FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 2

Background and Risk Management Report – A1055

Short Chain Fructo-oligosaccharides

Executive summary

This document describes in detail several background matters, terminology and issues considered in developing and assessing the regulatory options for this Application.

In relation to terminology, fructan is a general term to describe any polymer of fructose in which one or more fructosyl-fructose links constitute the majority of osidic bonds. The term inulin-type fructan is used to describe fructans that have β(2→1) linkages. Inulin-type fructans include inulin extracted from plant material (e.g. chicory inulin) and are produced commercially via two processes: enzymatic condensation of sucrose (short chain $FOS_{sucrose}$) and partial hydrolysis of plant-derived inulin (short chain FOS_{inulin}).

Short chain FOS generally is permitted and used as an optional ingredient in several infant formula products, infant foods and Formulated Supplementary Foods for Young Children (FSFYC) manufactured overseas.

FSANZ must have regard to all statutory objectives outlined in s18 of the FSANZ Act including relevant Ministerial policy guidelines, which in this case relate to Part 2.9 of the Code and infant formula products. The assessment that led to the preferred option has been favourably compared against each relevant specific policy principle of the infant formula product guideline.

The cost/benefit analysis summarises the likely qualitative impacts of each regulatory option on the key stakeholder groups. It concludes that the option that provides the greatest net benefit to consumers, industry and government is Option 1. This option provides the greatest net benefit to consumers, industry and government. Industry is able to be innovative and use the optional permissions in a range of its products in a variety of combinations up to the maximum amount. Consumers will have access to a broader range of products, with a range of oligosaccharides at a prescribed maximum amount to protect their health and safety. Enforcement agencies will have clear definitions and regulations.

Where infant formula products, infant foods and FSFYC contain short chain $FOS_{sucrose,}$ labelling requirements in the Code would apply in the same way as they currently apply for IDS. These are detailed for information of submitters.

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1 Introduction

SD2 describes in detail several background matters and the issues considered in developing and assessing the regulatory options for this Application.

2 Background

2.1 Terminology

Fructan is a general term to describe any polymer of fructose in which one or more fructosyl-fructose links constitute the majority of osidic bonds[1]. Fructans have a degree of polymerisation (DP) ranging from two up to about 60. Fructans with a mean DP greater than nine are generally termed inulin and are commercially extracted from plant material (e.g. chicory inulin). This is not to be confused with the term 'inulin-type', which is used to describe all fructans with the β(2→1) glycosidic bond. Inulin-type fructans are usually produced commercially by two different processes: enzymatic condensation of sucrose (short chain $FOS_{sucrose}$) and partial hydrolysis of plant-derived inulin using endo-inulinase (short chain FOS_{inulin}). Each polymer chain produced by the enzymatic condensation method will have one terminal glucose molecule per chain with the following configuration – kestose (glucose α(1→2) fructose β(1→2) fructose); nystose (glucose α(1→2) fructose β(1→2) fructose β(1→2) fructose) etc. For $scFOS_{inulin}$ polymers, an α-D-glucose moiety may be present, but most will not terminate with α-D-glucose[2].

In Standard 1.1.1 of the *Australia New Zealand Food Standards Code* (the Code), IDS means

> *mixtures of polymers of fructose with predominantly β(2→1) fructosyl-fructose linkages, with or without a terminal glucose molecule and includes inulin, but does not include those polymers of fructose produced from sucrose by enzymatic action.*

The Application describes short chain FOS as:

> *Fructans (fructose polymers with β(2→1) fructosyl-fructose linkages, where the DP is equal to or less than 5 and is typically produced from enzymatic condensation of sucrose.*

Except for the restriction on DP, this is similar to the notation for short chain $FOS_{sucrose}$ used in the FSANZ reports assessing this Application

2.2 Current standard – Australia and New Zealand Food Standards Code

The Call for submissions report outlines the current standards in the Code relevant to this Application.

2.3 International and overseas regulations – Infant Formula Products, Infant Foods and Formulated Supplementary Foods for Young Children

The terminology used for carbohydrates in Section 2.3 aligns with that used in the relevant overseas or international standards and therefore it may not be consistent with the remainder of this SD.

2.3.1 Codex Alimentarius

There are no Codex standards or guidelines which contain specific provisions for short chain FOS in infant formula products, infant foods, and formulated supplementary foods for young children

[1] Roberfroid MB, Delzenne NM (1998) Dietary fructans. Annual Review of Nutrition **18**: 117-143
[2] Roberfroid M (2005) Inulin-type fructans: functional food ingredients. Inulin-type fructans: functional food ingredients. 359pp

(FSFYC).

However, Codex standards and guidelines for these categories of foods contain provisions for 'optional ingredients', 'other ingredients' or 'nutritive material' which apply to the inclusion of substances such as short chain FOS. These standards require that the suitability of 'optional ingredients' must be scientifically demonstrated in each case as described in Table 1 below.

Table 1: Codex Standards

Codex Standard	
Infant Formula[3]	This standard allows the addition of *optional ingredients* to infant formula, providing that *the suitability for the particular nutritional uses of infants and the safety of these substances shall be scientifically demonstrated* and that *the formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.*
Follow-up Formula[4] (formula for infants from six months to 36 months of age)	This standard provides for optional ingredients in addition to ingredients necessary to achieve the essential composition. It requires the suitability and safety of substances/ingredients in these products to be scientifically demonstrated. It also requires that the formula contain significant amounts of these nutrients, based on the requirements of infants from the sixth month onwards.
Canned Baby Foods[5]	This standard states that *baby foods may* be *prepared from any suitable nutritive material that is used, recognized or commonly sold as an article or ingredient of food, including spices.*
Processed Cereal-based Foods for Infants and Young Children[6]	This standard allows for the addition of *other ingredients suitable for infants who are more than six months of age and for young children.*
Formulated Supplementary Foods for Older Infants and Young Children[7]	This guideline is currently under revision by the Codex Committee on Nutrition and Foods for Special Dietary Uses. These foods are suitable for use during the infant's weaning period and for feeding young children as a supplement to breast milk or a breast milk substitute. The guidelines include guidance on dietary fibres and other non-absorbable carbohydrates.

2.3.2 United States of America (U.S.)

Infant formula available in the US must comply with the requirements of the Federal Food, Drug, and Cosmetic Act (FFDC Act). Infant formula and follow-on formula containing short chain FOS are available in the United States. Infant formula notices are confidential and are handled by the Office of Nutrition, Labelling and Dietary Supplements CFSAN-FDA, a separate office from the GRAS Division. Section 412 of the FFDC Act[8] requires infant formula to be registered with US Food and Drug Administration (FDA). Any manufacturer with a new infant formula or major change to the formulation must make a submission to USFDA ninety days before marketing the infant formula.

Fructo-oligosaccharide, with fructose units from two to four, is designated as Generally Recognised as

[3] Codex (2007) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. CODEX STAN 72-1981 www.codexalimentarius.org/input/download/standards/288/CXS_072e.pdf accessed 19 October 2012
[4] Codex (1989) Standard for Follow-up Formula. CODEX STAN 156-1987 www.codexalimentarius.org/input/download/standards/293/CXS_156e.pdf accessed 19 October 2012
[5] Codex (1989) Standard for Canned Baby Foods. CODEX STAN 73-1981. www.codexalimentarius.org/input/download/standards/.../CXS_073e_u.pdf accessed 19 October 2012
[6] Codex (2006) Standard for Processed Cereal-Based Foods for Infants and Young Children. CODEX STAN 74-1981. www.codexalimentarius.org/input/download/standards/290/cxs_074e.pdf accessed 19 October 2012
[7] Codex (CAC/GL 8-1991) Guidelines on Formulated Supplementary Foods for Older Infants and Young Children www.codexalimentarius.org/input/download/standards/298/CXG_008e.pdf accessed 19 October 2012
[8] Federal Food Drug and Cosmetic Act Section. 412. Requirements for Infant Formulas http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/ucm107864.htm

Safe (GRAS) by the USFDA in an extended list of foods including infant foods and toddler foods[9]. Infant formula is excluded from the GRAS notification.

2.3.3 European Union

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formula and follow on formula in the European Union. The content of these substances should not exceed 0.8 g/100 mL in *a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose*[10]*.* Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Article 5, which requires the suitability of an ingredient for a particular nutritional use by infants to be established by generally acceptable scientific data.

2.3.4 Asian countries

2.3.4.1 Japan

The Applicant states that the use of short chain FOS in infant formula has been used since the early 1990s and today it is widely used in Japan in products for infants and young children. In Japan, oligosaccharides have 'foods of specified health use' (FOSHU) status, relating to a *health function* as a food to *modify gastrointestinal conditions*[11]. Examples provided include infant formula for up to 9 months and follow-on formula for infants 9 months and older.

2.3.4.2 China

The National Standard of China, Hygienic standard for the use of nutritional fortification substances in foods[12], permits infant formula, follow-on formula and formula for young children in dry powder form to contain up to 64.5 g/kg of fructo-polysaccharide, including fructo-oligosaccharide, as a prebiotic. The same maximum level of galacto-oligosaccharides is also permitted. The permission appears to be general for the inclusion of fructopoly-saccharide from any source and any molecular size.

2.3.4.3 Other Asian countries

Infant formula products with added inulin and oligosaccharides, such as oligofructose and oligogalactose have been marketed in some Asian countries for a number of years. In some of these countries imported products are required to be registered before import. In some instances, this requires the product to be compliant with the food regulations of the country of origin.

2.3.5 Other arrangements

In New Zealand, the Ministry of Primary Industries published an exemption from the requirements of the Code[13], in relation to the use of oligosaccharides, including fructo-oligosaccharide, in the manufacture of dairy-based infant formula products for export to: China, The Customs Union of Belarus, Kazakhstan and Russia, the European Union, Malaysia, Indonesia and Republic of Korea.

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[9] US Food and Drug Administration. Agency Response Letter GRAS Notice No. GRN 000044, 1 June 2007 http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154400.htm accessed 19 October 2012

[10] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. *Official Journal of the European Union, L 401/1, 30/12/2006.* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0033:EN:PDF accessed 19 October 2012

[11] Ministry of Health, Labour and Welfare. Available at: http://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html accessed 19 October 2012

[12] National Standard of the People's Republic of China, GB 14880-94, Hygienic standard for the use of nutritional fortification substances in foods, including supplement 6, 2007 of GB2760-1996 Hygienic standards for uses of food additives

[13] New Zealand Ministry of Primary Industry Animal Products (Dairy Based Infant Formula products – Food Standards Exemption) Notice 2011 http://www.foodsafety.govt.nz/industry/exporting/introduction/infant-formula.htm accessed 19 October 2012

2.4 International regulations – Invertase (EC 3.2.1.26) from *Aspergillus niger* as a processing aid (enzyme).

Invertase (EC 3.2.1.26) is defined and approved internationally. *A. niger* is recognised internationally as a safe organism and suitable for the manufacture of enzyme preparations.

Enzyme preparations from *A*. *niger*, and the *A. niger* organism itself, have repeatedly been reviewed and accepted by FAO/WHO experts, listing them with an acceptable daily intake of 'not specified'. The European Commission and USFDA have also concluded that food enzymes made from *A. niger* are safe.

3 Assessment against Ministerial Policy Guideline on the Regulation of Infant Formula Products

During the assessment of an Application, FSANZ must consider the three objectives in subsection 18(1) of the FSANZ Act. These are discussed in the Call for submissions report.

When developing or modifying regulatory measures, FSANZ must also have regard to the lower order section 18(2) objectives, which include having regard to Ministerial Policy Guidelines provided by the Legislative and Governance Forum on Food Regulation (the Forum).

There are two Ministerial Policy Guidelines that apply to this Application. They are:

- Intent of Part 2.9 – special purpose foods
- Regulation of infant formula products.

The Ministerial Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals does not apply to special purpose foods.

This Application is consistent with the Ministerial Policy Guideline on the Intent of Part 2.9 of the Code. The Application does not change the intended purpose of the three food categories, and the assessments undertaken have taken into consideration the vulnerability of the infant and young child populations.

The Ministerial Policy Guideline on the Regulation of Infant Formula Products has many elements. The specific policy principles that are particularly relevant to this Application are (d), (e), (h) and (j). FSANZ's previous approach to the assessment of applications for infant formula products has been consistent with principles (d), (e), and (h). Assessments considered safety, presence in breast milk and physiological equivalence with substances in breast milk, and applied caution. A summary of FSANZ's consideration of this Application against the specific policy principles can be found in Appendix 1.

FSANZ considers that the Ministerial Policy Guideline for the Regulation of infant formula products is met if short chain $FOS_{sucrose}$ were to be permitted addition to infant formula products.

4 Cost Benefit Analysis

A summary of the cost/benefit analysis is described in the Call for submissions report. The following information provides more detail of the potential impacts of each of the regulatory options on the key stakeholder groups in relation to addition of short chain $FOS_{sucrose}$ to special purpose foods:

4.1 Option 1 - amend Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3

Consumers/carers

Option 1 is likely to provide carers with an additional choice of special purpose foods for infants and young children. This option may give carers increased product choice and any potential advantages derived from the addition of short chain $FOS_{sucrose}$. Carers may incur additional costs as a result of short chain $FOS_{sucrose}$ being added to the existing products, as any extra manufacturing costs may be passed on to carers who purchase the products. The voluntary nature of the proposed permission will maintain choice for carers, as standard formula products without the addition of short chain $FOS_{sucrose}$ and the associated additional costs are expected to remain available.

Industry

Option 1 would provide explicit permission (within current limits) for the addition of short chain $FOS_{sucrose}$ to infant formula products, infant foods and FSFYC thereby providing for alternative formulations which could promote competition in the food industry.

Closer alignment with international regulations may allow for a single formulation and manufacturing of products for both local and overseas markets thereby minimising production costs and reducing trade barriers.

Option 1 may potentially encourage product innovation by providing an alternative or complement to IDS and/or GOS for infant formula manufacturers. Manufacturers may have to conduct their own research for developing new products.

Government

No additional monitoring costs are likely to be incurred by state or territory enforcement agencies as this is an optional addition. However there may be a small increase in compliance costs if there is a need to develop further testing for short chain FOS.

4.2 Option 2 – Reject the Application (maintain the status quo)

Maintaining the status quo may result in the following costs and benefits to the affected parties.

Consumers/carers

Maintaining the status quo may not have any significant impact on consumers, as suitable foods for this age group are already available in the market. However, any potential benefits that are to be derived as a result of adding short chain $FOS_{sucrose}$ will not be available to infants and toddlers.

Industry

Maintaining the status quo may limit the options available to manufacturers of products that are suitable for both the local and overseas markets, as regulations may not harmonise with other countries. Under Option 2, manufacturers may have to manufacture separate products for internal and external markets which would not allow economies of scale and may result in an increase in manufacturing costs.

In Australia, the status quo may restrict the ability to export products to countries that permit the addition of short chain $FOS_{sucrose}$, thereby restricting trade opportunities. Industry has noted that some countries do not accept or register products that do not comply with local regulations, for example some Asian countries. This may result in lost markets for those manufacturers and may have financial implications. Some manufacturers may need to reformulate products in order to meet overseas

requirements and this may lead to additional costs. It is noted, however that New Zealand has issued an exemption to permit formula containing short chain FOS to be exported to some countries. Furthermore, the status quo may not encourage innovation in product development by manufacturers.

Government

No additional monitoring costs are likely to be incurred by state or territory enforcement agencies.

4.3 Preferred Option

The preferred option is Option 1 i.e. amend the Code to permit the voluntary addition of short chain $FOS_{sucrose}$ either singularly, or in combination with IDS and/or GOS in infant formula products, infant foods and FSFYC, at maximum amounts currently permitted in the Code. This option includes a revised definition in Standard 1.1.1 that covers both short chain FOS and IDS (See Section 6 below). This option also permits invertase from *A. niger* as a processing aid.

This regulatory approach extends the scope of the current permissions for IDS by permitting a chemically similar substance that has similar physiological effects in the gut, up to the same maximum amounts. The proposed amounts of inulin-type fructans, which incorporates both IDS and short chain $FOS_{sucrose}$, are well below the amounts of oligosaccharides found in breast milk.

This option provides the greatest net benefit to consumers, industry and government. Industry is able to be innovative and use the optional permissions in a range of its products in a variety of combinations up to the maximum amount. Consumers will have access to a broader range of products, with a range of oligosaccharides at a prescribed maximum amount to protect their health and safety. Enforcement agencies will have clear definitions and regulations.

5 Labelling

Ingredient labelling requirements that currently apply to IDS would be expected to apply to ITF.

General labelling provisions in Standard 1.2.4 – *Labelling of Ingredients* apply to infant formula products, infant foods and FSFYC. Clause 4 of this Standard specifies in part that ingredients must be declared in the statement of ingredients using the common name of the ingredient; a name that describes the true nature of the ingredient; or where applicable, a generic name set out in the Table to clause 4.

If short chain $FOS_{sucrose}$ is added to these special purpose foods, it would need to be declared in the statement of ingredients.

5.1 Nutrition information labelling

Nutrition information labelling requirements that currently apply to IDS would also be expected to apply to ITF. The following sections describe these labelling requirements in more detail.

5.1.1 Infant formula products

Standard 2.9.1 sets out what nutrition information must be declared on the label of an infant formula product. The Standard does not prescribe the format of the nutrition information statement, but the *Guidelines for Infant Formula Products* contains guidance on how mandatory nutrition information may be presented.

Clause 16 states that the label on a powdered or concentrated form of infant formula product must include a statement that contains the following information when the infant formula product has been

reconstituted according to directions:

(a) the average energy content expressed in kJ per 100 mL,

(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL,

(c) the average amount of each vitamin, mineral or any other nutritive substance permitted by this Standard expressed in weight per 100 mL,

(d) a declaration –

  (i) of the weight of one scoop in the case of powdered infant formula; and

  (ii) of the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(e) when added, the average amount of –

  (i) a combination of IDS and GOS; or
  (ii) IDS; or
  (iii) GOS

  expressed in weight per 100 mL.

There are similar requirements for 'ready to drink' infant formula products.

Where short chain FOSsucrose is added to infant formula products, the same requirements will apply, including where short chain FOSsucrose is added to infant formula products for special dietary use (as regulated under Division 3 of Standard 2.9.1).

5.1.2 Foods for infants

Apart from exemptions to some provisions in Standard 1.2.8 – Nutrition Information Requirements (identified in subclause 9(1) of Standard 2.9.2 – Foods for Infants), general requirements for nutrition information labelling under Standard 1.2.8 apply to foods for infants. Nutrition information labelling for short chain FOS is voluntary, unless a nutrition claim is made in accordance with paragraph 5(1)(g) of Standard 1.2.8.

Subclause 9(2) prescribes the format for the nutrition information panel. If short chain $FOS_{sucrose}$ is added to foods for infants and a claim made, it would be declared in the nutrition information panel under sodium, and include the average quantity of short chain $FOS_{sucrose}$ in grams per serving and per 100 g (or 100 mL).

5.1.3 Formulated supplementary foods for young children

FSFYC are regulated under Division 4 of Standard 2.9.3.

Sub clause 7(1) of Standard 2.9.3 mandates the declaration in the nutrition information panel of the average quantity of a vitamin or mineral present, where that vitamin or mineral is listed in column 1 of Table 3 to the Schedule and has been added to the food. Otherwise, general provisions in Standard 1.2.8 for the nutrition information panel apply to FSFYC; that is, nutrition information labelling for short chain $FOS_{sucrose}$ is not required unless a nutrition claim is made (refer to paragraph 5(1)(g) of Standard 1.2.8).

5.2 Nutrition and health claims

5.2.1 Infant formula products

FSANZ must have regard to the overarching principles listed in the Policy Guidelines on the Regulation of Infant Formula Products. Specific policy principles applicable to labelling and advertising

of infant formula products reflect the current regulatory approach taken, which is a clear and effective prohibition and restriction on nutrient content, health, therapeutic and prophylactic claims.

Paragraph 20(1)(f) of Standard 2.9.1 already prohibits a reference to the presence of a nutrient or nutritive substance except where it relates to the name of a low lactose or lactose free infant formula and is in accordance with clause 30 of the Standard; is in the ingredient list in accordance with Standard 1.2.4; or is in the nutrition information statement in accordance with clause 16 of Standard 2.9.1. In effect, this paragraph is intended to prohibit nutrition claims or health claims from being made elsewhere on the label.

In addition, paragraph 3(f) of Standard 1.1A.2 – *Transitional Standard – Health Claims* prohibits foods standardised in Standard 2.9.1 from carrying a health claim.

When added, short chain $FOS_{sucrose}$ must be declared in the same manner as IDS and GOS, and the existing prohibition on nutrition claims and health claims would extend to short chain $FOS_{sucrose}$.

5.2.2 Foods for Infants

General requirements for nutrition claims, as prescribed in Standard 1.2.8, apply to foods for infants regulated under Standard 2.9.2, except where specific conditions in Standard 2.9.2 apply, specifically in:

- clause 8 (claims about vitamins and minerals)
- clause 9 (certain provisions in Standard 1.2.8 that do not apply).

In particular, paragraph 9(1)(b) of Standard 2.9.2 states that subclause 5(5) of Standard 1.2.8 (as it relates to how dietary fibre is declared in the nutrition information panel) does not apply to food for infants. Instead, specific conditions relating to the nutrition information format required under subclause 9(2) of Standard 2.9.2 prevail if a nutrition claim about dietary fibre is made on a food for infants.

Similar to infant formula products, paragraph 3(f) of Standard 1.1A.2 currently prohibits foods standardised in Standard 2.9.2 from carrying a health claim.

If short chain $FOS_{sucrose}$ is permitted to be added to foods for infants, existing provisions relating to nutrition and health claims would apply to the short chain $FOS_{sucrose}$.

5.2.3 Formulated supplementary foods for young children

Other than the requirements in subclause 7(2) regulating vitamin and mineral claims, there are no specific provisions in Standard 2.9.3 limiting the use of nutrition claims.

Standard 1.1A.2 does not expressly prohibit foods standardised in Standard 2.9.3 from carrying a health claim. But the only health claim currently permitted by Standard 1.1A.2 is a claim relating to folate intake in women around conception.

Based on current requirements, nutrition claims would be permitted for short chain $FOS_{sucrose}$. General labelling provisions for nutrition claims in Standard 1.2.8 would apply where no conflict exists between Standards.

Appendix 1 – Assessment of the Application in relation to the Specific Policy Principles for the Regulation of Infant Formula Products

INFANT FORMULA PRODUCTS ***Specific Policy Principles – Overarching Principles***	***Approach***	***Does the assessment meet the Policy Principles?***
a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant	Not relevant to this application.	Not applicable
b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding	Not relevant to this application.	Not applicable
c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.	FSANZ assessed the application using risk analysis. The risk assessment has considered the safety, functional effects and benefits of the optional addition of short chain FOS to infant formula products. The vulnerability of the intended population has been considered as part of the risk analysis process.	Yes
Specific Policy Principles - Composition		
d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/o functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to 6 months of age.	The risk assessment concludes that short chain $FOS_{sucrose}$ is as safe as IDS (including short chain FOS_{inulin}) which are already permitted to be added to infant formula products. Short chain $FOS_{sucrose}$ is chemically similar to short chain FOS_{inulin} and has similar physiological effects in the gut. The amounts proposed to be permitted are well below the amount of oligosaccharides found in breast milk. The assessment also concluded that the consumption of short chain FOS-supplemented formula supports normal growth in infants.	Yes
e) The composition of follow on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.	See response for Policy Principle (d)	Yes
f) The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.	Not relevant to this application as optional addition is requested.	Not applicable

INFANT FORMULA PRODUCTS ***Specific Policy Principles – Overarching Principles***	***Approach***	***Does the assessment meet the Policy Principles?***
g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.	Not relevant to this application as optional addition is requested.	Not applicable
h) The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula	The risk assessment has considered the composition of breast milk as a primary reference for determining the composition of infant formula products.	Yes
i) Pre-market assessment, relative to principles d) and e), should be required for any substance proposed to be used in infant formula and follow on formula that: *i. Does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or* *ii. Has a history of safe use in these products in Australia and New Zealand, but which having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.*	Short chain $FOS_{sucrose}$ does not have a history of safe use in infant formula products in Australia New Zealand and thus requires a pre-market assessment.	Yes
j) Substances subject to pre-market assessment for use in infant formula and follow on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substances role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and /or functional effects of the substance to specific health outcomes for infants in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.	The risk assessment concludes that there was no discernible difference in infant growth patterns between infants consuming formula containing short chain $FOS_{sucrose}$ and infants fed unsupplemented formula. The quantity of poly- and oligosaccharides present in breast milk is ~ 25 g/L following birth, and decreases to around 15 g/L from one to four months. The risk assessment concludes that short chain $FOS_{sucrose}$ has the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered beneficial effects. FSANZ has applied caution in developing the proposed regulatory measure, which is an extension of the current permissions for IDS.	Yes
Specific Policy Principles – Labelling and Advertising		
k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand	Not relevant to this application	Not applicable

INFANT FORMULA PRODUCTS ***Specific Policy Principles – Overarching Principles***	***Approach***	***Does the assessment meet the Policy Principles?***
l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breast milk	Not relevant to this application.	Not applicable
m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products	Not relevant to this application.	Not applicable
n) The Authority should: *i) ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and* *ii) consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.*	If approved, short chain $FOS_{sucrose}$ must be declared on a label of an infant formula product in the same manner as inulin-derived substances. The current prohibition on nutrition claims and health claims will also apply to short chain $FOS_{sucrose}$.	Yes
Expert Group		
FSANZ should consider establishing an independent scientific expert group that may provide advice prior to pre-market assessment, based on scientific criteria established by the Authority, on whether: *i) a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and* ii) *there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.*	FSANZ has sought advice from an independent Infant and Child Health Scientific Advisory Group on the risk assessment.	Yes
Relevant international agreements		
The regulation of infant formula products in Australia and New Zealand should be consistent *to the greatest extent possible with:* • *relevant World Health Organization agreements; and* • *relevant World Trade Organization agreements, Codex standards and guidelines*	FSANZ has taken account of the relevant World Trade Organization agreements, Codex standards and guidelines. Short chain $FOS_{sucrose}$ is permitted and used in some overseas infant formula products.	Yes