

**5 October 2020**  
**[137-20]**

Review – Application A1155

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

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On 17 February 2020, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) asked FSANZ to review its decision in relation to draft variations to Standard 2.9.1, Schedule 26 and Schedule 29.

FSANZ was required to review the decision by 17 May 2020. FSANZ sought an extension to the review timeline given the number of grounds for review raised by Ministers. The Forum advised FSANZ they will consider the review report in November 2020.

FSANZ has reviewed its decision and re-affirmed the approval of the voluntary addition of 2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), produced by microbial fermentation, in infant formula products and formulated supplementary foods for young children on 16 September 2020.

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## Supporting documents

The following documents which informed the review are available on the [FSANZ website](#):

- SD1 Safety and growth assessment (at review)
- SD2 Benefit assessment (at review)
- SD3 Peer review of the safety assessment
- SD4 Summary of the IEAG views
- SD5 Report on innovation in manufactured food and infant formula sectors

# Executive summary

On 17 February 2020, the Forum requested a review of the FSANZ Board's decision to approve the addition of 2'-FL and LNnT to infant formula products and formulated supplementary foods for young children (FSFYC) up to 2.4 g/L combined. 2'-FL and LNnT are non-digestible oligosaccharides found naturally in human milk. The applicant's 2'-FL and LNnT are produced by microbial fermentation using genetically modified (GM) production strains. These oligosaccharides are chemically and structurally identical to those in human milk. FSANZ recognises that breastfeeding is the recommended way to feed a baby, however infant formula products are intended to be the only safe and suitable alternative for infants who are not breastfed. FSANZ also recognises that in both Australia and New Zealand, feeding guidelines for young children recommend that toddlers from 12 months of age and beyond should be consuming family foods consistent with the dietary guidelines to meet their energy and nutrient intakes, and in such circumstances, toddler milks, the main type of FSFYC, are not necessary for healthy children. However, these products are recognised as supplementary nutrition for some young children whose diets do not reflect dietary recommendations

## Matters addressed in the review

The Forum requested FSANZ reconsider the draft variations on the following grounds:

- (i) it is not consistent with existing policy guidelines set by the Forum
- (ii) it is not consistent with the objectives of the legislation which establishes FSANZ
- (iii) it does not protect public health and safety
- (iv) it does not promote consistency between domestic and international food standards where these are at variance
- (v) it does not provide adequate information to enable informed choice
- (vi) it is difficult to enforce or comply with in both practical or resource terms

## Statutory context for the review

Section 87 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) requires FSANZ to review an approved draft variation when requested by the Forum. The FSANZ Act requires FSANZ to have regard to certain matters when undertaking that review. These are in addition to the Forum's stated reasons for requesting the review.

Subsection 18(1) of the FSANZ Act lists in order of priority three objectives for FSANZ when undertaking a review. The protection of public health and safety has the highest priority. Subsection 18(2) lists other secondary matters which FSANZ must have regard to in reviewing food regulatory measures. Section 29 of the FSANZ Act requires FSANZ to have regard to specific matters when assessing a proposal and when deciding to approve a draft variation developed as a result of a proposal. These matters remain relevant considerations for FSANZ when conducting a review requested by the Forum. Each of the above sections and matters are considered in section 4 of this report.

Paragraph 18(2)(e) of the FSANZ Act requires FSANZ to have regard to any written policy guidelines formulated by the Forum. The section makes clear that the requirement is only to have regard to the policy guidelines; they are not binding on FSANZ. The FSANZ Act also makes clear that the Forum cannot direct what FSANZ must decide in a review.

## Decision

FSANZ's decision is to re-affirm the approval of the draft variations to Standard 2.9.1, Schedule 26 and Schedule 29. FSANZ emphasises that this decision was taken after having regard to the Forum's review request and all the matters required by the FSANZ Act – including the above-mentioned statutory objectives and policy guidelines – and after careful consideration of the best available evidence.

## Reasons for decision - Overview

In reaching its decision the FSANZ Board had regard to the comments received; additional research and the input of an independent expert advisory group.

The FSANZ Board notes that the comprehensive safety assessment has not identified any health and safety risks for infants or for young children at the proposed maximum levels and further that the safety assessment conclusions are consistent with international assessments.

Infant formula products with 2'-FL and LNnT are currently approved and used in 69 countries. FSFYC or similar products for young children containing added 2'-FL and LNnT are also available in most of these countries. Permitting the oligosaccharides in Australia and New Zealand supports domestic companies' ability to stay competitive in the global market and to continue product export. The permission improves harmonisation with international regulations, supports cost-effective manufacturing through consistency with overseas regulations, and supports innovation for manufacturers and researchers in Australia and New Zealand.

Re-affirming the draft variation does not pose a risk to health and safety, confers possible health benefits and, with labelling restrictions, protects consumers and benefits Australia and New Zealand formula manufacturers. It also encourages ongoing innovation to continue the improvement of infant formula products and FSFYC. These have broader benefits to the community.

A more detailed summary is given below.

## Reasons for Decision - detail

FSANZ considered the Forum's issues (summarised in the table below) and further considered the objectives listed in Section 18 of the FSANZ Act, including those in subsection 18(2).

### *Safety and benefit – infant formula products*

- The comprehensive safety assessment has not identified any health and safety risks for infants at the proposed maximum levels. The safety assessment conclusions are consistent with international assessments. FSANZ did not find any adverse event or food recall data for 2'-FL or LNnT from the many other countries in which these products are sold.
  - The proposed maximum levels are well below the total amount of oligosaccharides found in human milk, and lower than the maximum levels of the currently permitted oligosaccharides: inulin type fructans (ITF) and galacto-oligosaccharides (GOS).
- FSANZ has considered the normal growth and development in healthy breastfed infants (Regulation of infant formula policy guidelines specific policy principle (SPP) (d) and (e)). Human milk composition is used as a primary reference (SPP (h)). Assessment of SPP (j) has been undertaken using the best available evidence; noting oligosaccharides constitute the third largest solid component in human milk.
  - The proposed maximum levels of 2'-FL and LNnT are equivalent to the levels of these specific substances found in human milk.
- Many factors influence infant health, and it is often not possible to determine a direct relationship between the presence of one substance in human milk and a specific health outcome.

- Breastfed infants have fewer infections (gastrointestinal infections, ear infections and respiratory tract infections) than formula-fed infants, and, when infected, have shorter and less severe illness than formula-fed infants. Observational studies show that several components of human milk are attributed to the development of the infant immune system, including antibodies, oligosaccharides, lactoferrin and lysozyme.
  - The Australian Infant Feeding Guidelines note that ‘human milk oligosaccharides promote bifidus bacteria in the large intestine, and inhibit attachment of pathogenic bacteria to intestinal and urinary tract mucosa’. Also that human milk oligosaccharides are recognised as one of the components in human milk that contribute to facilitation of optimal function of the infant’s immature systems and confer both active and passive immunity.
  - In the context of this review, FSANZ considers that a ‘health outcome’ for a voluntary addition to infant formula products should be considered in the context of shifting outcomes of formula-fed infants closer to those of breastfed infants, recognising that not all infants are able to be breastfed.
  - FSANZ recognises that infant formula products will never provide the same benefits as breastfeeding or human milk. However infants who are not breastfed should not be prevented from having access to products that more closely resemble human milk.
- Development of the infant microbiome is considered an important part of normal development. There is no universal standard for a healthy intestinal microbiota. However, the composition of exclusively breastfed infants is generally the accepted reference standard for the normal, healthy development of an infant’s gut microbiome.
    - There is broad scientific consensus that a Bifidobacterium-enriched microbiota has functional effects in the normal growth and development of breastfed infants. However, this cannot be linked directly to a specific health outcome in either breastfed or formula-fed infants.
    - Supplemented formula shows a bifidogenic effect in shifting the microbiome of formula-fed infants towards that of breastfed infants. These effects are similar to those in breastfed infants and are thus regarded as favourable to infants.
  - A consistent body of evidence demonstrates that 2’-FL provides a pathogen binding inhibitory mechanism against invasive *Campylobacter* in a dose-dependent manner. Infant trials cannot ethically test if 2’-FL added to infant formula inhibits pathogen-binding of *Campylobacter* and subsequent infection rates in infants. Evidence from one human study showing a decreased incidence of *Campylobacter*-associated diarrhoea in infants of mothers with a higher proportion of 2’-FL in their milk is consistent with the proposed pathogen-binding effect of 2’-FL, but is insufficient to conclusively demonstrate the likelihood of a positive health outcome from supplementation of infant formulas with 2’-FL.
    - FSANZ sought advice from the independent expert advisory group (IEAG) on the approach to the assessment of the benefits of 2’FL and LNnT used in infant formula and FSFYC; the strength and adequacy of the evidence base; and the appropriateness of the conclusions of the assessment. The advice and key conclusions of the IEAG discussions have been taken into account.
  - When added to infant formula products, only the chemical names of the oligosaccharides can be used. The terms ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ or any word, abbreviation or words having the same or similar effect cannot be used.

*Safety and benefit - Formulated supplementary foods for young children*

- Toddler milk is the main type of FSFYC currently available and has been the focus of the issues raised for this product category. Some of the issues raised by the Forum relate to proposed changes to the current regulations and policy applicable to toddler milk products. FSANZ acknowledges the issues raised but notes that its legislation does not anticipate using review processes to be the vehicle to address a concern that relates to the broader regulation and supply of all FSFYC.
- The Australian Infant Feeding Guidelines recommend that toddler milks are not required for healthy children (NHMRC 2012,). The Australian Infant feeding Guidelines also recommend that from 12 months of age and beyond, toddlers should be consuming family foods consistent with the Australian Dietary Guidelines. The New Zealand Food and Nutrition Guidelines also note '*If a toddler is eating a variety of foods, including good sources of iron, and is not consuming more than 500 mL of cows' milk per day, then the extra nutrients in toddler milks generally provide no benefits*' (Ministry of Health 2008) '
- The purpose of FSFYC (as defined in the Code) is to supplement young children's diets when energy and/or nutrient intakes may be inadequate.
  - The literature indicates that toddler milk products as supplementary product can be a useful source of certain nutrients for some groups of young children in Australia, New Zealand and similar developed countries when nutrient intakes are inadequate.
  - FSFYC, like infant formula products, are already permitted to contain other oligosaccharides – ITF and GOS.
  - Both oligosaccharides are safe at the proposed levels.
- The policy guideline for special purpose foods contains high order principles (consistent with the FSANZ Act) and four specific policy principles. A key consideration is that '*the composition of the special purpose food should be consistent with its intended purpose*'. The Forum considered that 2'-FL & LNnT added to FSFYC served no nutritional purpose, since a young child has no physiological need for human milk oligosaccharides. In this context, our assessment considered whether there is any benefit to the voluntary inclusion of 2'-FL & LNnT in FSFYC, noting these foods are not breast milk substitutes.
  - Voluntary addition of 2'-FL and LNnT to FSFYC safely contributes to the composition of the product, and is consistent with the purpose of FSFYC in providing supplementary nutrition for young children.
  - The evidence demonstrates that both 2'-FL & LNnT provide a bifidogenic mechanism. A limited number of studies in young children exist to confirm this mechanism, and there is no evidence to suggest the mechanism is not valid for this particular population.
  - It is recognised that the diet in early childhood influences the continuing establishment of the gut microbiota. In this context, a prebiotic bifidogenic effect can be relevant to young children, particularly if they are not consuming fibre-rich foods.
- The benefit assessment also determined that 2'-FL provides a pathogen binding inhibitory mechanism against invasive *Campylobacter* in a dose-dependent manner. The observational data and mechanistic evidence suggest this contributes to a lower incidence of diarrhoea in young children.
  - *Campylobacter jejuni* is recognised as one of the major bacterial causes of diarrhoea in young children in developing and developed countries – including Australia and New Zealand. In both countries, children aged 1-4 years have the highest rate of notifications of *Campylobacter* infection.
  - FSANZ concludes that consuming a FSFYC containing 2'-FL may provide favourable risk reduction and, therefore, health effects for young children when they are not consuming an adequate diet. This aligns with Ministerial Priority One

of the food regulation system – to reduce foodborne illness, particularly related to *Campylobacter* and *Salmonella*, with a nationally-consistent approach.

- The optional permission for 2'-FL and LNnT is separate from the existing ITF and GOS permissions (they provide an alternative), which introduces innovation opportunities for Australian and New Zealand industry.
- The Applicant did not apply for a permitted health claim for FSFYC. FSANZ considers that this assessment could not be used as the basis of a health claim, since assessment of any health claim, including claims of a protective nature, was not part of FSANZ's consideration of this application.
  - To minimise the risk of misleading consumers, labelling prohibitions have been introduced for FSFYC. The following words cannot be used: 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect. Similarly the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect cannot be used.

### *Economic and trade benefit*

After re-confirming the conclusions about safety and benefit, FSANZ reviewed the regulatory analysis previously undertaken (as per Section 29 of the FSANZ Act). This identified that the economic benefits of an innovative food manufacturing sector and the advantages of an internationally competitive food sector to the economy were not adequately captured at Approval. Given the broader policy environment to deregulate, and to support food export growth and innovation, the extent to which commercial objectives would be achieved has been more closely assessed.

The food regulatory system aims to support a strong, sustainable food industry that offers a diverse, affordable food supply that also benefits the Australian and New Zealand economies. This is reflected in the Food Regulation System Ministerial priority three – *Maintaining a strong, robust and agile food regulation system of the food regulation system*. Such an aim requires the Australian governments and the New Zealand government to work together to help align both countries' domestic and export food standards, and to facilitate their harmonisation with international food standards<sup>1</sup>.

Infant formula products are heavily traded globally and several Australia and New Zealand products are exported. Infant formula products and FSFYC exports are a strong and growing sector for both countries. Export growth has occurred in general trade export, and through cross border e-commerce (CBEC) and on-line sales (predominantly in China). New Zealand exported infant formula was valued at more than NZ \$1.7 billion in 2019, and Australia's 2018 exports were approximately AU \$789 million. Australia and New Zealand predominantly trade in 'premium' and 'super premium' infant formula products, leveraging off our reputation as clean, green and safe.

Infant formula products with 2'-FL and LNnT are currently approved and used in 69 countries. Certain importing countries require some categories of products, including infant and toddler products, to be permitted in the country of origin. Therefore, permitting these oligosaccharides in Australia and New Zealand supports domestic companies' ability to stay competitive in the global market and to continue product export. The permission improves harmonisation with international regulations, supports cost-effective manufacturing through consistency with overseas regulations, and supports innovation for manufacturers and researchers in Australia and New Zealand.

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<sup>1</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/system-aims-and-objectives>

Innovations are also key to creating products that are preferred by consumers both domestically and in the competitive international markets. This in turn supports the profitability of the firms and the jobs in the sector. Without the permission, local companies are likely to lose market share in a very global competitive market.

#### Cost benefit analysis

FSANZ's cost benefit assessment has determined that permitting the voluntary addition of 2'-FL and LNnT to these products is likely to benefit the community. Re-affirming the draft variation does not pose a risk to health and safety, confers possible health benefits and, with labelling restrictions, protects consumers and benefits Australia and New Zealand formula manufacturers. It also encourages ongoing innovation to continue the improvement of infant formula products and FSFYC. These have broader benefits to the community.

#### Summary of FSANZ response to issues raised by the Ministerial Forum

Ground for review and Forum issue	Summary of FSANZ's response
<p><b><i>The proposed draft variation is not consistent with existing policy guidelines set by the Forum</i></b>  <i>FSANZ concludes the draft variation - and the assessment on which is based - is consistent with existing policy guidelines set by the Forum. The best available evidence on which FSANZ's assessment is based sufficiently establishes favourable outcomes.</i></p>	
<p><b>Infant formula products</b></p> <p>The approval does not have sufficient regard for Specific Policy Principle (J)</p>	<ul style="list-style-type: none"> <li>• SPP (J) calls for evidence to link physiological effects to a health outcome. Noting the proposed level of 2'-FL and LNnT is comparable to human milk, evidence demonstrates favourable physiological effects of a bifidogenic effect that shifts the microbiome of formula-fed infants towards that of breastfed infants although this effect cannot be linked directly to a specific health outcome.</li> <li>• 2'-FL also exhibits a pathogen-binding inhibitory effect against <i>Campylobacter jejuni</i> in a dose-dependent manner, with limited and largely indirect evidence for a reduction of intestinal colonisation by <i>C. jejuni</i> and the incidence of diarrhoea. However, ethical limitations prevent testing the effect in clinical studies.</li> <li>• SPP (J) cannot totally be met for many substances in human milk, particularly non-essential nutrients or substances intended for voluntary addition, due to the many factors in human milk that influence infant health.</li> </ul>
<p><b>FSFYC</b></p> <p>Object to the inclusion of 2'-FL and LNnT in formulated supplementary foods for young children because the application has not demonstrated a physical or physiological need for these substances by this age group.</p>	<ul style="list-style-type: none"> <li>• The policy guideline specifies 'the composition of the food should be consistent with its intended purpose'.</li> <li>• FSFYC are specifically formulated for children aged 1 to &lt;4 years as a supplement to address nutritional inadequacy.</li> <li>• Consuming FSFYC containing 2'-FL and LNnT may provide favourable health effects for young children by reducing risk of GI infection. Children under 4 years have the highest rates of <i>Campylobacter</i> infections.</li> <li>• A prebiotic effect is relevant to the developing gut microbiota in young children, particularly if not consuming fibre-rich foods.</li> <li>• On balance, FSANZ considers 2'-FL and LNnT addition to FSFYC is consistent with the intended purpose of FSFYC.</li> </ul>
<p><b><i>It has not been demonstrated that addition of 2'-FL and LNnT to infant formula at the proposed levels is consistent with the protection of public health and safety</i></b>  <i>FSANZ assessment – which is evidence based - is that addition of 2'-FL and LNnT to infant formula at the proposed levels is consistent with the protection of public health and safety.</i></p>	
<p>The safety of long term consumption of 2'-FL at levels of up to 2.4 g/L has not been demonstrated in infants or young children.</p>	<ul style="list-style-type: none"> <li>• There is no evidence of harm or of any safety concerns for consumption of these oligosaccharides at any level, including above the proposed maximum levels.</li> <li>• The applicant's 2'-FL and LNnT are identical to those found in human milk, and the maximum levels are within the midrange of concentrations found in human milk, well below the upper end of</li> </ul>

	<p>the range of 2'-FL (7.8 g/L).</p> <ul style="list-style-type: none"> <li>• While clinical studies in infants have not tested 2'-FL at 2.4 g/L, studies in neonatal animals, have tested doses up to 5000 mg/kg bw/day (equivalent to a 6.4 kg 3 month old consuming around 32 g 2'-FL or LNnT/day) with no adverse effects. Neonatal animals are likely to be substantially more sensitive due to their relative gut immaturity compared to human neonates.</li> <li>• The external peer review of FSANZ's safety assessment (SD3) agreed with the conclusions of FSANZ's assessment that no plausible hazards or risks are identifiable for 2'-FL &amp; LNnT at the proposed maximum levels.</li> </ul>
<p>The health outcomes cited by the applicant (i.e. anti-infective and bifidogenic effects) are not sufficiently established in the FSANZ assessment or in the scientific literature.</p>	<ul style="list-style-type: none"> <li>• FSANZ reassessed the beneficial roles and health outcome for 2'-FL and LNnT concluding that: <ul style="list-style-type: none"> <li>- for infants, the addition of 2'-FL and LNnT to infant formula products contributes to a <i>Bifidobacterium</i>-enriched microbiota more similar to breastfed infants than in those fed unsupplemented formula although the size of the effect is difficult to estimate.</li> <li>- for infants and young children, a consistent body of evidence demonstrates a credible mechanism for 2'-FL inhibition of the binding of pathogenic strains of <i>Campylobacter jejuni</i> to intestinal epithelial cells, and limited evidence for a reduction of intestinal colonisation by <i>C. jejuni</i> and the incidence of diarrhoea.</li> <li>- evidence for a link between 2'-FL and/or LNnT in human milk or formula and any specific health outcome is limited to secondary outcomes of one randomised control trial and observational studies for infants</li> </ul> </li> <li>• FSANZ sought advice and comment from an Independent Expert Advisory Group (IEAG) on our approach and conclusions. The IEAG advised that: <ul style="list-style-type: none"> <li>- the approach to FSANZ's assessment is appropriate</li> <li>- there is a bifidogenic effect; but limited evidence in humans to estimate the size of that effect or to link the bifidogenic effect to a beneficial health outcome</li> <li>- there is a dose response effect in relation to the competitive inhibition by 2'-FL of binding of <i>C. jejuni</i> to its epithelial cell receptor; but this inhibitory effect at a cellular level cannot be linked causally to a reduction in infection rates in infants or children because, for obvious reasons, <i>C. jejuni</i> challenge studies in humans are unethical.</li> </ul> </li> </ul>
<p><b><i>The proposed draft variation does not promote consistency between domestic and international food standards where these are at variance</i></b></p> <p><i>Based on the considerations below FSANZ concludes that the draft variation does promote consistency between domestic and international food standards.</i></p>	
<p>The addition of 2'-FL to a maximum level of 2.4 g/L is twice the 1.2 g/L level permitted in most comparable international jurisdictions' standards.</p>	<ul style="list-style-type: none"> <li>• The level sought by the applicant sums to 1.8 g/L for both 2'-FL and LNnT.</li> <li>• 2.4 g/L is currently the highest maximum permitted amount for 2'-FL among 69 approving countries. Other countries' regulations are influenced by approval of 2'-FL alone or in combination with other human milk oligosaccharides and/or other oligosaccharides i.e. ITF/GOS. FSANZ is not permitting combined use.</li> <li>• FSANZ notes 2.4 g/L is a maximum permitted amount – not the proposed use level. This higher maximum level is not trade prohibitive, but enables flexibility for lower use levels permitted elsewhere.</li> <li>• Other countries also permit the addition of 2'-FL to general foods at higher amounts i.e. in Europe, 3 g/L in food supplements, 9.6 g/L in coffee, teas and infusions, 4.8 g/L in total diet</li> </ul>

	<p>replacements<sup>2</sup>.</p> <ul style="list-style-type: none"> <li>• Withholding approval of 2'-FL and LNnT in infant formula products and FSFYC will not promote consistency with international food standards.</li> </ul>
<p><b>The proposed draft variation does not provide adequate information to enable informed choice</b></p> <p><i>Based on the considerations below FSANZ concludes the draft variation does ensure consumers will have sufficient information to make an informed choice.</i></p>	
<p>Failure to require minimum effective concentrations in products may result in consumers being misled as to the efficacy of the products for the stated benefits</p>	<ul style="list-style-type: none"> <li>• There is no minimum effective dose, thus, as for other substances without a health based guidance value, there is no justification to specify a minimum level.</li> <li>• FSANZ has taken an approach which balances provision of adequate information for consumers to select products while also reducing the potential for consumers to be misled. Specific prohibition of references to 'human milk identical oligosaccharides' or similar wording and abbreviations for infant formula products and FSFYC minimises risk of consumers being misled. When added, the substances must use the descriptive names 2'-fucosyllactose and Lacto-N-neotetraose in the statement of ingredients. This also applies to any content claims made on FSFYC.</li> </ul>
<p>No minimum level may prevent consumers making informed decisions about the claimed bifidogenic effects.</p>	<ul style="list-style-type: none"> <li>• This issue is only relevant to FSFYC because infant formula products are prohibited from making claims.</li> <li>• A claim about a bifidogenic effect has not been assessed or permitted as a result of assessing this application. FSANZ concluded the evidence does not support a minimum effective dose for a bifidogenic effect. The independent Expert Advisory Group agreed with FSANZ's conclusion.</li> </ul>
<p><b>The proposed draft variation is difficult to enforce or comply with in both practical or resource terms</b></p> <p><i>FSANZ concludes that the existing Code requirements will enable enforcement.</i></p>	
<p>Failure to specify minimum levels would result in there being no legislative basis for regulators to respond adequately to complaints that may be received during the 15-month exclusivity period</p>	<ul style="list-style-type: none"> <li>• The Code and draft variation will provide enforcement agencies with the information required to respond to complaints. If the oligosaccharides are added, they must be: <ul style="list-style-type: none"> <li>- declared in the ingredient list</li> <li>- quantified in the nutrition information statement (for infant formula products) or nutrition information panel (for FSFYC, if a claim is made).</li> </ul> </li> </ul>
<p><b>The proposed draft variation is not consistent with the objectives of the legislation which establishes FSANZ</b></p> <p><i>Based on the considerations below FSANZ concludes that the draft variation is consistent with the objectives of the legislation that establishes FSANZ and which governs standards development by both FSANZ and the Forum.</i></p>	
<p>Claims that 2'-FL and LNnT 'reduce severity of invasive <i>Campylobacter jejuni</i> infection' and provide 'inhibitory effect against invasive <i>C. jejuni</i> infection' are about alleviating or preventing disease and therefore therapeutic rather than nutritive in nature.</p>	<ul style="list-style-type: none"> <li>• The assessment does not relate to a therapeutic purpose such as prevention or treatment. It relates to the normal growth and development of healthy full term infants and young children including through reduction of risk. Risk reduction is a common aim of food regulation such as in mandatory folate fortification to reduce the risk of infants born with neural tube defects.</li> <li>• There is a consistent body of evidence demonstrating a credible mechanism for 2'-FL inhibition of the binding of pathogenic strains of <i>Campylobacter jejuni</i> to intestinal epithelial cells. Limited studies provide evidence for a reduction of intestinal colonisation by <i>C. jejuni</i> and the incidence of diarrhoea. This is consistent with observational data that breastfed infants of mothers with a higher</li> </ul>

<sup>2</sup> EC Union list of novel foods <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2470>

	<p>proportion of 2'-FL in their milk have lower rates of <i>Campylobacter</i>-induced diarrhoea, although it is not possible to attribute the difference in infection rates to the 2'-FL alone.</p> <ul style="list-style-type: none"><li>• No claim has been assessed by FSANZ in this application. Therapeutic claims are also prohibited by the Code.</li></ul>
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The decision to re-affirm is based on a risk analysis including assessment of the best available evidence, consideration of the objectives in section 18 of the FSANZ Act, a cost benefit analysis and consideration of the concerns of the Forum.

# Introduction

On 17 February 2020, the Forum requested a review of the FSANZ Board's decision to approve an amendment to permit the addition of 2'-FL and LNnT to infant formula products and formulated supplementary foods for young children (aged 1 to <4 years) (FSFYC, particularly products known as toddler milk) up to 2.4 g/L combined.

Glycom A/S applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of 2'-O-fucosyllactose (2'-FL), either alone or in combination with Lacto-N-neotetraose (LNnT) to infant formula products and FSFYC. The applicant also requested exclusive permission for their brand of 2'-FL and LNnT for a period of 15 months after gazettal.

The applicant's stated purpose for adding 2'-FL and LNnT to infant formula products was to create products that better reflected the oligosaccharide profile of human milk. In addition, the substances are claimed to: exert bifidogenic effects, adhere to pathogens in the gut with anti-infective benefits, and provide immune modulation, improved intestinal barrier function and alleviation of allergic responses. Addition to formulated supplementary foods for young children was to extend these beneficial effects to this population.

## 1.1 FSANZ Assessment of A1155 at Approval

In December 2019, FSANZ approved the voluntary addition of Glycom's human milk identical 2'-FL and LNnT to infant formula products and FSFYC up to 2.4 g/L combined. This decision was based on the following conclusions of comprehensive risk analysis using the best available evidence:

- The two oligosaccharides are found in human milk. The applicant's 2'-FL and LNnT are structurally and chemically identical to the oligosaccharides in human milk, and are produced by microbial fermentation from genetically modified (GM) *Escherichia coli* K12 production strains SCR6 and MP572, respectively.
- The proposed concentrations to be added to infant formula products are in the midrange of concentrations found in mature human milk.
- There are no safety concerns with the use of 2'-FL and LNnT at the proposed levels. Clinical studies in formula-fed infants and appropriate toxicological studies in experimental animals, including studies in neonatal animals, were available to support the safety of these substances.
- FSANZ's safety assessment conclusions are consistent with the assessments and approvals in several overseas markets.
- The FSANZ assessment considered the best available evidence on: the levels of both oligosaccharides in human milk, data on the differences between formula-fed and breastfed infants, the mechanisms of action and demonstrated physiological effects. The assessment concluded that 2'-FL and LNnT have a demonstrated mechanism for a bifidogenic effect and some evidence it. There is also a demonstrated pathogen binding mechanism and a benefit by reducing the risk of invasive strains of *Campylobacter jejuni* binding to intestinal epithelial cells. These effects are similar to those in breastfed infants and are thus regarded as favourable to infants and young children.
- The assessment also concluded insufficient evidence exists to substantiate an immune modulating effect, improved intestinal barrier function, or protective effects against allergic responses for 2'-FL and LNnT.
- Permitting these oligosaccharides benefits trade and international harmonisation, and supports innovation in the food system and thus provides net benefits to the community.

## 2 The Review

The [Forum requested FSANZ review its decision](#) to approve the draft variations arising from Application A1155 on the following grounds:

- (i) it is not consistent with existing policy guidelines set by the Forum
- (ii) it is not consistent with the objectives of the legislation which establishes FSANZ
- (iii) it does not protect public health and safety
- (iv) it does not promote consistency between domestic and international food standards where these are at variance
- (vi) it does not provide adequate information to enable informed choice
- (vi) it is difficult to enforce or comply with in both practical or resource terms

Additional comments were provided by Ministers and are detailed in section 4.

### 2.1 Statutory context for the review

Section 87 of the FSANZ Act requires FSANZ to review an approved draft variation when requested by the Forum. The FSANZ Act requires FSANZ to have regard to certain matters when undertaking that review. These are in addition to the Forum's stated reasons for requesting the review.

Subsection 18(1) of the FSANZ Act lists in order of priority three objectives for FSANZ including when undertaking a review. The protection of public health and safety has the highest priority. Subsection 18(2) lists other secondary matters to which FSANZ must have regard in reviewing food regulatory measures. Paragraph 18(2)(e) of the FSANZ Act requires FSANZ to have regard to any written policy guidelines formulated by the Forum. The section makes clear that the requirement is only to give regard to the policy guidelines; they are not binding on FSANZ. The FSANZ Act also makes clear that the Forum cannot direct what FSANZ must decide in a review.

Section 29 of the FSANZ Act requires FSANZ to have regard to specific matters when assessing an application and when deciding to approve a draft variation developed as a result of an application. These matters remain relevant considerations for FSANZ when conducting a review requested by the Forum.

Each of the above sections and matters are considered in section 4 of this report.

### 2.2 Scope of the review

The objective of this Review is to reconsider the decision and draft variation in light of the Forum's concerns and the FSANZ Act requirements.

FSANZ's original assessment considered several possible beneficial roles for 2'-FL and LNnT. Only two of these were substantiated. The others have not been considered in this review: immune modulation, improved barrier function, and alleviation of allergic responses as our assessment previously concluded there is limited evidence to support a substantiated role of 2'-FL and LNnT for these effects. Several issues related to toddler milk were raised by the Jurisdictions and Forum of this review. FSANZ's consideration of these is summarised below:

#### *Nutrition content and health claims*

The Code's conditions for making voluntary nutrition content and health claims are regulated by Standard 1.2.7, Schedules 4, 5 and 6. Section 1.2.7—4 of Standard 1.2.7 expressly

prohibits nutrition content and health claims from being made about infant formula products. FSANZ notes two current policy guidelines (Nutrition, Health and Related Claims; and Special Purpose Foods) and the existing claims framework allow claims to be made about nutritive substances, vitamins and minerals on FSFYC. Therefore, prohibiting claims relating to 2'-FL and LNnT on FSFYC would be inconsistent with current policy guidance and existing labelling permissions, as described above.

The scope/aim of the policy guideline on the intent of Part 2.9 Special Purpose Foods specifically states 'policy guidance in relation to nutrition, health and related claims on special purpose foods is covered by the Policy Guideline on Nutrition, Health and related claims.' The Policy Guideline on Nutrition, Health and Related Claims was updated and endorsed on 29 June 2018.

#### *Need for toddler milk products*

The Forum raised their concerns that FSFYC (toddler milk) is not needed for healthy children, noting the Australian Dietary Guidelines advise children over 1 year of age should consume foods consistent with dietary guidelines. As these products are permitted and regulated and already on the market in Australia and New Zealand, this issue is broader than the scope of this review.

#### *Marketing of toddler milk products*

Concerns have been raised about broader marketing practices for toddler milk products on the basis that mechanisms to prevent inappropriate marketing in relation to toddler milk are limited. Advertising and labelling is subject to the Code requirements and restrictions, however marketing of foods including FSFYC is not within the remit of the Code. FSANZ is therefore unable to address issues related to marketing in this review.

#### *Cross promotion of toddler milks and infant formula*

Concerns have been raised about the general promotion of toddler milks, and claims on toddler milk being used to promote infant formula products (i.e. cross promotion). We acknowledge approval of this application will allow nutrition content and health claims about these substances to be made on FSFYC subject to meeting the conditions and requirements of Standard 1.2.7. As noted above, the current policy and regulatory environment permits claims on FSFYC. In this case, prohibiting such claims would be inconsistent with current Ministerial policies: Nutrition, Health and related claims; and Special Purpose Foods. It would also create an inconsistency with existing labelling permissions for other nutritive substances such as vitamins. FSANZ considers a restriction on nutrition content and health claims for FSFYC should be addressed more broadly as a policy matter.

Further, a prohibition on nutrition content and health claims would not address the broader issue of 'cross marketing' between FSFYC and infant formula products. Given that nutrition content and health claims about other permitted nutritive substances are permitted for FSFYC (e.g. lutein, vitamins and minerals), FSANZ considers it would be more appropriate for this issue to be considered as a policy matter separately.

#### *Summary*

Having considered these concerns FSANZ notes they relate to the current general regulation of nutrition and health claims and toddler milk products, whereas this application relates to the addition of optional ingredients to both infant formula products and FSFYC. This application review cannot not be the vehicle to address a concern that relates to the all toddler milk products. As such, FSANZ considers it is not open to rejecting the application or the draft variation on the basis of the concerns raised above.

### 3 Decision

FSANZ's decision has been reached after having regard to the Forum's review request and all the matters required by the FSANZ Act – including the section 18 objectives (in that section's required order of priority) and the policy objectives - and after careful consideration of the extensive evidence available (including the best available scientific evidence).

FSANZ re-affirms permission for addition of the applicant's 2'-FL and LNnT to infant formula products and FSFYC at the levels proposed at approval. In reviewing the approval decision, FSANZ used the best available evidence to further assess the health risks and benefits, the commercial and economic impacts, and consistency with Ministerial policy guidelines.

FSANZ's review re-affirms the proposed addition to infant formula products and FSFYC poses no health risk, engenders favourable physiological effects similar to breastfed infants, with outcomes more similar to breastfed infants than infant consuming unsupplemented formula and a possible link to a favourable health outcome through risk reduction, especially for toddlers. It also applies labelling requirements to enable informed choice and lessen the risk of consumers being misled, and provides opportunities for industry to innovate, efficiently compete internationally through supported export, thus providing a net community benefit. In coming to this conclusion, FSANZ has had extensive regard to both high order and specific policy principles in relevant Ministerial policy guidelines.

The FSANZ Board re-affirms its approval of the draft variation. The reaffirmed draft variation is at Attachment A and explanatory memorandum at Attachment B.

### 4 Reasons for decision

The reasons for decision relate to the grounds for review and the FSANZ Act requirements. These are discussed in the following sections.

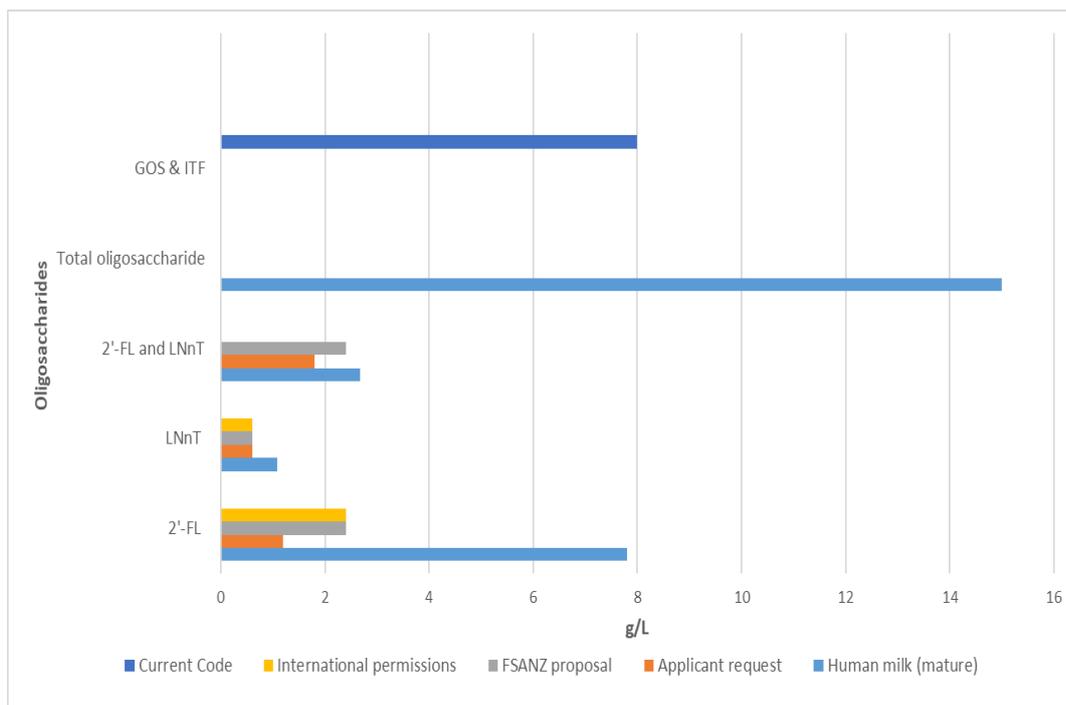
#### 4.1 Protection of public health and safety

Infants are recognised as a vulnerable population group, hence infant formula is tightly regulated in the Code. FSANZ uses the internationally accepted risk analysis framework in our decision making; this takes into account the importance of the role of formula as a potential sole source of nutrients and the vulnerability of the formula-fed infant population. The Forum raised three concerns related to the FSANZ Act objective of protection of public health and safety, two are discussed below while the third is discussed in section 4.2.

##### **4.1.1 FORUM CONCERN: It has not been demonstrated that addition of 2'-FL and LNnT to infant formula at the proposed levels is consistent with the protection of public health and safety**

FSANZ has undertaken a comprehensive safety assessment, based on international best practice, using standard approaches to toxicological and safety assessment. The updated safety assessment (detailed in SD1) continues to support the levels proposed at Approval.

The proposed maximum permitted amount and the concentrations expected to be added to infant formula products are within the midrange of concentrations found in mature human milk. This is about one fifth of the total concentration of oligosaccharides present in mature human milk (10–15 g/L). Figure 1 below provides a comparison of oligosaccharide levels in regulation and human milk.



Notes to figure:

Human milk levels based on [Table 3.13 and 3.14 in SD1 at 2nd CFS](#).

Figure 1: Comparison of oligosaccharide levels in regulation and human milk

There is no evidence of adverse effects in an extensive and comprehensive set of preclinical toxicity studies, including in appropriate neonatal animal models. Neonatal animals are considerably more sensitive to systemic toxicity, local irritation and osmotic related effects than human term neonates due to their comparative gut immaturity. The animals were also dosed at levels far exceeding those of the target population and for a much greater relative period of their life (e.g. up to 9–10 years in human terms). The absence of any identifiable hazard in these studies, which include detailed histopathology unavailable in human clinical studies, provides robust evidence of safety in humans (Table 1).

Three human milk cohort studies and six clinical trials of supplemented infant formula were assessed. None of the clinical studies examined by FSANZ identified adverse effects or any difference in growth between infants fed formula containing 2'-FL and/or LNnT compared with infants fed control formula. A real-world evidence study of infants fed formula containing 2'-FL and LNnT also found the formula was well tolerated.

#### Safety assessments by other regulatory bodies

The European Food Safety Authority (EFSA) assessed 2'-FL<sub>chem</sub> and LNnT<sub>chem</sub> produced by Glycom as a novel food ingredient in 2015. It was concluded that 2'-FL was safe for use alone or in combination with LNnT when added to infant formula, follow-on formula and young-child formula at concentrations up to 1.2 g/L 2'-FL and 0.6 g/L LNnT at a ratio of 2:1 (total 1.8 g/L) (EFSA 2015a; EFSA 2015b). The Food Safety Authority of Ireland (FSAI) has issued opinions concluding that Glycom's 2'-FL<sub>micro</sub> and LNnT<sub>micro</sub> are substantially equivalent to the previously approved chemically synthesised form, and therefore raise no safety concerns (FSAI 2016a; FSAI 2016b).

The Netherlands Committee on Safety Assessment of Novel Foods completed an evaluation of 2'-FL<sub>micro</sub> produced by Jennewein in 2016 (NFU 2016). This assessment concluded that the evidence presented adequately demonstrated that 2'-FL can be safely used as an ingredient in infant formula and follow-on formula at the proposed use level of up to 2 g/L.

EFSA has also assessed a mixture of 2'-FL and difucosyllactose (7:1 ratio). EFSA concluded that the use of this mixture in infant formula can be considered safe at the requested maximum use level of 1.6 g/L because the intake of 2'-FL and DFL is unlikely to exceed the intake level of naturally occurring 2'-FL and DFL in breastfed infants (EFSA 2019).

Several other regulatory agencies have undertaken assessments on different 2'-FL and LNnT products including Singapore, Malaysia, Russia, and Thailand. Several companies have GRAS for their particular 2'-FL and LNnT in the US and several infant formula manufacturers have approval for the use in infant formula products from the US FDA.

#### *Peer review of FSANZ's safety assessment*

FSANZ requested a peer review of the safety assessment by Professor (adj) Andrew Bartholomeus of the University of Queensland and University of Canberra (SD 3). The peer review concluded that FSANZ's assessment is of high quality, reflects careful and competent evaluation of the available data and the conclusions are consistent with and proportionate to the data available. The review also noted that there is nothing either present or absent in the data that would provide a scientifically justifiable basis for rejecting the application on the grounds of safety. It was concluded that no plausible hazards, and therefore risks, are identifiable for 2'-FL and LNnT at the levels proposed to be permitted.

#### *Adverse event reporting*

Based on information provided to FSANZ, 69 countries currently permit the addition of 2'-FL to infant formula products. FSANZ contacted the applicant and infant formula companies seeking information on volumes of product sold and on post market surveillance data including adverse event reporting, and any food or ingredient recalls. The applicant provided information on the volumes of 2'-FL/LNnT going to make infant formula and toddler milk products in approved in markets around the world. In 2017/2018 there was >450 MT of 2FL/LNnT and in 2019 >700 MT sold to formula companies. FSANZ is not aware of any evidence of adverse effects related to the addition of 2'-FL/LNnT in infant formula products and toddler milk products in other countries.

#### **4.1.2 FORUM CONCERN: The safety of long term consumption of 2'-FL at levels of up to 2.4 g/L has not been demonstrated in the target population.**

FSANZ's safety assessment has concluded that the proposed maximum levels do not pose a safety risk. Oligosaccharides are indigestible short chain carbohydrates and the third largest solid component of human milk. The synthesised 2'-FL and LNnT are chemically and structurally identical to those found in human milk. Intestinal absorption of 2'-FL and LNnT is limited, and a large proportion of these substances passes to the large intestine, where they are fermented by the intestinal microbiota or excreted intact in the faeces. The proposed maximum permitted amount and the concentrations expected to be added to infant formula products are consistent with levels found in mature human milk (refer to Figure 1 above). This provides an appropriate history of safe human use in the target populations. The safety assessment is summarised in Table 1.

**Table 1 Summary of the key findings of the safety assessment**

Evidence	What this means
Human milk oligosaccharides (HMOs) are the third largest component in human milk after lactose and fats. Human milk contains a range of HMOs, including 2'-FL and LNnT.	There is a history of safe consumption of 2'-FL and LNnT by the human infant population.
The synthesised 2'-FL and LNnT have been shown to be structurally identical to the 2'-FL and LNnT found in human milk.	As they are identical there is no reason to assume that 2'-FL and LNnT would be less safe than 2'-FL and LNnT found in human milk.
Concentrations of 2'-FL and LNnT found in human milk range from: <ul style="list-style-type: none"> <li>• 2'-FL: 1.0 – 7.8 g/L</li> <li>• LNnT: 0.09 – 1.08 g/L</li> </ul>	The maximum concentrations of added 2'-FL and LNnT proposed in infant formula are within the midrange present in human milk, and well below the upper end of the range. Therefore there is a history of safe use in the target population at concentrations well in excess of the proposed concentrations.
Absorption of 2'-FL and LNnT is very limited.	<p>Only very small amounts of 2'-FL and LNnT are absorbed and enter the circulation. Once absorbed they are eliminated in the urine.</p> <p>A recent study comparing breastfed infants with those consuming infant formula supplemented with a chemically-synthesised form of 2'-FL found no evidence to suggest that absorption or urinary elimination of the synthetic 2'-FL is significantly different to that of 2'-FL in human milk.</p>
<p>Toxicity studies that confirm the safety of 2'-FL and LNnT include:</p> <p><u>2'-FL</u></p> <ul style="list-style-type: none"> <li>• Three studies in neonatal rats showing no harmful effects at doses up to 5000 mg/kg bw/day</li> <li>• A study in neonatal piglets showing no harmful effects with formula containing 2'-FL at 2 g/L</li> <li>• Three studies in older rats showing no harmful effects at doses up to more than 7000 mg/kg bw/day</li> <li>• Thirteen negative genotoxicity studies with 2'-FL from six different sources</li> </ul> <p><u>LNnT</u></p> <ul style="list-style-type: none"> <li>• Two studies in neonatal rats showing no harmful effects at doses up to 5000 mg/kg bw/day</li> <li>• Five negative genotoxicity studies with LNnT from two different sources</li> </ul>	<p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has concluded that safety studies in very young animals are critical for substances used in infant formula. These studies provide a more complete evaluation of safety than human clinical studies. This is because they include detailed investigations that cannot be done in human studies, such as microscopic examination of organs and tissues.</p> <p>In addition, neonatal rats are likely to be substantially more sensitive to any adverse health effects due to their relative gut immaturity compared to human neonates.</p> <p>No treatment-related harmful effects were observed in these studies even at very high doses.</p>
<p>At the maximum levels proposed in infant formula, follow-on formula &amp; FSFYC the 90<sup>th</sup> percentile intake of 2'-FL or LNnT is estimated at the following daily levels:</p> <p><i>2'-FL max of 2.4 g/L</i>  3 month old infants - 1.9 g/day  9 month old infants - 1.3 g/day  12 month old infants – 0.9 -1.9 g/day  depending on the serving size (115 - 230 ml)</p>	<p>The estimated dietary intakes are similar to or less than those for younger formula-fed and breastfed infants (&lt; 12 months).</p> <p>No adverse effects were observed in neonatal animals at doses up to 5000 mg/kg bw/day. This would be equal to a 3 month old infant (weighing 6.4 kg) consuming around 32 g 2'-FL or LNnT/day. This is substantially higher than the intakes estimated based on the proposed maximum levels.</p>

Evidence	What this means
<p><i>LNnT max of 0.6 g/L</i>            3 month old infants - 1.1 g/day            9 month old infants – 0.71 g/day            12 month old infants – 0.24 – 0.48 g/day            depending on the serving size (115 - 230 ml)</p>	
<p>Seven clinical studies of infants found that 2'-FL and/or LNnT were well tolerated at concentrations up to 1.2 g/L 2'-FL and 0.6 g/L LNnT.</p>	<p>The lack of harmful effects in clinical studies supports the findings of the toxicity studies in neonatal animals.</p>
<p>FSANZ is unaware of any reports of adverse events associated with the use of 2'-FL and LNnT in countries in which it is approved. Infant formula containing 2'-FL and LNnT is currently available in 69 countries.</p>	<p>Companies maintain in house post-market surveillance systems. A number of countries have some type of post-marketing monitoring system and adverse event reporting. FSANZ has been unable to find any issues related to 2'-FL &amp; LNnT in infant formula products. Companies have reported they have not received any adverse event reports or had to undertake any food recalls related to 2'-FL and LNnT in foods.</p> <p>Use is well tolerated in these countries with no evidence of harmful effects.</p>

## 4.2 FORUM CONCERN: The draft variation does not have sufficient regard to Ministerial Policy Guidelines

Two Ministerial policy guidelines are relevant to this application. Each guideline provides both high order and specific policy principles. The high order policy principles reiterate the statutory objectives in the FSANZ Act. FSANZ has given full regard to both policy guidelines in further assessment and decision making. The Forum raised concerns that FSANZ's assessment and decision was not consistent with the policy guidelines, and did not have sufficient regard to the policy guidelines. The following discussion summarises FSANZ's consideration of each policy guideline and response to the issues raised.

### 4.2.1 Policy Guidelines for Regulation of Infant Formula Products

In addition to the high order principles, this policy guideline contains 17 Specific Policy Principles (SSP) grouped into: overarching principles, and principles for composition, labelling & advertising, and infant formula products for special dietary uses. Additional advice suggests the establishment of an independent advisory scientific group, and consistency as much as possible with WHO and WTO agreements, and Codex standards.

The major concern raised by the Forum is relevant to only one SPP – *“insufficient regard has been given to Specific Policy Principle (j)”*. The Forum stated that the health outcomes cited by the applicant (i.e. anti-infective and bifidogenic effects) are not sufficiently established in the FSANZ assessment or in the scientific literature. SPP (j) outlines the need for substantiation of a beneficial role in normal growth and development at levels comparable to human milk. Specifically, appropriate evidence should exist to link physiological, biochemical or functional effects to health outcomes in infants or children. It also provides for a cautionary approach where such links are not clear.

Substantiation refers to the process of evaluating the evidence. FSANZ's assessments are undertaken with regard to all high and specific order principles of the policy guideline (including SSP (j)); they outline the framework for consideration of beneficial roles and health effects. Using the best available evidence, the assessment will consider the normal growth

and development in healthy breastfed infants (SSP (d) and (e)). Human milk composition is used as a primary reference (SSP (h)). In the context of this review, FSANZ considers that a health outcome should be considered in the context of shifting outcomes of formula-fed infants closer to those of breastfed infants.

### ***Health effects and Human milk***

Human milk is well recognised for its benefits to infant health and development, in particular for immunological protection (ABA 2013; Agostini et al., 2009; NHMRC, 2012). Breastfed infants have fewer infections (gastro intestinal infections, ear infections and respiratory tract infections) than formula-fed infants, and when infected have shorter and less severe illness than formula-fed infants (Agostini et al., 2009, Ip et al., 2007; Horta et al. 2013).

Several components of breast milk are attributed to the development of the infant immune system including antibodies, oligosaccharides, lactoferrin and lysozyme (NHMRC, 2012). These associations are based primarily on observational studies, and it is difficult to infer causality for any one substance and the health outcome (Ip et al., 2007; Valdes et al 2018). It is often not possible to conclusively attribute a specific breast milk component to a particular health outcome. There are inherent practical and ethical issues that prohibit prospective randomised intervention trials of different infant feeding regimens. There are also challenges with measuring a 'health outcome' resulting from the addition of a substance to infant formula, noting outcomes can range from biochemical effects to clinical effects that have significance on the functioning of the entire body. In this context, evidence comparing outcomes in healthy breastfed infants with formula-fed infants and supplemented formula-fed infants is considered an internationally accepted approach (IOM, 2004; Ryan & Hay 2016). Evidence which demonstrates a plausible mechanism of action, preferably in infancy or childhood, is an important contribution to this consideration.

### ***Bifidogenic effect***

FSANZ has reassessed the evidence for a bifidogenic effect of 2'-FL and LNnT, by examining the differences between healthy formula-fed and breastfed infants and the mechanisms of action for the bifidogenic effect. This is discussed in more detail in SD2.

Development of the infant microbiome is considered an important part of normal development. There is no universal standard for a healthy intestinal microbiota, however the composition of exclusively breastfed infants is generally the accepted reference standard for the normal, healthy development of an infant's gut microbiome. There is broad scientific consensus that a *Bifidobacterium*-enriched microbiota has functional benefits in the normal growth and development of breastfed infants and plays a role in reported differences in health outcomes between breastfed and formula-fed infant populations. As prebiotics, human milk oligosaccharides are recognised as one of the principal growth factors for bifidobacteria in the infant gut and are considered responsible for the composition of the gut microbiota found in breastfed infants (EFSA 2014). The link between breastfeeding and higher levels of bifidobacteria in the infant gastrointestinal tract (GIT) is reasonably well established from numerous observational studies on the effects of formula feeding and breastfeeding on the composition of the infant gastrointestinal microbiota. Although there is variability in the results, most conclude that the proportion of bifidobacteria and lactobacilli is significantly lower for formula-fed infants. In most cases, the precise molecular mechanisms underlying such beneficial effects are still to be fully characterised. A direct link between levels of 2'-FL and LNnT in human milk and levels of bifidobacteria in the infant gastrointestinal tract is not well established, as there is significant variability in the results of observational studies investigating this relationship.

A credible mechanism by which HMOs influence the composition of the gastrointestinal microbiome has been established through a number of *ex vivo*, *in vitro* and *in silico* studies on the utilisation of specific HMOs by bifidobacteria isolated from infant gastrointestinal tracts. The results from a small number of human intervention and observational studies on breastfed and formula-fed infants are also supportive of a bifidogenic effect of 2'-FL and LNnT, but the quality of the body of evidence limits confidence in the size of the effect.

Evidence for a link between specific outcomes and supplementation with 2'-FL and/or LNnT is limited. Secondary outcomes from one randomised controlled clinical trial support a conclusion that addition of synthetic 2'-FL and LNnT to infant formula contributes to outcomes for formula-fed infants more in line with those of healthy breastfed infants. However, certainty about the extent of any beneficial effects of 2'-FL and LNnT on infant health is low because the body of evidence is limited.

#### *Independent expert advisory group*

A1155 Independent Expert Advisory Group (IEAG) provided advice to FSANZ on the approach to the assessment of the health benefits of 2'FL and LNnT used in infant formula products and FSFYC; the strength and adequacy of the evidence base; and the appropriateness of the conclusions of the assessment. FSANZ has taken the advice and key conclusions of the IEAG discussions into account in benefit assessment as part of the review report, as appropriate. The IEAG noted that:

- The approach comparing microbiome compositions of breastfed vs formula fed infants, the levels of bifidobacteria and levels of oligosaccharides in milk is appropriate.
- bifidogenesis is important in normal infant development
- There are differences in the effects of human milk and infant formula on the microbiome. The changes can be considered normal development, but there is contextual variation.
- there is a bifidogenic effect; but limited evidence in humans exists to estimate the size of the effect or to link the bifidogenic effect to a beneficial health outcome
- there are many different factors which influence infant health, and that it is not possible to determine a linear effect from the presence of one substance in human milk and a specific health outcome.

#### ***Pathogen-binding and inhibition effect***

As discussed in SD2, further consideration was given to the assessment of the inhibitory effect of 2'-FL on the binding of pathogenic strains of *Campylobacter* to the infant gastrointestinal epithelium.

As glycans, human milk oligosaccharides are recognised as one of the components in human milk that contribute to facilitation of optimal function of the infant's immature systems and confer both active and passive immunity (NHMRC, 2012; Varki and Gagneux, 2017). Many glycans function, in humans and other organisms, as binding sites for viruses, bacteria, parasites and their toxins. Unsurprisingly, they also undertake a similar function for some commensal bacteria (Smilowitz et al 2014; Varki et al., 2017; Orczyk-Pawłowicz & Lis-Kuberka , 2020).

Gastrointestinal illness is a leading cause of infant and toddler morbidity and mortality, with an estimated 300 000 episodes of diarrhoea leading to the death of infants globally in 2011 (Walker et al., 2013). *Campylobacter jejuni* is recognised as one of the major bacterial causes of infant diarrhoea in developing and developed countries (Fullerton et al., 2007; Kotloff et al., 2013). *Campylobacter* infections are one of the most common causes of gastrointestinal disease, particularly in children under 5 years of age. In Australia, the rate of

notifications of *Campylobacter* infection is highest in children aged up to 4 years old (NNDSS Annual Report Writing Working Group, 2019). In New Zealand in 2018 infants less than 1 year (241.0 per 100,000) had the highest *Campylobacter* infection notification rates (Institute of Environmental Science and Research Ltd., 2019).

In full-term infants, breastfeeding exclusively to 6 months of age and partially thereafter, has been associated with a significant reduction in infections of the gastrointestinal tract of infants (Kramer et al. 2001; Kramer et al. 2003; Duijts et al. 2010; Tarrant et al. 2010). Oligosaccharides in human milk are one of the components attributed to this protective effect (Lawrence and Pane 2007; Cacho and Lawrence 2017). Several observational studies report a strong protective effect of exclusive and partial breastfeeding specifically for *Campylobacter* infection and diarrhoea (Ruiz-Palacios et al., 1990; Nachamkin et al., 1994; Fullerton et al., 2007; Bilenko et al., 2008).

In cases where individuals develop clinical enteritis after exposure to *C. jejuni*, the bacteria preferentially adhere to the mucus layer of the small intestine. Some strains may attach directly to intestinal epithelial cells, which may lead to bacterial invasion, translocation and bacteraemia (Cooling, 2015). Evidence from *in vitro*, *ex-vivo* and animal studies consistently demonstrate a credible mechanism for competitive inhibition by 2'-FL of the binding of pathogenic *C. jejuni* to H-2 histo-blood group antigens on intestinal epithelial cells. Synthetic 2'-FL inhibits this binding—and binding-dependent invasion of epithelial cell lines—in a dose-dependent manner. It has also been demonstrated that pathogenic *C. jejuni* bind with high avidity to immobilised 2'-FL *in vitro*. Results from animal studies are consistent with such inhibition reducing *C. jejuni* intestinal colonisation and the incidence of diarrhoea.

However, there is no direct evidence from human clinical trials that 2'-FL undertakes this beneficial role in breastfed infants or as a component of infant formula products. For obvious ethical reasons, infant trials cannot test if 2'-FL added to infant formula inhibits pathogen-binding of *Campylobacter* and subsequent infection rates in infants. Evidence from one human study showing a decreased incidence of *Campylobacter*-associated diarrhoea in infants of mothers with a higher proportion of 2'-FL in their milk is consistent with the proposed pathogen-binding effect of 2'-FL, but is insufficient to conclusively demonstrate the likelihood of a positive health outcome from supplementation of infant formulas and FSFYC with 2'-FL.

Since the link between 2'-FL in infant formula and a reduction in infections in infants is less clear, FSANZ used particular caution to reach its conclusions. FSANZ has used appropriate evidence to understand the pathogen binding mechanism and considered this in the context of observational studies and epidemiological studies indicating 2'-FL may contribute to reducing the risk of *C. jejuni* infections. FSANZ considers it to be self-evident that any reduction in severity of an invasive infection with *C. jejuni* is beneficial to infants. A reduction in GI infections in formula-fed infants to rates similar in breastfed infants would align with the intention of the ministerial policy guidelines (SSP d & e). FSANZ therefore considers this assessment aligns with SPP (j).

#### *Independent expert advisory group*

The IEAG concluded that the approach to the assessment taken by FSANZ is appropriate. Also there is a 'dose response effect' in relation to the competitive inhibition by 2'-FL of binding of *C. jejuni* to its epithelial cell receptor; but that this cannot be extrapolated to a dose response effect on reducing infection in infants or children, because those types of studies cannot be done in humans.

#### 4.2.2 Policy Guideline on the intent of Part 2.9 – Special Purpose Foods as it relates to FSFYC

The Policy Guideline for special purpose foods contains the same high order policy principles as the infant formula products guideline, and four specific policy principles; it applies to all food standards in Part 2.9 of the Code including FSFYC. The high order policy principles reiterate the objectives outlined in section 18(1) and (2) of the FSANZ Act. As 2'-FL and LNnT are permitted in this food in several other countries, the proposed permission supports consistency between international and domestic regulation as well as an efficient and competitive food industry (high order policy principles 2(b) and (c)), providing trade opportunities; and provides an alternative to existing permitted oligosaccharides (GOS and ITF) which introduces innovation opportunities for Australian and New Zealand industry.

Several concerns relating to FSANZ's regard for this policy guideline were highlighted in the reasons for review. However, a consistent theme related to the specific policy principle that '*the composition of the special purpose food should be consistent with its intended purpose*'. Specifically the Forum indicated that 2'-FL & LNnT added to FSFYC served no nutritional purpose since a young child has no physiological need for HMO.

The Australian Infant Feeding Guidelines recommend that toddler milks are not required for healthy children also that from 12 months of age and beyond, toddlers should be consuming family foods consistent with the Australian Dietary Guidelines (NHMRC 2012). The New Zealand Food and Nutrition Guidelines note that '*If a toddler is eating a variety of foods, including good sources of iron, and is not consuming more than 500 mL of cows' milk per day, then the extra nutrients in toddler milks generally provide no benefits*' (Ministry of Health 2008).

The purpose of FSFYC (as defined in the Code) is to supplement young children's diets when nutrient intakes may be inadequate. Although these products are not necessary for healthy children, they are recognised as supplementary nutrition for some groups whose diets do not reflect dietary recommendations. The EFSA (2013) concluded products such as 'toddler milks' are one of several means to increase intakes of key nutrients in young children, in combination with other foods sources. Suthutvoravut et al (2015) also noted that, when children do not achieve adequate nutrient intakes from eating normal foods, these products can be considered as one way to improve nutrient intakes (in combination with other foods). The literature indicates that toddler milk products can be a useful source of nutrients for young children in Australia, New Zealand and similar developed countries (Szymlek-Gay et al 2019; Walton & Flynn 2013) under such circumstances.

It is recognised that the diet in early childhood influences the continuing establishment of the gut microbiota (Mohammadkahah et al 2018; Robertson et al 2019). In this context a prebiotic bifidogenic effect can be relevant to young children, particularly if they are not consuming fibre-rich foods. As shown in figure 1 above, GOS and ITF are already permitted in FSFYC at higher levels than proposed for 2'-FL and LNnT.

*Campylobacter jejuni* is recognised as one of the major bacterial causes of diarrhoea in infants and young children in developing and developed countries (Fullerton et al., 2007; Kotloff et al., 2013). In Australia, the rate of notifications of *Campylobacter* infection is highest in children aged up to 4 years old (NNDSS Annual Report Writing Working Group, 2019). In 2018, the notification rate for the age group was 210.1 cases per 100 000 resident population, compared to 135.5 cases per 100 000 resident population for all age groups (NNDSS, 2020). A similar trend is observed in New Zealand, in 2017 children aged 1–4 years (257.9 per 100,000) had one of the highest *Campylobacter* infection notification rates (Institute of Environmental Science and Research Ltd., 2019).

Young children who have not received any human milk as an infant have been shown to have more gastrointestinal infections and diarrhoea. FSANZ concludes that consuming a FSFYC may provide favourable risk reduction and therefore health effects for young children when they are not consuming an adequate diet.

The evidence assessed by FSANZ from *in vitro* and human studies demonstrates the likelihood of FSFYC supplemented with 2'-FL and LNnT having a bifidogenic effect in humans, including in toddlers. Direct evidence that a bifidogenic effect occurs in children fed FSFYC supplemented with synthetic 2'-FL and/or LNnT is very limited. The available clinical studies were mainly conducted in infants, with only one in young children (up to 24 months) and one adult study.

### **4.3 The draft variation is not consistent with the objectives of the legislation that establishes FSANZ.**

The Forum noted claims that 2'-FL and LNnT 'reduce severity of invasive *Campylobacter jejuni* infection' and provide 'inhibitory effect against invasive *C. jejuni* infection' are about alleviating or preventing disease and therefore therapeutic rather than nutritive in nature.

The infant formula policy guideline specifies that substances added to infant formula products should have either a technological function, or a beneficial role – with a determined physiological, biochemical or functional effect in normal growth and development for infancy or childhood. Applications must specify this role and provide evidence to substantiate the effect. Consistent with this, the applicant provided evidence for a number of health effects of 2'-FL and LNnT. FSANZ assessed the evidence for these specified effects. The assessment is not considered to relate to a therapeutic purpose such as prevention or treatment.

As discussed in section 4.2, FSANZ has determined there is a credible mechanism for 2'-FL binding of invasive *C. jejuni* strains and its subsequent inhibition of their attachment and growth. FSANZ considers this competitive binding is likely to reduce the risk of infection when infants and young children are exposed to invasive strains of *C. jejuni*. This is consistent with observational data that breastfed infants have lower rates of *Campylobacter* induced diarrhoea. It is also consistent with the knowledge that breastfed infants have less severe and shorter GI infections than formula-fed infants. In the context of comparing outcomes of formula-fed infants with breastfed infants, FSANZ does not consider this is a therapeutic effect. In the earlier reports we have termed this 'an anti-infective' as the mechanism can reduce the number of *C. jejuni* that are available to bind to the gut and contribute to development of an infection. In the Approval report and this review report we have described the effect as a pathogen binding effect to avoid confusion.

Therapeutic claims are about preventing and treating conditions. FSANZ is not suggesting the evidence treats or prevents *Campylobacter* infections. Rather it relates to a reduction in risk of pathogenic infection. This approach is similar to that for high level health claims (i.e. risk reduction) and impact of mandatory folate fortification (i.e. reduces the risk of infants born with neural tube defects).

### **4.4 The promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry**

Section 18(2)(b) and (c) of the FSANZ Act require FSANZ to have regard to promoting consistency with international food standards and the desirability of an efficient and internationally competitive food industry. In addition to this, one of the key objectives of the food regulatory system is to support a strong, sustainable food industry that offers a diverse,

affordable food supply that also benefits the Australian and New Zealand economies<sup>3,4</sup>. To achieve this, it is recognised that the system requires the Australian Government, states and territories and the New Zealand government to work together to help align Australia's and New Zealand's domestic and export food standards, and facilitate their harmonisation with international food standards<sup>5</sup>.

The food regulatory system also requires food standards developed by FSANZ and the Forum to be consistent with Australia's and New Zealand's obligations under international trade law<sup>6</sup>.

Australia and New Zealand have a prominent role in international standard setting and the facilitation of standards harmonisation. Infant formula products and products for young children are traded globally. Products sold in Australia and New Zealand are manufactured locally (in Australia or New Zealand) or imported (mostly from Europe and Asia). In both Australia and New Zealand, export through various channels has been a large growth area in the last decade.

Export-only products are required by legislation to comply with the Code<sup>7</sup>, the regulations of the importing country, as well as additional legislation in both countries. In Australia this includes the *Export Control Act 1982*, the *Export Control (Prescribed Goods – General) Order 2005* and the *Export Control (Milk and Milk Products) Orders 2005*. In New Zealand the *Animal Products Act 1999* imposes additional legislative requirements. Inconsistencies between the regulations can create trade barriers. Broader government policy including the Australian government deregulation reform agenda, emphasise facilitating trade through aiding standards convergence and promoting health, particularly within our region (Department of Agriculture, Water and the Environment, 2020; Ministry of Primary Industries 2020(a)(b)).

Exports are critical to Australia and New Zealand's economies. Exporting companies expand economic activity by bringing in new income to the country. These businesses are also more likely to be high-performing, innovative and have stronger jobs growth potential (Innovation and Science Australia, 2017). Expanding exports is a key Government strategy to grow the wealth of Australia and New Zealand (The Commonwealth of Australia 2019). There are currently several Australian State and Territory and New Zealand Government strategies to specifically grow food and agricultural exports<sup>8,9,10,11</sup>.

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<sup>3</sup> The Food Regulation Agreement <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/key-system-documents>

<sup>4</sup> The Joint Food Standards Treaty  
<http://www.foodstandards.gov.au/about/foodlawandtreaties/documents/41A%20Treaty%20amendments%202012%20UNOFFICIAL.pdf>

<sup>5</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/system-aims-and-objectives>

<sup>6</sup> See, for example, clause 4.3 and Item 2(c) of Annex A of the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System

<sup>7</sup> Where there are inconsistencies between regulations Australian businesses need to demonstrate why they cannot be compliant with the Code. Businesses in New Zealand can be issued with an exemption from the domestic compositional requirements of the Code as per section 347(1) of the *New Zealand Food Act 2014*. These exemptions are usually product and country specific, and require companies to go through a process to seek exemption (NZ MPI 2020a).

<sup>8</sup> <https://www.agric.wa.gov.au/agribusiness-food-trade/food-beverages>

<sup>9</sup> Advancing Trade and Investment - Queensland Trade and Investment Strategy 2017–2022  
<https://www.tiq.qld.gov.au/ti-strategy/>

<sup>10</sup> <https://dti.sa.gov.au/trade>

<sup>11</sup> <https://www.business.nsw.gov.au/export-from-nsw/getting-started-in-export>

The export growth for infant formula products and FSFYC has occurred in both general trade export sales and through cross border e-commerce (CBEC) on-line sales (principally to China). New Zealand exported infant formula to 39 countries in 2019 valued at more than NZ \$1.7 billion with a growth of approximately 700%, in nominal terms, since 2009<sup>12</sup>. Statistics from the Department of Agriculture, Water and the Environment suggest total infant formula exported from Australia in 2018 were approximately AU \$789 million, an increase of over 57% in value compared to 2017<sup>13</sup>.

China is Australia's largest dairy export market (by volume and value). Australia's most valuable export product to a single market is infant formula to China (Dairy Australia, 2018a). In 2017/18, 'infant powder' was the top Australian dairy export to China by value (USD\$325 million), with the volume of exports growing by 614% from 2013/14 to 2017/18 (Dairy Australia, 2018a). Real annual growth in exports over the last three years have averaged around 58%, but vary considerably from year to year.

Australia and New Zealand predominantly trade in 'premium' and 'super premium' infant formula, leveraging off our reputation as clean, green and safe. Infant formula exports are a strong and growing sector for both countries, due in part to the growing Asian middle-class consumer and their increased demand from increased trust in premium dairy products sourced from Australia and New Zealand, and innovation and value addition to products (Destremau and Siddarth, 2018).

As high value-added dairy products, infant formula and young child products have played an important role in the development and growth of dairy global exports. The size of the Chinese market means it is a significant export destination for many countries and thus is very competitive. Many Chinese parents show a preference for imported infant formula over domestically produced infant formula (Cui, 2016; El Benni, 2019; Gong and Jackson, 2012; Guo, 2008; Xia and Guan, 2014). In particular, European, North American, Japanese, Australian and New Zealand brands are preferred (Gan, 2020). This is reflected in a higher willingness to pay for imported brands of infant formula, including for Australian brands (Cui, 2016). Many Chinese caregivers believe infant formula from Australia and New Zealand is higher quality than domestically produced formula, as it is viewed as safe and pure. The ingredients in an infant formula product are an important factor Chinese caregivers consider when choosing a brand. A survey conducted by Chen (2013), reported the nutrient value of an infant formula product was the second most important factor (after quality) for parents selecting products. Another study found evidence that particular nutrients were sought after. In a focus group study conducted by Gong and Jackson (2013), participants had heard of ARA and DHA and believed they were important in infant formula products. Similarly, a survey conducted with mothers in Hong Kong found "Constituents of the formula, including additives such as DHA, prebiotics, probiotics, etc." were the second most influential factor when choosing an infant formula product (Family Health Service, 2013).

CBEC trade into China involves Chinese domestic consumers purchasing goods from overseas via third party platform operators and transporting the goods into the country through net-purchasing bonded imports or direct purchasing of imports. CBEC is particularly beneficial to potential entrants to the general export trade, to test the market and begin building product recognition. The products are governed by the regulations of the market of origin. From a survey conducted by the Infant Nutrition Council, cross-border ecommerce trade contributes significantly towards total sales for some companies.

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<sup>12</sup> Source: Global Trade Atlas

<sup>13</sup> Correspondence with the Department of Agriculture, Water and Environment

The daigou market is also significant form of unofficial 'export'. This refers to the practice of people purchasing goods through normal retail channels in a country and posting them to customers in China. Daigou trade is an important distribution channel for infant formula products and toddler milks and is a key influencer in the success and failure of some firms (Marano, 2018). Daigou exports are not captured in formal exporting statistics. However the daigou phenomenon has resulted in significant growth of Australian infant formula retail sales. As with CBEC trade, the regulatory requirements of the country where products are purchased apply i.e. the Code. Approving the use of 2'-FL and LNnT as proposed will allow Australia and New Zealand companies to continue to better compete with overseas businesses in the daigou and CBEC Chinese market that have access to and use these ingredients.

Where there are inconsistencies in international regulations of permitted ingredients that are safe, suitable and desired by consumers then there will not be an even playing field in the Chinese CBEC market. 2'-FL is currently permitted in infant formula in 69 countries; demand for premium Australia New Zealand infant formula may erode if we are not able to provide the same quality of infant formula as other suppliers. This will likely impact the overall infant formula trade with China given the importance of CBEC to establishing a product in China.

#### *Role of innovation*

Key to governments' strategies of expanding exports, is industry's ability to access new markets, increase productivity, and remain competitive. Innovation in infant formula product development is primarily focused on replicating the normal composition of human milk and modifying the identified changing the outcomes of formula-fed infants to move towards those of breastfed infants. The infant formula market is highly innovative as the products continue to be modified as better technologies enable more advanced analysis of human milk, and the replication and commercialisation of identified substances. In this context innovation can contribute to improved outcomes for formula-fed infants. It is not uncommon for FSANZ to receive upward of 16 enquiries per annum from industry in relation to adding novel and nutritive substances to infant formula products.

Innovation increases the profits of businesses in two ways. Firstly, innovation potentially reduces input costs (increasing profit margins). Second it may result in the development of products that are better aligned to consumer demand (increasing market share) (FIAL, 2019). Undertaking innovation to develop cost-effective and differentiated offerings that meet the demands of consumers is essential to obtaining, maintaining and growing market share. This in turn can provide benefits to export growth and to the broader sector contributing to greater investment in employment and investment in manufacturing facilities (NZIER, 2018).

Encouraging an innovative business environment in Australia and New Zealand is critical to supporting an internationally competitive industry. The Australia New Zealand infant formula industry's exports are primarily 'premium' products. The ability of the industry to incorporate the latest scientific findings in their products, such as newly commercialised substances like oligosaccharides identical to those found in human milk, is a prerequisite to maintaining premium product status. Not being able to compete with the innovative developments of other countries is likely to erode the competitive position of the Australia New Zealand industry as other products will be better targeted to consumer demands.

There is significant investment of resources to be able to bring innovation to the market in infant formula products. Uncertainty in the likelihood of safe and suitable innovations being permitted by standard setting bodies may discourage future Research and Development (R&D) investments. This could have ramifications for future jobs and the earning potential of the sector.

FSANZ commissioned a report from The Centre for Transformative Innovation, Swinburne University (Kollman, Palangkaraya, and Webster, 2020) exploring some of the economic benefits of an innovative manufactured food sector (Supporting document 4). The report found that the infant formula industry represents the research-intensive extreme of the processed food industry and is a prime example of continued innovation improving the standard of living of citizens by closing the health and development gap between breastfed and formula-fed infants. In order to remain competitive in the international infant formula market, Australia and New Zealand must foster an innovative industry.

While falling behind the international frontier will not necessarily lead to the complete cessation of new products or innovations being developed in Australia and New Zealand, industry representatives noted that innovations help propel export growth. Kollman et al (SD4) simulated the potential economic impacts of non-innovative sector. They assumed that higher regulatory hurdles would result in a one-standard deviation reduction in the number of firms innovating in a given year<sup>14</sup>. This would result in fewer new products being introduced, fewer design rights being filed by firms, and fewer firms exporting. Within the dairy industry, patents are relatively important and thus a one standard deviation fall in innovation is associated with a A\$27.5 million decline in dairy exports, while the fall in design rights will contribute a further \$8.6 million loss in exports. This equates to approximately 1.4 percent of annual dairy exports in Australia.<sup>15</sup> If the magnitude is similar within New Zealand, we would expect New Zealand annual dairy exports to fall by NZ\$234.6 million a year.

This demonstrates that there could be very real costs associated with an industry that falls behind the innovative status of its international counterparts. Whilst this is only one application and as such the economic impacts of re-affirming the draft variations on the industry and their longer term competitiveness is likely to be limited, it may have more significant ramifications as a precedent. FSANZ is aware of ongoing industry interest and research to increase the number and variety of oligosaccharides identical to HMOs available for addition to infant formula to bring the composition closer to human milk composition. We have already fielded industry enquiries about other HMOs and note that additional HMOs have been approved overseas.

#### **4.5 The draft variation does not promote consistency between domestic and international food standards where these are at variance**

The Forum cited concern that the addition of 2'-FL to a maximum level of 2.4 g/L is twice the 1.2 g/L level permitted in most comparable international jurisdictions' standards.

At approval report FSANZ provided a table outlining the maximum permissions of 2'-FL in seven (of 37) other countries. Of the seven reported, four set a maximum of 1.2 g/L, two set a max 2 g/L and one at 2.4 g/L. This does not account for the additional permission for LNnT in many countries which raises the total above 1.2 g/L.

FSANZ is now aware that the addition of 2'-FL and LNnT to infant formula products and 'toddler milk products' is permitted in 69 countries with maximum permitted levels ranging

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<sup>14</sup> Where innovation is measured as patents, trademarks and design rights applications filed in a given year. The one-standard deviation (34.1%) reduction in the number of firms innovating is taken from the average share of firms innovating in a given year. The reductions is calculated using the following formula:  $OSD = np * (1 - p)$ . Where  $n$  is the number of firms in a given industry and  $p$  is the probability that a given firm will innovate in a year. For example, at the Food Product Manufacturing level, we would expect around 3 fewer firms to patent, 15 fewer firms to issue a trademark and 2 fewer firms to issue a design right each year.

<sup>15</sup> This figure excludes re-exports of dairy products.

from 0.6 g/L to 2.4 g/L. There are variations in the regulations across these countries and in the maximum permitted levels, and combinations of oligosaccharides that are permitted. For example in some countries only 2'-FL is permitted, whereas in others a number of other human milk identical oligosaccharides are permitted which extend the range beyond 2'-FL and LNnT.

Permitting a higher maximum level than some other jurisdictions provides flexibility for businesses and ensures robustness of the Code where there are likely to be future applications requesting higher levels or where trading partners may revise their permitted levels upward. Proactively permitting a higher level where an environmental scan suggests there is likely to be future demand for higher permitted levels, will prevent unnecessary duplication of FSANZ efforts in the near future. Aligning the Code's permission with the current highest permitted levels provides companies with the ultimate flexibility to be compliant with both the Code and any other relevant regulation.

Infant formula products and 'toddler milk' products are globally traded. Both Australia and New Zealand export large volumes of infant formula products. FSANZ considers that not permitting the addition of 2'-FL and LNnT to infant formula products and FSFYC will deviate from greater global alignment of infant formula standards. The ability to remain competitive in an international market is highly relevant to trade for Australia and New Zealand.

#### **4.6 The draft variation does not provide adequate information to enable informed choice and may mislead consumers**

The prevention of misleading or deceptive conduct is one of the objectives of Subsection 18(1) of the FSANZ Act. The Forum also raised concerns that the draft variation does not provide adequate information to enable informed choice because: the minimum 2'-FL and LNnT levels in a serve to support the bifidogenic effect are not specified; failure to require minimum effective concentrations in products may result in consumers being misled as to the efficacy of the products for the stated benefits; and thereby prevent consumers making informed decisions about the claimed bifidogenic effects

FSANZ has taken an approach which balances provision of adequate information for consumers to choose products while reducing the potential for consumers to be misled. Given the differences between the two products, these two objectives of the FSANZ Act (Section 18(1)) are considered separately for each product category.

##### ***Infant formula products – information for informed choice***

Mandatory labelling requirements for infant formula products are intended to inform consumers' purchase decisions. When 2'-FL or LNnT are added voluntarily to infant formula products they will have to be declared in the ingredient list. In addition, consumers can refer to the mandatory nutrition information statement (NIS), which would indicate the presence and average amount of 2-FL and LNnT.

FSANZ will also consider how mandatory nutrition information is presented in the NIS as part of Proposal P1028, including mandatory requirements for permitted nutritive substances that are voluntarily added, to clarify that declarations do not constitute a nutrition content claim.

### ***Infant formula products – prevention of misleading or deceptive conduct***

The Code prohibits voluntary nutrition content and health claims (e.g. a general level health claim about bifidogenic health effect) to be made about infant formula products. However FSANZ has specifically prohibited references to ‘human milk identical oligosaccharides’ or similar wording and abbreviations for any elements of the label i.e. the ingredient list. When added, the substances must be declared in accordance with generic labelling requirements, for example using the descriptive names 2'-fucosyllactose and Lacto-N-neotetraose.

### ***Formulated supplementary foods for young children - informed choice***

Similar to infant formula products, the voluntary addition of 2-FL and LNnT to FSFYC would trigger the requirement to declare these oligosaccharides in the statement of ingredients. Voluntary nutrition content and health claims made about 2-FL and LNnT would also alert consumers to the presence of these substances. When a claim is made, the Code requires the average amount of 2-FL and/or LNnT to be declared in the nutrition information panel.

FSFYC are permitted to carry voluntary nutrition content and health claims in accordance with the existing claims framework. Suppliers that wish to make a nutrition content claim about 2'-FL and LNnT must comply with subsection 1.2.7—13(1). This subsection restricts nutrition content claims about the property of food (i.e. 2-FL and LNnT) to its presence or absence in the food or to a specified amount of the property of food in a specified amount of the food. Use of descriptors such as ‘enriched’ or ‘high in’ are prohibited for properties of food that are not listed in Section S4—3. General level health claims are also permitted if existing Code conditions and requirements are met (these are described below).

As discussed below in section 4.7, there is no evidence to support a minimum effective dose for a bifidogenic effect. Hence FSANZ has not specified a minimum level for the oligosaccharides.

### ***Formulated supplementary foods for young children – prevention of misleading or deceptive conduct***

As noted earlier, the Applicant did not seek to add a food-health relationship to the Code (Section S4—5) about the physiological effects of 2-FL and LNnT as the basis for making a health claim. FSANZ made no assessment for a health claim and noted existing claim requirements in Standard 1.2.7 and Section S4—5 would apply for FSFYC. Suppliers will need to comply with generic conditions for making health claims, including the requirement to undertake a systematic review to establish the relationship between 2-FL and/or LNnT (the property of food) and the bifidogenic effect or pathogen binding effect (health effects) since neither of these elements are mentioned in the Table to Section S4—5 (paragraph 1.2.7—18(3)(b) and section 1.2.7—19).

The onus is on the supplier to substantiate any health effects claimed about the food or property of food. Section S6—2 sets out the requirements for a systematic review. One of these requirements is that the conclusion (of the systematic review) is to be based on the results of studies that includes the amount of the food or property of food required to achieve the health effect (Schedule S6—2(g)(ii)(A)).

Other generic claim requirements would also apply. These requirements are intended to prevent consumers from being misled.

In summary, FSANZ re-affirms the approach which balances provision of adequate information for consumers to make informed choices while reducing the potential for consumers to be misled.

## **4.7 The draft variation is difficult to enforce or comply with in both practical or resource terms**

### **4.7.1 Minimum level is required to provide a legislative basis for regulators to respond adequately to complaints during the exclusivity period**

#### *Infant formula products*

The rationale for previously setting minimum levels for permitted voluntary substances to infant formula products has been to ensure that these substances, if added, would be present at levels sufficient to achieve their intended purpose. On this basis there is no justification to specify a minimum level in this case. The available evidence has not established a minimum effective dose. As discussed at [Approval \(Section 2.3.3\)](#) the effect of 2'-FL and LNnT on gut microflora may vary due to individuals' unique microbial ecology and a variety of host and environmental factors. For these reasons setting a minimum effective 'dose' is not an appropriate approach. This means that, if 2'-FL and LNnT are added to or are present in the formula the minimum amount is set at above the level of detection or level of quantification according to the method of analysis. FSANZ noted this approach is consistent with the permissions overseas.

The issue of voluntary nutrition content and health claims does not apply because the Code prohibits these claims being made about infant formula products.

#### *Formulated supplementary foods for young children*

As 2'-FL and LNnT do not occur naturally at detectable levels in these food products, general labelling requirements would apply if they are added voluntarily to FSFYC. If 2'-FL and LNnT are added to FSFYC, they must be declared in the statement of ingredients. If a claim requiring nutrition information is made, the average amount of 2'-FL and LNnT must be listed in the nutrition information panel. FSANZ considers these generic labelling requirements provide the information required to respond to questions or complaints.

### **4.7.2 It is difficult to enforce or comply with in both practical or resource terms**

Ministers raised concerns that the absence of a minimum effective dose in the regulation will make it difficult to enforce any complaints as there will be no legislative basis for responding to complaints.

As discussed in the sections above, FSANZ considers that the generic labelling requirements will provide information for enforcements agencies. If this issue relates to the nutrition content and health claims on FSFYC, claims for 2'-FL and LNnT will only be likely to be made when they are added to the FSFYC as they do not occur in detectable levels otherwise.

Requirements in the Code work in conjunction with requirements in consumer protection legislation in Australia and New Zealand which prohibit misleading or deceptive conduct, and false or misleading representations about goods and services. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the *Competition and Consumer Act 2010* (Cth); and States and Territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the *Fair Trading Act 1986* (NZ) which prohibits false and misleading conduct by businesses.

When assessing a complaint, both the ACCC and NZCC state that they consider whether the overall representation of the product is misleading. The ACCC advise they follow a

[Compliance and Enforcement Policy](#), whilst the NZCC advise they use their [enforcement criteria](#) to assess complaints.

FSANZ understands that where there is evidence consumers are being misled by representations made about food products, enforcement agencies have powers under consumer protection legislation to take appropriate enforcement or compliance action.

## 4.8 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed in response to this application (OBPR correspondence dated 1 February 2018, reference 23349). This was due to OBPR being satisfied that the requested variation is voluntary and deregulatory and likely to have only a minor effect on consumers, businesses, and government. However, Section 29 of the FSANZ Act requires consideration of whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (S29(2)(a)).

The consideration of costs and benefits has been revised for the purpose of FSANZ's response to the Forum. The update provides a more comprehensive outline of the costs and benefits and continues to demonstrate that the community, government, and industry is likely to benefit, on balance, from a move away from the status quo (no permission to add the oligosaccharides). The consideration 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 outline the likely positives and negatives of moving away from the status quo by permitting the voluntary addition of 2'-FL alone, or in combination with LNnT, to infant formula products and FSFYC as proposed in the variation.

However, the analysis does reiterate FSANZ's original finding that approving the voluntary use of 2'-FL and LNnT is likely to generate a net benefit for Australia and New Zealand as a whole.

### *Context of the cost benefit considerations*

FSANZ recognises breastfeeding is the normal way to feed infants. Breastfeeding benefits the infant and mother and is associated with improved population health outcomes. However, where an infant is not breastfed or is partially breastfed, commercial infant formulas are the only safe alternative to human milk to be used until 12 months of age (National Health and Medical Research Council, 2012; Ministry of Health, 2012).

Registered births in Australia and New Zealand have been relatively stable over the last decade at approximately 310,000 babies in Australia (Australian Bureau of Statistics, 2018) and 60,000 babies in New Zealand (New Zealand Ministry of Health 2019). In Australia, it is estimated that between 40% and 55% of babies will be fed some infant formula by six months of age which increases to around 80% infants by twelve months (Australian Institute of Health and Welfare, 2020). The rates are expected to be similar in New Zealand. FSANZ has a role in ensuring the regulation of infant formula products maintains a supply of safe and suitable products for those that require them.

Australian domestic sales of milk formula was 305,000 tonnes in 2018 up from 192,000 in 2013. Sales are forecast to reach 373,000 tonnes in 2023 (Euromonitor International, 2018a). New Zealand domestic sales of milk formula were 3,694.2 tonnes in 2018 up from 3,346.8 tonnes in 2013. Sales are forecast to reach 3,911.9 tonnes in 2023 (Euromonitor 2018b). It is thought that daigou trade has been largely responsible for the increase in

domestic scanned sales. As these goods are purchased locally and posted back to China, they do not show up formally as exports, but rather as domestic sales.

New Zealand exported infant formula valued at more than NZ \$1.7billion<sup>16</sup> in 2019, and Australia's 2018 exports were approximately AU \$789 million<sup>17</sup>. Daigou exports are not captured in formal exporting statistics as it refers to informal activity; these sales are captured in the Australia, New Zealand domestic sales data.

### ***Consideration of options***

At review, there are three options available to FSANZ:

1. re-affirming approval of the draft variations
2. re-affirming approval of the draft variations with amendments.
3. withdrawing approval of the draft variations.

Amendments were proposed to FSANZ relating to FSFYC. It was recommended that FSANZ apply a general prohibition on all nutrition content and health claims on FSFYC. As noted in section 2.2, FSANZ considers that this is out of scope of the review. A prohibition of all claims for these substances on FSFYC would be inconsistent with existing labelling permissions and current policy guidance, thus the amendment was not further considered.

Given the grounds of the Forum's review request, the review work undertaken by FSANZ and feedback received to date, has not considered amendments to the re-affirmed approval. As such two options are considered below: withdrawing approval (status quo) and re-affirming approval of the draft variations.

#### ***Option 1 – Withdraw approval (status quo)***

Infant formula consumers would continue to have access to formula that is safe and supports the growth and development of infants. However, formula-fed infants in Australia and New Zealand may have different growth and development outcomes compared to formula-fed infants from other countries who consume formula supplemented with 2'-FL and LNnT, and compared with the outcome of breastfed infants. There are numerous health effects associated with optimal breastfeeding such as children being less likely to die from diarrhoea or pneumonia. Globally, less than optimal breastfeeding is also associated with lower IQs and lifelong incomes (UNICEF, 2019; WHO, 2020) which has been estimated to cost the global economy 0.49% of lost world gross national income (Rollins et al 2016). The permission to add voluntary ingredients to infant formula, using the composition of breast milk as the primary reference and striving to achieve, as closely as possible, the normal growth and development of a full term exclusively breastfed infant may go some way to reducing the economic burden to the individuals, the health system, and broader.

This application is the first request to permit a nutritive substance in infant formula since the Policy guideline came into effect. Industry may view this as a precedent indicating an intention to limit permission of innovative ingredients despite them being assessed safe and suitable for the intended use and commonly used in other countries. This introduces regulatory uncertainty and risk that could impact innovation investment considerations. The decision on this application could also affect future requests for permitting nutritive substances and general R&D investments generally from industry. There are several applications to amend the Code likely to be made to FSANZ in the near future. These include additional human milk identical oligosaccharides and macronutrient ingredients found in human milk. These may not proceed if industry come to the view that they are unlikely to be

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<sup>16</sup> Correspondence with New Zealand Ministry for Primary Industries

<sup>17</sup> Correspondence with Department of Agriculture, Water and Environment

successful. This could lead to a downturn in expenditure on future R&D which could affect jobs in this sector. The food and beverage manufacturing sector invested AU\$474 million in R&D in 2015-16 (ABS, 2017). This uncertainty may undermine the Food Regulation System's Priority 3 work<sup>18</sup> that seeks to create an agile food system that supports business activities.

Withdrawing approval of the draft variation will place a regulatory limitation on companies' abilities to operate domestically as they would have fewer opportunities to better align with consumer wants and ultimately obtain market share through the production of better products. This will mean in the longer term that Australian and New Zealand babies will not have access to the nutritional premium formulas that become progressively available internationally.

A non-innovative sector that does not keep pace with the best available science and overseas regulatory approvals may lead to a gradual erosion of international market share for Australian and New Zealand manufactured products. Exports are predominantly destined for Asia where our major competitors for market share are European brands. The 'premium' status of the infant formula may be jeopardised by not including ingredients that reflect the best available science. Chinese consumers as the largest market have a preference for imported premium products and believe imported brands are more advanced or scientific than domestic brands (Marano, 2018). Thus if Australia and New Zealand do not keep pace with the best available scientific findings and regulatory approvals, it is likely to reduce the medium and longer-term competitiveness of their products in international markets. This would negatively affect Australian and New Zealand exports with obvious flow on effects to the dairy industry and their wider economies. 2'-FL and LNnT is permitted for use in infant formula products and FSFYC in some 69 overseas countries including the EU and US. Rejecting this application creates a divergence between the Code and international standards and does not support our capacity to compete in international markets.

The option of withdrawing approval of the draft variation (status quo) is not a passive option. Whilst infants will continue to have access to safe infant formula, it will potentially reduce our capacity in the future to reduce the gap in health outcomes between breastfed and formula fed babies and cause significant damage to our currently competitive position in export markets.

### ***Option 2 – Re-affirm approval to use 2'-FL and LNnT***

FSANZ considers the substances to be a safe and suitable addition to infant formulas and FSFYC. The use of 2'-FL and LNnT in infant formula products and FSFYC as proposed will not pose a health or safety risk for infants. These substances are chemically and structurally identical to those naturally present in human milk. The FSANZ pre-market assessment process aligns with the infant formula policy guidelines.

There is a known gap between formula-fed and breastfed infants that has associated health and lost productivity costs (WHO, 2020). Facilitating the endeavour to achieve, as closely as possible, the normal growth and development of a full term exclusively breastfed infant will help to close the gap for infant formula-fed infants and toddlers. Achieving this may put downward pressure on the economic burden to the individuals, the health system, and broader society.

Whilst FSANZ does recognise that increasing infants' access to human milk is the preferred manner to address the health differences between formula-fed and breastfed infants, this is a wider societal issue outside the scope of A1155. Not enabling infant formula products to

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<sup>18</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/current-activities>

incorporate new ingredients that can improve the outcomes of formula-fed infants may allow unnecessary disadvantage to occur. Reaffirming the draft variation will give Australia New Zealand consumers access to infant formula compositions that align with the latest scientific findings and international compositions. This may reduce the health and lost productivity costs that can result from healthy formula-fed infants not achieving the same growth and development outcomes as breastfed infants. This will also ensure that Australia and New Zealand infant formula consumers will be on par with their international peers.

Although the socioeconomic factors from reaffirming this particular application may not be significant at the broader society level; this application is precedent setting in terms of approving nutritive substances in infant formula. Reaffirming the draft variation will protect the innovative status of the Australia New Zealand infant formula sector and the investments and jobs associated with this. This in term will protect the long term wellbeing of our citizens, where there continues to be improvements to infant formula, and the long term international competitiveness of the sector.

Sales of infant formula product with HMOs has increased rapidly in international markets in the last three years<sup>19</sup>. Domestic consumers may benefit from the choice of infant formula products and FSFYC containing applicant's 2'-FL alone or with LNnT that become available.

As the proposed permission is voluntary, industry will use 2'-FL alone or in combination with LNnT in infant formula products and FSFYC only where they believe a net benefit exists for themselves. Industry will benefit from having alternative options available to existing permitted oligosaccharides GOS and ITF providing product innovation opportunities.

The applicant's 2'-FL and LNnT is permitted for use in infant formula products and FSFYC in some 69 overseas countries in the EU, North America, South America, Middle East and Asia. Permitting the use of the ingredients will better align the Code with international food standards. This will allow multi-national companies and domestic exporters to use the one compositional recipe for multiple jurisdictions which will reduce production costs. Facilitating trade opportunities may lead to flow-on economic and employment benefits to Australia and New Zealand, although there may also be competing imports from these countries into the domestic market.

CBEC trade and the daigou market into China is governed by the regulations of the market of origin. Approving the use of 2'-FL and LNnT as proposed will potentially allow Australia and New Zealand industries to better compete with overseas businesses in the CBEC Chinese market that have access to and use these ingredients. The size of the Chinese market means it is a significant export destination for many countries and thus is very competitive, refer to Section 4.7 above for further detail.

Creating the conditions which encourage entrepreneurship and investment is important to foster innovation in the food industry in Australia (FIAL, 2019). The Food Regulatory System's Priority 3 work<sup>20</sup> seeks to update the food regulation system to facilitate an environment where an efficient and internationally competitive food industry can exist – in alignment with the objectives of the system. Improving the enabling environment for business, investment and innovation has been a key strategy to supporting the growth of exports which in turn ensures the viability of domestic businesses (FIAL, 2019). Re-affirming the draft variation will encourage businesses confidence in the Food Regulatory System and their expected investment's translations into profitability. This will support the sector to be resilient and market-focused. Small businesses that innovate are more likely to increase their

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<sup>19</sup> Internal research

<sup>20</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/current-activities>

profitability, productivity, employment and export penetration (ABS, 2011; Palangkaraya et al, 2011).

Reaffirming the draft variation will encourage the infant formula sector to continue its long history of innovation. It is hoped that by staying the course, there will be improvements that substantially close the gap between formula and breastfed infants. This will have flow on economic benefits to the broader society from reduced use of publically funded health care services and reduced tax receipts associated with lower productivity.

The infant formula industry is global, and Australia and New Zealand are able to leverage the good reputations of our countries to participate in the ‘premium’ formula export market. The competitive status of Australia New Zealand companies is protected by aligning with the best scientific evidence and overseas regulatory approvals. This in turn supports the profitability of the firms and the jobs in the sector.

**Table 3: Overview of impacts of re-affirming the permissions to use 2’-FL and LNnT**

<b>Community group</b>	<b>Impact</b>	<b>Notes on Impact</b>
<b>Infant formula consumers</b>	Harmonised with international standards.	Reduces risk of imported products, especially ‘special needs’ formulas being unavailable to Australia and New Zealand consumers.
	Able to access infant formula compositions that aligns with latest scientific findings and international compositions.	May reduce health and lost productivity costs from infant formula not achieving the normal growth and development of a full term exclusively breastfed infant. Australia and New Zealand infant formula consumers will be on par with their international peers. Increased choice in available infant formulas potentially increases purchaser’s utility where it better aligns with their wants.
<b>Australia New Zealand infant formula manufacturers</b>	Internationally competitive industry	Expected maintenance of export market shares.
	Reduced regulatory risk in innovation investment decisions.	Maintenance of current R&D expenditure levels. Continued trend for infant formula compositions to improve.
<b>Multinational infant formula manufacturers</b>	Harmonised international standards.	Doesn’t put upward pressure on production costs.

<b>Community group</b>	<b>Impact</b>	<b>Notes on Impact</b>
<b>Government</b>	Infant formula use better emulates the normal growth and development of a full term exclusively breastfed infant.	May reduce demands on the health system and increase worker productivity
	Internationally competitive industry	Market resilience and profitability protected Economic benefits from ongoing or growing exports
<b>Other Australia New Zealand manufacturers</b>	Less uncertainty regarding regulatory approval of safe and suitable novel foods.	Maintenance of current R&D expenditure levels.

### ***Comparison of options and conclusions***

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the voluntary addition of 2'-FL and LNnT in the manner proposed i.e. safe, possible benefits, and labelling requirements, are likely to outweigh the associated costs to the community. Reaffirming the draft variation has immediate benefits to consumers and the Australia New Zealand infant formula manufacturers, it also encourages ongoing innovation to continue the improvement of infant formula products and FSFYC.

Whilst re-affirming approval of the draft variation may not, of itself, substantially act to bridge the socioeconomic gap between formula-fed and breastfed infants, the precedent safeguards the economic viability of the substantial R&D investments in this sector which may lead to further formula improvements. Innovations are also key to creating products that are preferred by consumers both domestically and in the competitive international markets. This in turn supports the profitability of the firms and the jobs in the sector. The Australia New Zealand exports of infant formula and FSFYC are economically significant and bring substantial wealth in to the countries.

## **4.9 Other FSANZ Act requirements**

### ***4.9.1 Fair Trade***

No issues were identified

### ***4.9.2 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.

### ***4.9.3 Any relevant New Zealand standards***

There are no relevant New Zealand Standards.

## 5 Summary

After reviewing the best available scientific evidence, having regard to the Forum's review request, and the matters prescribed by the FSANZ Act, FSANZ's decision is to re-affirm the approval of the draft variations to Standard 2.9.1, Schedule 26 and Schedule 29.

### Summary of the regulatory measures being re-affirmed

To permit both 2'-FL with or without LNnT to be *used as a nutritive substance*, and also as *food produced using gene technology* linked to the gene-gene donor information specific to the production of the oligosaccharides, for use in infant formula products and FSFYC

*At the following maximum levels*

Infant formula products:

- If only 2'-FL added – not more than 96 mg/100 kJ of 2'-FL (equivalent to 2.4 g/L)
- If both 2'-FL and LNnT added – not more than 96 mg/100 kJ of 2'-FL and LNnT combined (equivalent to 2.4 g/L), of which contains not more than 24 mg/100 kJ of LNnT (equivalent to 0.6 g/L).

FSFYC:

- If only 2'-FL added – not more than 0.55 g/serving (equivalent to 2.4 g/L)
  - If both 2'-FL and LNnT added – not more than 0.55 g/serving of 2'-FL and LNnT combined, of which contains not more than 0.14 g/serving of LNnT (equivalent to 0.6 g/L).
- Prohibit the use of 2'-FL alone or with LNnT in combination with existing permissions for GOS and ITF for infant formula products and FSFYC (i.e. permissions for 2'-FL and LNnT would be used as alternatives to GOS and ITF).
  - Prohibit the following terms on the label of infant formula products and FSFYC:
    - the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect
    - the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect.
  - Set specifications for 2'-FL and LNnT based on the specifications provided by the applicant (without specific methods of analysis).

Provide 15 months exclusivity from the date of gazettal of the variation for the applicant's brands of 2'-FL and LNnT.

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



### Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation

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

Dated [To be completed by Delegate]

[Insert name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

**Note:**

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

## 1 Name

This instrument is the *Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation*.

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

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

## 3 Commencement

The variation commences on the date of gazettal.

### Schedule

#### [1] Standard 2.9.1 is varied by

[1.1] omitting section 2.9.1—7, substituting

#### 2.9.1—7 **Restriction on addition to infant formula product of inulin-type fructans and galacto-oligosaccharides**

- (1) If an inulin-type fructan or a galacto-oligosaccharide is added to an infant formula product, the product must contain (taking into account both the naturally-occurring and added substances) no more than:
  - (a) if only \*inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or
  - (b) if only \*galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or
  - (c) if both inulin-type fructans and galacto-oligosaccharides are added:
    - (i) no more than 110 mg/100 kJ of inulin-type fructans; and
    - (ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.
- (2) An infant formula product to which an inulin-type fructan or a galacto-oligosaccharide is added must not contain any of the following added substances:
  - (a) 2'-O-fucosyllactose; or
  - (b) a combination of 2'-O-fucosyllactose and lacto-N-neotetraose.

[1.2] inserting after paragraph 2.9.1—24(1)(c)

- (ca) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or
- (cb) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

#### [2] Standard 2.9.3 is varied by

[2.1] inserting after subsection 2.9.3—7(2)

- (2A) A substance listed in Column 1 of the table to section S29—15A may be \*used as a nutritive substance in a formulated supplementary food for young children if:
  - (a) the substance is in a permitted form listed in Column 2 of the table; and
  - (b) the amount of the substance in the food (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 3 of the table.

[2.2] omitting subsection 2.9.2—7(3), substituting

- (3) If \*inulin-type fructans or \*galacto-oligosaccharides are added to a formulated supplementary food for young children:
  - (a) the total amount of those substances, both added and naturally occurring, must not be more than 1.6 g/serving; and

- (b) the food must not contain any of the following added substances:
  - (i) 2'-O-fucosyllactose; or
  - (ii) a combination of 2'-O-fucosyllactose and lacto-N-neotetraose.

[2.3] omitting subsection 2.9.3—7(4)

[2.4] omitting subsection 2.9.3—8(6), substituting

- (6) The label on a package of a formulated supplementary food for young children must not contain:
  - (a) the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or
  - (b) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or
  - (c) any words indicating, or any other indication, that the product contains lutein unless the total amount of lutein is no less than 30 µg/serving.

[3] **Schedule 2** is varied by inserting in the table to section S2—2, in alphabetical order

EU/mg	Endotoxin units per milligram
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[4] **Schedule 3** is varied by

[4.1] inserting in the table to subsection S3—2(2) in alphabetical order

2'-O-fucosyllactose	section S3—40
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[4.2] inserting in the table to subsection S3—2(2) in alphabetical order

lacto-N-neotetraose	section S3—41
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[4.3] inserting after subsection S3—39

**S3—40 Specification for 2'-O-fucosyllactose**

For 2'-O-fucosyllactose (2'-FL), the specifications are the following:

- (a) chemical name— $\alpha$ -L-fucopyranosyl-(1→2)- $\beta$ -D-galactopyranosyl-(1→4)-D-glucopyranose;
- (b) chemical formula— $C_{18}H_{32}O_{15}$ ;
- (c) CAS number—41263-94-9;
- (d) description—white to off white powder or agglomerates;
- (e) assay (water free) for sum of 2'-FL, lactose, difucosyllactose and fucose—not less than 96.0%;
- (f) assay (water free) 2'-FL—not less than 94.0%;
- (g) D-lactose—not more than 3.0%
- (h) L-fucose—not more than 1.0%
- (i) difucosyllactose—not more than 1.0%
- (j) 2'-fucosyl-D-lactulose—not more than 1.0%
- (k) pH (20°C, 5% solution)—3.2 to 5.0
- (l) water—not more than 5.0%
- (m) ash, sulphated—not more than 1.5%
- (n) acetic acid (as free acid and/or sodium acetate)—not more than 1.0%
- (o) residual proteins—not more than 0.01%
- (p) lead—not more than 0.1 mg/kg
- (q) microbiological:
  - (i) *salmonella*—absent in 25 g
  - (ii) total plate count—not more than 500 cfu/g

- (iii) enterobacteriaceae—absent in 10 g
- (iv) *cronobacter (Enterobacter) sakazakii*—absent in 10 g
- (v) *listeria monocytogenes*—absent in 25 g
- (vi) *bacillus cereus*—not more than 50 cfu/g
- (vii) yeasts—not more than 10 cfu/g
- (viii) moulds—not more than 10 cfu/g
- (ix) residual endotoxins—not more than 10 EU/mg

### S3—41

#### Specification for lacto-N-neotetraose

For lacto-N-neotetraose (LNnT), the specifications are the following:

- (a) chemical name— $\beta$ -D-galactopyranosyl-(1→4)-2-acetamido-2-deoxy- $\beta$ -D-glucopyranosyl-(1→3)- $\beta$ -D-galactopyranosyl-(1→4)-D-glucopyranose
- (b) chemical formula— $C_{26}H_{45}NO_{21}$
- (c) CAS number—13007-32-4
- (d) description—white to off white powder or agglomerates
- (e) assay (water free) for sum of LNnT, lactose, lacto-N-triose II, and *para*-lacto-N-hexaose—not less than 95.0%
- (f) assay (water free) LNnT—not less than 92.0%
- (g) D-lactose—not more than 3.0%
- (h) lacto-N-triose II—not more than 3.0%
- (i) *para*-lacto-N-neohexaose—not more than 3.0%
- (j) LNnT fructose isomer—not more than 1.0%
- (k) pH (20°C, 5% solution) —4.0 to 7.0
- (l) water—not more than 9.0%
- (m) ash, sulphated—not more than 1.5%
- (n) methanol—not more than 100 mg/kg
- (o) residual proteins—not more than 0.01%
- (p) lead—not more than 0.1 mg/kg
- (q) microbiological:
  - (i) *salmonella*—absent in 25 g
  - (ii) total plate count—not more than 500 cfu/g
  - (iii) enterobacteriaceae—absent in 10 g
  - (iv) *cronobacter (Enterobacter) sakazakii*—absent in 10 g
  - (v) *listeria monocytogenes*—absent in 25 g
  - (vi) *bacillus cereus*—not more than 50 cfu/g
  - (vii) yeasts—not more than 10 cfu/g
  - (viii) moulds—not more than 10 cfu/g
  - (ix) residual endotoxins—not more than 10 EU/mg

[5] **Schedule 26** is varied by

[5.1] omitting subsections S26—3(1), (2), (2A), and (3), substituting

- (1) The table to subsection (4) and the table to subsection (7) list permitted food produced using gene technology.
- (2) Items 1(g), 2(m), 7(e), (g) and (h), and 9(a) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.  
**Note** That section requires the statement 'genetically modified'.
- (2A) Products containing beta-carotene from item 6(b) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.
- (3) Item 2(m) of the table to subsection (4) is also subject to the condition that, for the labelling provisions, unless the protein content has been removed as part of a

refining process, the information relating to \*foods produced using gene technology includes a statement to the effect that the high lysine corn line LY038 has been genetically modified to contain increased levels of lysine.

[5.2] omitting the words 'gene technology' from the heading to the table to subsection (4), substituting the words 'gene technology of plant origin'.

[5.3] inserting after the table to subsection (4)

- (5) A food listed in the table to subsection (7) must comply with any corresponding conditions listed in that table.
- (6) A source listed in the table to subsection (7) may contain additional copies of genes from the same strain.
- (7) The table for this subsection is:

**Food produced using gene technology of microbial origin**

<b>Substance</b>	<b>Source</b>	<b>Conditions of use</b>
<b>1 2'-O-fucosyllactose</b>	(a) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i>	<ol style="list-style-type: none"> <li>1. May only be added to infant formula products and to formulated supplementary food for young children.</li> <li>2. During the exclusive use period, may only be sold under the brand GlyCare.</li> <li>3. For the purposes of condition 2 above, <b>exclusive use period</b> means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.</li> </ol>
<b>2 Lacto-N-neotetraose</b>	(a) <i>Escherichia coli</i> K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from <i>Neisseria meningitides</i> and the gene for beta-1,4-galactosyltransferase from <i>Helicobacter pylori</i>	<ol style="list-style-type: none"> <li>1. May only be added to the following foods in combination with 2'-O-fucosyllactose that is permitted for use in infant formula products; and formulated supplementary food for young children.</li> <li>2. During the exclusive use period, may only be sold under the brand GlyCare.</li> <li>3. For the purposes of condition 2 above, <b>exclusive use period</b> means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.</li> </ol>

[6] **Schedule 29** is varied by

[6.1] omitting section S29—5, substituting

**S29—5 Infant formula products—substances permitted as nutritive substances**

For section 2.9.1—5, the table is set out below.

**Infant formula products—substances permitted for use as nutritive substances**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<i>Substance</i>	<i>Permitted forms</i>	<i>Minimum amount per 100 kJ</i>	<i>Maximum amount per 100 kJ</i>
2'-O-fucosyllactose permitted for use by Standard 1.5.2	2'-O-fucosyllactose		96 mg
A combination of: 2'-O-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2	2'-O-fucosyllactose and lacto-N-neotetraose		96 mg which contains not more than 24 mg of lacto-N-neotetraose
Adenosine-5'-monophosphate	Adenosine-5'- monophosphate	0.14 mg	0.38 mg
L-carnitine	L-carnitine	0.21 mg	0.8 mg
Choline	Choline chloride	1.7 mg	7.1 mg
	Choline bitartrate		
Cytidine-5'-monophosphate	Cytidine-5'-monophosphate	0.22 mg	0.6 mg
Guanosine-5'-monophosphate	Guanosine-5'-monophosphate	0.04 mg	0.12 mg
	Guanosine-5'-monophosphate sodium salt		
Inosine-5'-monophosphate	Inosine-5'-monophosphate	0.08 mg	0.24 mg
	Inosine-5'-monophosphate sodium salt		
Lutein	Lutein from <i>Tagetes erecta L.</i>	1.5 µg	5 µg
Inositol	Inositol	1.0 mg	9.5 mg
Taurine	Taurine	0.8 mg	3 mg
Uridine-5'-monophosphate	Uridine-5'-monophosphate sodium salt	0.13 mg	0.42 mg

[6.2] inserting after section S29—15

**S29—15A Formulated supplementary food for young children—other substances permitted as nutritive substances**

For subsection 2.9.3—7(2A), the table is set out below.

**Formulated supplementary food for young children—other substances permitted for use as nutritive substances**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<i>Substance</i>	<i>Permitted form</i>	<i>Maximum amount per serving</i>
2'-O-fucosyllactose permitted for use by Standard 1.5.2	2'-O-fucosyllactose	0.55 g
A combination of: 2'-O-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2	2'-O-fucosyllactose and lacto-N-neotetraose	0.55 g which contains not more than 0.14 g of lacto-N-neotetraose
Lutein	Lutein from <i>Tagetes erecta L.</i>	100 µg

## **Attachment B – Explanatory Statement (at Approval)**

### **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.

FSANZ accepted application A1155 which sought to permit the voluntary addition of 2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), produced by microbial fermentation, to infant formula products and formulated supplementary foods for young children (FSFYC). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

### **2. Purpose**

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

- Amend Schedule 26 to permit 2'-FL and LNnT derived from specific microbial sources for use in infant formula products and FSFYC; and to provide an exclusive use period of 15 months for the applicant's brand of 2'-FL and LNnT.
- Amend Schedule 29 to permit the same 2'-FL alone or combined with LNnT for use as nutritive substances in infant formula products and FSFYC, within specified maximum levels.
- Amend Standards 2.9.1 and 2.9.3 to prohibit certain representations (e.g. 'human milk identical oligosaccharide') on labels of infant formula products and FSFYC; and to prohibit the use of 2'-FL alone or with LNnT, in combination with existing permissions for ITF and GOS.
- Insert prescribed specifications for 2'-FL and LNnT into Schedule 3.
- Insert a new unit of measure, as used in the prescribed specifications, in Schedule 2.

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

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1155 included two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries. Submissions were first called for on 22 November 2018 for a six week consultation period. Submissions on a proposed draft variation were sought on 22 July 2019 for a six week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standards 2.9.1 and 2.9.3 and Schedules 2, 3, 26 and 29 are likely to have a minor impact on business and individuals (OBPR ID 23349).

## 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## 6. Variation

### *Item [1]*

Item [1.1] varies Standard 2.9.1 by omitting the existing section 2.9.1—7 and substituting a new subsection. The new subsection restates the permitted quantities of ITF and GOS in the current subsection, and includes a new requirement which will prohibit an infant formula product to which ITF or GOS are added, from containing 2'-FL alone, or a combination of 2'-FL and LNnT.

Item [1.2] varies Standard 2.9.1 by inserting new subparagraphs 2.9.1—24(1)(ca) and (cb). These new subparagraphs will prohibit the use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide (or any word or words of similar effect)', and the use of abbreviations 'HMO' or 'HiMO' (or any abbreviation having the same or similar effect), on the label on a package of infant formula product (i.e. not used in associated with 'human milk' or 'human milk identical') on the label on a package of an infant formula product.

### *Item [2]*

Item [2.1] varies Standard 2.9.3 by inserting a new subsection 2.9.3—7(2A). The effect of this new subsection is to permit substances listed in a new table in section S29—15A in Schedule 29 to be *used as a nutritive substance* in FSFYC (see Item 6.2 below), providing the substance meets the permitted form and maximum levels set in this table. 2'-FL alone, and 2'-FL and LNnT combined, are listed in the new table.

Item [2.2] varies Standard 2.9.3 by omitting the existing subsection 2.9.3—7(3) and substituting a new subsection. The new subsection restates the permitted quantity of ITF and GOS in the current subsection, and includes a new requirement which will prohibit FSFYC to which ITF or GOS are added, from containing 2'-FL alone, or a combination of 2'-FL and LNnT.

Item [2.3] varies Standard 2.9.3 by omitting subsection 2.9.3—7(4) relating to the permission for lutein to be *used as a nutritive substance*. This permission is relocated to the new table in section S29—15A in Schedule 29 (see Item [2.1] above and Item 6.2 below). This amendment does not change the existing permission and associated conditions for the use of lutein in FSFYC, it only relocates the permission.

Item [2.4] varies Standard 2.9.3 by omitting subsection 2.9.3—8(6) and substituting a new subsection. The new subsection restates the labelling restriction relating to lutein, and includes a new requirement which will prohibit use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide (or any word or words of similar effect)', and the use of abbreviations 'HMO' or 'HiMO' (or any abbreviation having the same or similar effect), on the label on a package of FSFYC. This amendment is not intended to prohibit the use of the term 'oligosaccharide' on its own (i.e. not used in associated with 'human milk' or 'human milk identical') on the label on a package of FSFYC.

### *Item [3]*

Item [3] varies Schedule 2 to insert a new unit of measurement EU/mg (endotoxin unit per milligram), as used in the new specifications in Schedule 3 (see Item [4] below).

*Item [4]*

Item [4] varies Schedule 3 to insert new specifications for 2'-FL (new section S3—40) and LNnT (new section S3—41).

*Item [5]*

Item [5] varies Schedule 26 to insert a new table under a new subsection (7) with the heading *Food produced using gene technology of microbial origin*. This new table lists 2'-FL and LNnT from permitted microbial sources. This amendment will not amend the existing approvals currently listed in the table to subsection (4), or change the requirements for pre-market assessment and approval of GM foods. The detailed amendments made to this Schedule are discussed below.

Item [5.1] omits subsections 26—3(1), (2), (2A) and (3) and substitutes a new subsection. New subsection (1) specifies that the existing table to subsection (4) and the new table to subsection (7) lists permitted food produced using gene technology. New subsections (2), (2A) and (3) restate the existing labelling requirements, but now specify that these apply to the existing table to subsection (4).

Item [5.2] omits the words 'gene technology' from the heading of the existing table to subsection (4) and replaces this with the words 'gene technology of plant origin' (i.e. the full table heading will now be *Food produced using gene technology of plant origin*). This amendment clarifies that permissions in the existing table to subsection (4) relate to food of plant origin, to distinguish these from the new permissions for 2'-FL and LNnT which are food of microbial origin (new table to subsection (7)).

Item [5.3] inserts new subsections 26—3(5), (6) and (7). Subsection (7) inserts a new table (*Food produced using gene technology of microbial origin*) which lists 2'-FL and LNnT sourced from specific gene-gene donor information. Subsections (5) and (6) require that a food listed in this new table must comply with any corresponding conditions listed in the table, and that the source listed in the table may contain additional copies of genes from the same strain. The new table includes the condition that 2'-FL and LNnT are only permitted to be added to infant formula products and FSFYC. It also includes the condition that, during the 'exclusive use period', 2'-FL and LNnT from the permitted source listed may only be sold under the brand name 'GlyCare'. 'Exclusive use period' is defined to be the period commencing on the date of gazettal of the variation, and ending 15 months after that date. This means that the new permission will apply exclusively to 2'-FL and LNnT as listed in Schedule 26, under the brand 'GlyCare'. Once this period ends, the exclusive use permission will revert to a general permission, meaning that the permission will apply to all brands of 2'-FL and LNnT that meet the specific source and associated specifications in Schedule 3.

*Item [6]*

Item [6.1] varies Schedule 29 by omitting section 29—5 and substituting a new section to add 2'-FL, and 2'-FL combined with LNnT, in the table to this section as new substances permitted for use as nutritive substances in infant formula products. 2'-FL and LNnT listed in this table are linked to these substances permitted for use by Standard 1.5.2 (*Food produced using gene technology*). This means that only 2'-FL and LNnT derived from the microbial sources listed in Schedule 26 (table to subsection 26—3(7)) are permitted for use in infant formula products. The permission in section 29—5 also lists permitted forms, and requires infant formula products to contain not more than 96 mg/100 kJ of 2'-FL; and not more than 96 mg/100 kJ of 2'-FL and LNnT combined (of which contains not more than 24 mg/100 kJ of

LNnT). A minimum amount is not set, as this was not requested in the application and has not been determined by FSANZ.

Item [6.2] varies Schedule 29 by inserting a new section S29—15A containing a table (as referred to in subsection 2.9.3—7(2A) under Item 2.1 above). This new table lists other substances permitted for use as nutritive substances in FSFYC (i.e. substances which are additional to the vitamins and minerals currently permitted to be used as nutritive substances in FSFYC in S29—15). 2'-FL alone, and 2'-FL and LNnT combined are listed in this table, along with the existing permission for lutein (relocated from existing section 2.9.3—7(4), see Item 2.3 above). 2'-FL and LNnT listed in this table are linked to these substances permitted for use by Standard 1.5.2. This means that only 2'-FL and LNnT derived from the microbial sources listed in Schedule 26 (table to subsection 26—3(7)) will be permitted for use in FSFYC. The permission in the table in subsection S29—15A also lists permitted forms, and (in relation to 2'-FL and LNnT) will require FSFYC to contain not more than 0.55 g/serving of 2'-FL; and not more than 0.55 g/serving of 2'-FL and LNnT combined (of which contains not more than 0.14 g/serving of LNnT). A minimum amount is not set, as this was not requested in the application and has not been determined by FSANZ.