consumer research undertaken by FSANZ to inform Proposal P1028 has highlighted that caregivers often lack knowledge about the contents of ingredient lists and nutrition information statements (see discussion on consumers in Section 2.5.1.1 of this Report below). FSANZ considers it unlikely that a significant proportion of consumers will notice the combination of ingredients and alter their purchasing behaviour as a result.
One submitter raised that an increased variety of products may lead to consumer confusion, rather than consumer benefit.	Queensland Health	FSANZ is not aware of any evidence to suggest that an increase in IFP product variety, as a result of the combination of 2′-FL with GOS and/or ITF, would occur and/or increase consumer confusion.
One submitter raised concerns that consumers may be misled if marketers use the combination to market IFP unethically, including in ways that use scientific imagery, language or pseudo-scientific claims, or that link products to being informed or derived from breast milk, or to having a positive impact on child development.	Dietitians Australia	FSANZ notes this comment. Marketing practices for IFP are controlled in Australia through the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (the MAIF Agreement), and in New Zealand through the *INC Code of Practice for the Marketing of Infant Formula in New Zealand* (and two other voluntary codes of practice). As stated in Section 1.3.1.4 of this Report, the Code prohibits the use of nutrition content and health claims and certain representations on the label of an IFP (e.g. the use of specific words such as 'human milk oligosaccharide'). Further, the Code prohibits information on IFP labels relating to the nutritional content of human milk (paragraph 2.9.1—24(1)(e)). These existing prohibitions aim to prevent misleading or deceptive conduct and will apply to IFP containing added 2′-FL with GOS and/or

Concerns were also raised that the combination would increase product cost, which in turn may influence consumer perceptions of quality, despite limited benefit.		ITF. Also, Commonwealth, state and territory, and New Zealand consumer protection legislation are in place to protect consumers from being misled about the products they purchase, including IFP.
Other		
Suggested long-term studies are needed to assess the impact on the infant's developing immune and gastrointestinal systems.	New Zealand Food Safety	FSANZ notes this comment. FSANZ anticipate studies will become available as part of the Applicants ongoing research, however FSANZ is confident there are currently no safety concerns. See Section 2.2 of this Report for further discussion.
Suggest a review of international IFP supply could assist building the safety profile for 2'FL and GOS/FOS in IFP. Cite maximum permitted amounts in IFP overseas do not reach the maximum (2.4 g/L) for 2'FL. Suggest this maximum permitted amount is reviewed to ensure it is associated with actual use either alone or in combination with other substances (e.g. GOS/FOS).	New South Wales Food Authority	FSANZ notes this comment. The safety assessments undertaken as part of this Application together with the safety assessments undertaken for earlier applications and proposals have demonstrated that the use of 2'FL and GOS/FOS is safe. FSANZ will maintain a watching brief in relation to IFP supply globally. As stated above, FSANZ will conduct a five-year review of the evidence of a substantiated beneficial role of 2′-FL in the normal growth and development of infants.

Recommend further permissions are withheld until the five-year review is completed.	Department of Health Tasmania	The five-year review will reassess the evidence of a substantiated beneficial role of 2′-FL in the normal growth and development of infants. During that time, FSANZ will consider each application requesting permission for or relating to the use of 2'-FL as a nutritive substance in IFP on its own merits. FSANZ assesses each application in accordance with the FSANZ Act, which includes undertaking risk analysis using the best available scientific evidence at the time.
Proposed the wording used to describe the nutrient composition of IFP to support '***normal*** growth and development' is amended to '***expected*** growth and development'.	Queensland Health	FSANZ is of the view that the term "*normal growth and development*" is both adequate and appropriate noting: - it is in keeping with our wording when discussing this topic in other applications and proposals, - it is consistent with the wording of the Ministerial policy guideline, namely Specific policy principle (g) which states *Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for* ***normal growth and development of infants***. FSANZ also notes the use of this phrase elsewhere in the Code (e.g. Schedule 4[7] - '…..contributes to *normal growth and development*') and is not aware of any evidence that would suggest a problem in relation to the use of this phrase.
Advocated for the implementation and enforcement of the *International Code of Marketing Breast-milk Substitutes* arguing self-regulation is not as effective as government-led mandatory policies to protect and promote	Dietitians Australia	Concerns regarding the effectiveness of IFP regulation are not within the scope of this Application. Policy decisions relating to implementation and enforcement of food regulatory measures are outside the remit of FSANZ's statutory responsibilities.

[7] Schedule 4 Nutrition, health and related claims.

appropriate infant and young child feeding.		

2.2 Risk assessment

The safety, technological aspects, nutritional impact and beneficial health effects from individual addition of these ingredients to IFP 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 was 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 amounts normally found in human milk. In addition, FSANZ has previously assessed the addition of a total amount 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 best 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 amounts.

The limited, best available evidence 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 maximum permitted amounts proposed by the Applicants.

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 amounts 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 dietary intakes 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 maximum permitted amounts.

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 Applicants 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.

2.3 Risk management

Breastfeeding is the recommended way to feed infants. However, a safe and nutritious substitute for human milk is needed for infants when breastfeeding is not possible. As infants are a vulnerable population group, infant formula products (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 had regard to the requirements of the FSANZ Act (see Section 2.5 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 at the current maximum permitted amounts, FSANZ has approved the removal of the current prohibition of this combination in the Code.

2.3.1 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:

- 2′-FL – 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;
- GOS/ITF – Proposal P306 - Addition of Inulin / FOS & GOS to Food; and Application A1055 - Short-chain Fructo-oligosaccharides assessed GOS and/or ITF.

Application A1155 did not seek the use of the proposed permissions for 2′-FL and LNnT together with existing permissions for GOS and ITF in infant formula products. FSANZ did however consider the available evidence for this potential combined use. As discussed in the public documentation, no adverse effects were reported in infant studies which tested formula supplemented with 2′-FL in combination with scFOS or GOS. However, the maximum amounts of scFOS or GOS permitted in the Code were not tested in these studies. Additionally, no evidence was provided which investigated the use of 2′-FL combined with both scFOS and GOS (i.e. scFOS and GOS are currently permitted to be used in combination in infant formula products in the Code). As such, the tolerance of infants to this total combination of added oligosaccharides could not be determined, noting also that this combination does not occur naturally in human milk.

Ultimately, based on the available evidence, and given the combined use of the proposed and existing permissions was not requested, FSANZ decided under Application A1155 to prohibit the use of 2′-FL and LNnT in combination with existing GOS and ITF permissions in IFP. At this time, 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 2021; pp 48-50). Though currently under consultation, submitters did not raise any issues in response to FSANZ's proposed approach to retain existing permissions, 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).

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

Standard 1.1.2—2 defines that ITF 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 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 9:1 scGOS/lcFOS. FSANZ had also previously assessed data containing scFOS under A1055.

Noting that lcFOS and scFOS are both considered ITF, and no specific individual permissions exist for substances recognised as an ITF i.e. any individual ITF is permitted, FSANZ 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.

2.3.3 Combinations of 2'-FL with GOS and/or ITF in IFP

Human milk oligosaccharides (HMO) present in human milk play an important role in the normal growth and development of infants, in particular to mature the infant microbiota. GOS and ITF have been permitted for addition to IFP since the gazettal of Proposal P306 in 2008, to emulate the effects of HMO and strive to achieve as closely as possible the normal growth and development of infants, consistent with specific policy principles (d), (e) and (h) of the ministerial policy guideline on *Regulation of Infant Formula Products*. Recent innovation has seen the synthesis of oligosaccharides biochemically identical to HMOs, such as the Applicants 2′-FL and can be seen as a positive development for infant health. This technology, however, remains expensive and if used as the sole source of oligosaccharides in IFP, could raise IFP prices to be prohibitive to consumers. While the technology is in development to become more efficient and affordable, Supporting Document 1 explains that the evidence for the combination of 2′-FL with GOS and/or ITF in IFP presents no safety, tolerance or growth concerns, and can benefit formula-fed infants.

The assessment on potential health effects found those observed from the combination of 2′-FL and GOS and/or ITF were consistent with beneficial health effects observed for the individual components and provide some indication of mechanisms involved. While the Applicants reported that the use in combination enhanced the overall benefit of consumption, at this time FSANZ 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.

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

2.3.4 Innovative ingredient combinations for use in IFP including exclusive use

Subparagraph 1.1.2—12(2)(c) sets out that ITF and GOS are taken not to be nutritive substances when added to general foods. This recognises ITF and GOS fulfil both a technological and nutritional purpose in general foods. This applies only to general foods and not to IFP. Under Proposal P306 *Addition of inulin/FOS & GOS to food*, FSANZ specifically excluded ITF (termed ‘inulin-derived substances’ at the time) from the definition of ‘used as a nutritive substance’ (then defined as ‘nutritive substances’) because it was already being added to some general foods and therefore readily available in the food supply. GOS was also excluded from this definition under P1025 *Code Revision* for clarity. This approach provided regulatory certainty for manufacturers who were using ITF and GOS in general

foods so they did not require express permission in the Code. Classifying ITF or GOS to be *used as a nutritive substance* would have rendered all foods that contained these substances as non-compliant until such time as they were approved. FSANZ did consider the safety in infants and young children because of the potential effect on water balance/dehydration, hence the development of limits around infant formula products containing inulin-derived substances and/or GOS.

While permissions for GOS, ITF and the Applicants 2′-FL as individual ingredients in IFP currently exist, a combination of these ingredients in IFP had not been assessed by FSANZ in a premarket approval process, as required by specific policy principle (i) of the ministerial policy guideline on *Regulation of Infant Formula Products*. IFP are special purpose foods for the highly vulnerable population of infants, and thus are the most stringently regulated food under the Code. Unlike in general foods, any new ingredient or combination of ingredients purported to have a beneficial health effect when added to IFP must undergo premarket assessment to protect and promote the safety, growth and development of infants. Where an ingredient or ingredient combination for addition to IFP has not been assessed as safe and beneficial, an explicit prohibition may be put in place. This occurred under Application A1155 where LNnT and 2′-FL were assessed as individual ingredients and in combination with each other in IFP, but not with GOS and/or ITF, thus prohibitions were put in place on the combination of 2′-FL with GOS and/or ITF and on LNnT with GOS and/or ITF in IFP. To remove either prohibition in the Code, an application was required including a dossier of evidence supporting the safety, stability, and beneficial effects of the oligosaccharide combination in IFP.

Paragraph 16(2)(b)) of the FSANZ Act provides that standards, and variations of standards, developed by FSANZ may relate to a particular brand of food. 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 provided evidence of their investment in preparing this Application. This included research and expenditure on ingredients processes, development of patented technology, manufacturing capital expenditure and trials, and conducting sensory, shelf-life and clinical trials (on both the individual ingredients and the combination of ingredients).

FSANZ decided to provide the Applicants with a 15-month exclusive use permission for the combination of 2′-FL with GOS and/or ITF in IFP, commencing on the date of gazettal of the variation. This means 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; contains their blend of scGOS/lcFOS (9:1); 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 has ended, the exclusive use permission will revert to a general permission and any brand of 2′-FL may be added to IFP in combination with GOS and/or ITF at any ratio that does not exceed maximum permitted amounts (subject to any conditions imposed by the Code), thereby allowing all manufacturers to innovate and benefit from the changed permission.

The 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. The approved draft variation will not change this.

2.3.5 Food technology

The food technology assessment of this Application, to allow the combination of 2′-FL with GOS and/or ITF, remains consistent with the findings in A1190, A1055 and P306 (FSANZ 2019, FSANZ 2013a, FSANZ 2008a). The previous Applications and Proposal found that 2′-FL_{micro}[8] (the subject of this Application) 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 blend of ingredients provides an adequate shelf-life. International studies of shelf-life and stability further confirm the information provided by Nutricia and Chr. Hansen A/S. No other food technology concerns were identified.

2.3.6 Maximum permitted amounts

The Applicants did not propose any change to existing maximum permitted amounts for 2′-FL, GOS and ITF individually or in any combination of the three ingredients. FSANZ's safety and risk assessment (SD1) reinforced findings of previous assessments (FSANZ 2020) that there were no public health and safety concerns associated with the addition of 2′-FL, GOS or ITF in IFP, up to the maximum permitted amounts currently in the Code.[9] The assessment also found the combination of 2′-FL, GOS and/or ITF to be well tolerated with no indications of adverse effects (SD1).

Therefore, there will be no change to the maximum permitted amounts of the substances when added in combination to IFP.

2.3.7 Labelling

The removal of the prohibition will 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, will apply to IFP containing added 2′-FL with GOS and/or ITF. Existing GM labelling requirements will also apply (see Section 1.3.1.4 of this Report).

2.3.8 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, GOS and/or ITF) 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.

---

[8] 2′-FL_{micro} is the term used to refer to the specific form of 2′-FL produced by microbial fermentation that is referred to within the Application and this assessment.

[9] Schedule 29—5 provides the maximum permitted amount of 2′-FL in IFP is 96 mg/100 kJ. Standard 2.9.1—7 provides the maximum permitted amount of ITF in IFP is 110 mg/100 kJ; and the maximum permitted amount of GOS in IFP is 290 mg/100 kJ.

2.3.9 Risk Management conclusion

Having considered the evidence and all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines[10], FSANZ has decided to approve a draft variation to the Code to remove the prohibition on the combination of 2′-FL with GOS and/or ITF. However, as stated above, FSANZ will review the evidence of a substantiated beneficial role of 2′-FL in the normal growth and development of infants and the outcomes of that review may affect provisions in the Code regulating the use of 2'-FL as a nutritive substance.

As a result of the approval, 2′-FL may be added to IFP in combination with GOS and/or ITF subject to the following Code requirements and/or conditions:

- An exclusive use permission will apply for a period of 15 months, commencing on the date of gazettal of the variation. During this period, IFP cannot be sold containing 2′-FL together with added ITF and/or GOS unless the IFP:
    - is manufactured by Nutricia Australia Pty Ltd;
    - contains, as a nutritive substance, 2′-FL developed by Chr. Hansen A/S and permitted as a result of Application A1190; and
    - contains Nutricia Australia Pty Ltd's blend of scGOS and lcFOS, namely scGOS/lcFOS (9:1).
- The current maximum permitted amounts for 2′-FL, GOS and/or ITF in Standard 2.9.1—7 and Schedule 29 apply.
- The combination of 2′-FL and LNnT with GOS and/or ITF remain 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 apply where relevant.

2.4 Risk communication

2.4.1 Consultation

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

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

A public consultation paper called for submissions on FSANZ's assessment and on a draft variation from 22 July to 19 August 2022. FSANZ received 11 submissions. FSANZ had regard to all submissions received for this Application as part of its assessment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. All comments are valued and contribute to the rigour of our assessment.

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

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

As explained above, Application A1251 seeks an amendment of the Code required to allow the addition of 2'-FL to IFP in combination with GOS and/or ITF, relying on existing genetically modified food and nutritive substance permissions for 2'-FL. 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, considered the costs and benefits that could 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 of 2′-FL together with added ITF and/or GOS where the IFP:
    - is manufactured by Nutricia Australia Pty Ltd;
    - contains, as a nutritive substance, 2′-FL developed by Chr. Hansen A/S and permitted as a result of Application A1190; and
    - contains Nutricia Australia Pty Ltd's blend of scGOS and lcFOS, namely scGOS/lcFOS (9:1).

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 by approving this Application.

Consumers

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

FSANZ considered that domestic consumers could 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.

Caregiver understanding and behaviour was 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). Many caregivers report not reading the ingredients list, often because they do not understand what the ingredients are. 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 supported 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, 2022). However, other caregivers find longer lists 'scary' or 'off putting' (FSANZ, 2022). On balance, FSANZ considered it unlikely that a significant proportion of consumers will notice the combination of ingredients and alter their purchasing behaviour as a result.

As explained in the Section 2.3.4 above, the role of granting an exclusive use permission is to encourage industry innovation and allow applicants to achieve return on their investment. That commercial reward could come at the expense of consumers as they could potentially be paying premium price if they choose to purchase products containing the combination of 2′-FL with GOS and/or ITF due to lack of competition during the exclusive use permission.

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, removing the prohibition in the Code as requested by the Application will allow 2′-FL to be used in combination with GOS and/or ITF, 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 were assumed to be outweighed by benefits to consumers from greater industry competition.

Granting an exclusive use period could potentially create a monopoly and restrict trade during those 15 months. However, the granting of exclusive use does not preclude any other company from requesting the exact same permission. Therefore, the market could be opened during those 15 months for any other companies willing to make an application. However, it does still represent a barrier to entry in terms of this specific market.

Due to the voluntary nature of the proposed permission and limited information available it is

hard to estimate impact of the exclusive use permission on other infant formula manufacturers. Although long term, industry as a whole is likely to benefit, on balance, from a move away from the status quo.

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 assessment is that the direct and indirect benefits that would arise from removing the current prohibition on the combination of 2′-FL with GOS and/or ITF and allowing the exclusive use permission are likely to outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that 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

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

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (Supporting Document 1) which is summarised in Section 2.2 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 amounts.

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

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

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

Using risk analysis, FSANZ 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. Removing the prohibition will promote consistency between domestic and international food standards.

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

Removing the prohibition will 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 Food Ministers' Meeting**

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 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 (2019) A1155: 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Second Call for Submissions. Safety, technical and health effects assessment. Food Standards Australia New Zealand, Canberra, Australia. https://www.foodstandards.gov.au/code/applications/Documents/A1155_SD1_Risk%20assessment%20-%202nd%20CFS.pdf Accessed 13 May 2022

FSANZ (2020), A1155 – 2'-FL and LNnT in infant formula and other products. Supporting Document 1: Safety and growth assessment. Available at: https://www.foodstandards.gov.au/code/applications/Documents/A1155_SD1_Riskassessment.pdf Accessed 9 November 2022

FSANZ (2021), 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

FSANZ (2022) P1028 First Call for Submissions - Attachment to Supporting Document 3: Consumer research on infant formula labelling. Available at: https://www.foodstandards.gov.au/code/proposals/Documents/Attachment%201%20to%20SD3%20-%20Consumer%20research%20on%20infant%20formula%20labelling.pdf Accessed 5 September 2022

WHO & UNICEF (2022) How the marketing of formula milk influences our decisions on infant feeding. Available at: https://www.unicef.org/documents/impact-bms-marketing, Accessed 5 September 2022

Zhang, N & Xu, H (2021) Reconciling the paradoxical findings of choice overload through an analytical lens, *MIS Quarterly, 45*(4),1893-1920, doi: 10.25300/MISQ/2021/16954

Attachments

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

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

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

---

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

Dated [To be completed by the Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application 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; and

(iii) contains Nutricia Australia Pty Ltd's blend of *short-chain galacto-oligosaccharides and long chain fructo-oligosaccharides, namely scGOS/lcFOS (9:1)*.

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1251 which sought to amend the Code to:

- remove the prohibition on the addition of 2'-fucosyllactose (2′-FL) to infant formula products (IFP) 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 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 and contains Nutricia Australia Pty Ltd's blend of short-chain GOS and long chain FOS, namely scGOS/lcFOS (9:1).

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

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

2. Variation is a legislative instrument

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

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

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under

an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the 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 approved 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 approved 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 22 July 2022 for a four-week consultation period.

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).

6. Statement of compatibility with human rights

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

7. Variation

Item [1] of the Schedule to the 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 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 and/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 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; and
- contains Nutricia Australia Pty Ltd's blend of *short-chain galacto-oligosaccharides and long chain fructo-oligosaccharides, namely scGOS/lcFOS (9:1)*.

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 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.

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

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

---

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

Dated [To be completed by the Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application 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.

.