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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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FIRST REVIEW REPORT

PROPOSAL P306

ADDITION OF INULIN/FOS & GOS TO FOOD

For information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

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Decision

FSANZ re-affirms its approval of the draft variations to the *Australia New Zealand Food Standards Code* as notified to the Ministerial Council, with amendments (see Attachment 1).

This decision clarifies that for general foods inulin-derived substances are taken not to be nutritive substances thus providing regulatory certainty for general food manufacturers who currently add inulin-derived substances to a range of general foods.

This decision also permits the voluntary addition of inulin-derived substances and galacto-oligosaccharides (GOS) to infant formula products, infant foods and formulated supplementary foods for young children (FSFYC) because:

- these substances are considered not to pose a risk to the health and safety of infants and young children at the proposed maximum levels;
- the permissions will provide infant formula manufacturers with regulatory certainty regarding the addition of these substances to infant formula products; and
- the permissions are broader than, but consistent with, overseas recommendations such as the addition of long chain inulin and GOS to infant and follow-on formula in Europe.

This decision does not permit the addition of fructo-oligosaccharides (FOS), as defined in the P306 Final Assessment Report, to these foods as there is insufficient evidence to support their addition.

FSANZ has made the following amendments to the draft variations:

- the maximum amount of inulin-derived substances that can be added to infant formula products has been reduced from 290 mg per 100 kJ (8 g/L) to 110 mg per 100 kJ (3 g/L);

FSANZ is proposing this amendment because infant formula manufacturers are not seeking to add inulin-derived substances to infant formula at levels up to 8 g/L at this time; a maximum of 3 g/L will meet their needs.

Summary Table

Matters Addressed in the First Review

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSES
Consistency with the objectives of the FSANZ Act	• The approach taken in this Proposal is consistent with the objectives of the FSANZ Act • However, FSANZ acknowledges that the outcomes of P306 are an interim regulatory response that provides short term regulatory certainty for general food manufacturers, as well as providing express permissions in the Code to voluntarily add inulin-derived substances and GOS to infant formula products, infant foods and toddler formula. • FSANZ agrees that this interim regulatory response does not provide the regulatory certainty for substances that do not meet the definition of substances requiring pre-market approval (such as nutritive substances). This situation will be addressed during the review of Standard 2.9.1 which will commence once the Policy Guideline on Infant Formula Products has been completed. • It is outside the scope of this section 36 Proposal to give consideration to broader issues such as the definition of nutritive substances but FSANZ will undertake a review of the definition of 'nutritive substance' in Standard 1.1.1 and its application in the Code at a later date when considering the response to the Policy Guideline on the Addition to Food of Substances Other Than Vitamins and Minerals. The definition of nutritive substances is fundamental to considering any changes to the Code arising from the policy guidance. • A section 36 Proposal is not an 'urgent' Proposal but simply omits one round of public comment. The basis for a decision to raise a Proposal under this section of the FSANZ Act (as was in force prior to 1 July 2007) includes that it will not have a significant adverse effect on any party. FSANZ remains satisfied that omitting one round of public consultation prior to making the Draft Assessment does not have significant adverse effects on the interests of anyone. By adopting this course of action all relevant issues have been addressed. • While it has been argued that FSANZ should not have raised this Proposal ahead of receiving the policy guidance on infant formula, three Applications have been submitted which relate to these issues and which can only have been delayed pending policy guidance with the agreement of the applicants.
Protection of public health and safety	• FSANZ's safety assessment was informed by studies involving the addition of GOS and inulin-derived substances alone or in combination, to infant formula products, infant food, and toddler formula. Although the majority of studies used the 9:1 ratio of these substances at a maximum level of 8 g/L, other studies have been undertaken with GOS or inulin-derived substances alone. At least one study was conducted with the 9:1 ratio at a level of 10 g/L. On this basis, FSANZ concludes that there are no safety concerns with regard to the addition of inulin-derived substances and/or GOS to infant and follow-on formula, infant foods and toddler formula, singularly or combined, in any ratio, up to 8 g/L. • FSANZ's assessment of the maximum permitted level of inulin-derived substances permitted to be added to infant formula products (8 g/L) is based on the totality of evidence available shown to be safe in clinical studies. The safety of this level is further supported by the presence of higher levels of HMOs (up to 25 g/L) in breast milk. • FSANZ acknowledges that at Final Assessment, one member of the Infant and Child Health Scientific Advisory Group did not support the proposed increase from 3 g/L to 8 g/L in the maximum amount of inulin-derived substances permitted to be added to infant formula products.

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSES
	• However, there was support from the two international experts consulted for the higher level and thus, FSANZ considered that the views of the majority of external experts consulted did not differ from FSANZ's recommendation. • While satisfied that there are no safety concerns with up to 8 g/L of inulin-derived substances added to infant formula products, FSANZ is recommending a reduced maximum of 3 g/L as this level will satisfy the needs of infant formula manufacturers at this time.
Consistency between domestic and international food standards	• Independent risk assessments are an integral part of FSANZ's approach to developing food standards for Australia and New Zealand. In this context, FSANZ considers, but is not bound by, relevant international regulations. • The European Commission (EC) Directive permits the addition of GOS and long chain inulin to infant and follow-on formula but also indicates that other substances can be added subject to a systematic review of the available data. • At Final Assessment, FSANZ undertook an independent systematic review of both the published and unpublished literature and assessed the safety of all inulin-derived substances, not just long chain inulin, and GOS when added to infant formula products. Thus, there is no inconsistency in the forms of the permitted substances between the proposed domestic and international standards. • FSANZ acknowledges that there is no agreed and consistent terminology used to describe these substances internationally. As a result there is confusion and misunderstanding when various terms are used. FSANZ has attempted to resolve this confusion by using the generic term 'inulin-derived substances' which includes oligofructose, inulin and long chain inulin, but not FOS. • As such, the proposed draft variations to Standards 2.9.1, 2.9.2 and 2.9.3 use the terms inulin-derived substances and GOS to clarify the compositional permissions (which are inclusive of, but broader than, the EC Directive) but do not prescribe the terms to be used in labelling. This approach allows manufacturers to use the terms of their choice on labels thus promoting consistency with the varying international terms used for inulin-derived substances. • There are insufficient data to support the addition of FOS (described at Final Assessment as being fructose polymers produced from the enzymatic condensation of sucrose) to infant formula products, infant foods and toddler formula; nor is there any evidence that FOS is added to these special purpose foods elsewhere in the world.
Enforcement and compliance.	• In the absence of ISC consideration or Ministerial Council policy guidance, FSANZ considers that it is the role of laboratories or enforcement agencies to develop analytical capability for monitoring inulin-derived substances and GOS in foods. Thus, methods of analysis for these substances have not been prescribed. This approach allows enforcement agencies and their appointed analysts to develop and agree on their own means of monitoring compliance thereby reducing the costs of developing suitable capability.

1. Introduction

In September 2008, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Proposal P306 – Addition of Inulin/FOS & GOS to Food. This section 36 Proposal seeks to amend the *Australia New Zealand Food Standards Code* (the Code) to confirm the regulatory position for the food industry regarding the addition of inulin-derived substances, including inulin, to general foods (and some special purpose foods) and to consider permissions for the addition of inulin-derived substances, FOS and GOS to special purpose foods for infants and young children including infant and follow-on formula, infant foods and formulated supplementary foods for young children (FSFYC), such as toddler formula.

The grounds for the First Review broadly relate to:

- whether the draft variations provide regulatory certainty for infant formula manufacturers regarding the addition of these substances to infant formula products;

- whether the proposed maximum amounts of GOS and inulin-derived substances are safe when added to infant formula products in amounts and ratios other than the EC recommendation of a maximum of 8 g/L in a ratio of 9:1;

- the use of different terminology in the proposed standard compared with international terminology for these substances; and

- methods and costs of analysing these substances in food.

FSANZ has addressed these issues by reviewing its assessment of the safety of these substances when added to infant formula products and reviewing its commentary in the Final Assessment[1] Report and responding to each of the identified issues in turn (see Section 6).

2. Terminology

FSANZ acknowledged at Final Assessment that there are no widely agreed definitions for the substances inulin, FOS and GOS. Therefore, in keeping with the terminology used at Final Assessment the following terms are used in this First Review Report: inulin, long chain inulin, oligofructose, FOS and GOS. The term 'inulin-derived substances' is used throughout this report to collectively refer to inulin, long chain inulin and oligofructose – it does not include FOS. The identity of these substances was described in Section 1.4 of the Final Assessment Report, but to ensure clarity in this Report this section has been repeated at Attachment 2.

3. Objective of the review

The objective of this First Review Report is to address the Ministerial Council's concerns expressed in the Review Request and to reconsider the draft variations (at Attachment 1) notified to the Ministerial Council by FSANZ in July 2008.

[1] The Final Assessment Report and the its attachments can be found at http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp306addition3639.cfm

4. Grounds for the review

The Ministerial Council requested a First Review on the grounds that approval of the draft variations:

- is not consistent with the objectives of the legislation which establishes FSANZ (or the Authority);
- does not protect public health and safety;
- does not promote consistency between domestic and international food standards where these are at variance; and
- will be difficult to enforce or comply with in both practical and resource terms.

Additional comments provided by Ministers included the following:

- The draft variations do not provide regulatory clarity and certainty in relation to the status of the substances which are arguably of a nutritive character in infant formula products. The Final Assessment Report for Proposal P306 does not clarify that these substances are either nutritive or non-nutritive; thus setting a precedent for other non-nutritive substances to be added to infant formula products in the future without requiring pre-market approval.
- The absence of Ministerial policy guidance on the addition of substances to special purpose foods – Part 2.9 of the Code – is resulting in piecemeal interim regulatory responses that do not provide long-term regulatory certainty for food manufacturers. In light of this uncertainty, policy guidance should not be pre-empted.
- Urgent standards, particularly for vulnerable populations such as infants, should not be used to do anything other than address the presenting problem and provide a regulatory response which is consistent with international permissions and which has been demonstrated to protect public health and safety.
- The majority of the studies used in FSANZ's risk assessment are based on a maximum of 8 g/L in a ratio of 9:1 of GOS to long chain inulin which is now included in the EC Directive. Thus, there is stronger case for the safety of this level and ratio compared with other ratios, particularly when either substance is added alone to infant formula products.
- Why is FSANZ recommending the addition of GOS and inulin-derived substances when the EC Directive recommends GOS and 'long chain inulin' and this appears to be the substances commonly added to infant formula products?
- Why is FSANZ recommending the use of oligofructose as an inulin-derived substance but not FOS when oligofructose has an average chain length of less than 10 and can vary from a DP of 2-10?

- There was no consensus among experts on FSANZ's Infant and Child Health Scientific Advisory Group (ICSAG) regarding the increase in the maximum amount of inulin-derived substances permitted to be added to infant formula products from 3 g/L at Draft Assessment to 8 g/L at Final Assessment. FSANZ based this increase on just one study undertaken by a manufacturer of inulin, however, the methodology and sample size of this study are not sufficiently robust to justify the increase. There was not wide consultation on this change and concerns were raised by the jurisdictions when the proposed increase in the maximum permitted amount was conveyed to them.

- The terminology, in particular the term inulin-derived substances, is not consistent with international terminology used for these carbohydrates and may confuse industry, particularly importers, as to whether products approved in other jurisdictions may lawfully be imported into Australia. The Australian and New Zealand food regulatory system should strive for consistency between our food standards and international food standards, especially where international standards clearly protect public health and safety.

- There appears to be no reliable and agreed methodology at present for the analysis of inulin/FOS and GOS in infant formula, and no acceptable laboratory in Australia which is capable of achieving reproducible and reliable results. Furthermore, there is considerable cost to be incurred by regulators with the development and verification of such methods. This and other costs to regulators are not itemised in the benefit cost analysis and no quantitative values are assigned to these costs.

5. Background

FSANZ initiated Proposal P306 in July 2007 in response to enforcement action taken in early 2007 against an infant formula manufacturer who had launched a brand of infant formula products containing added inulin-derived substances (specifically long chain inulin) and GOS in Australia and New Zealand. The addition of these substances to infant formula products is considered to require a pre-market safety assessment and an explicit permission in the Code.

An unintended consequence of this enforcement action was confusion among the broader food industry as to the regulatory status of inulin-derived substances when added to general foods. Food manufacturers have added inulin-derived substances to the general food supply in Australia and New Zealand since the mid 1990s.

In June 2008, the FSANZ Board approved draft variations to the Code and notified the Ministerial Council. This decision stated that inulin-derived substances were taken not to be nutritive substances and permitted the voluntary addition of GOS and inulin-derived substances in any ratio up to a maximum amount of 8 g/L in infant formula products, infant foods and FSFYC[2].

[2] The maximum amount proposed in the draft variation which is equivalent to 8 g/L is 290 mg/100 kJ in infant formula products; 0.8 g/100 g in infant foods and 1.6 g per serve in FSFYC.

6. Ministerial Council Review Grounds

The First Review of the draft variations to the Code has been undertaken addressing the matters stated in the Ministerial Council's request (as listed above). FSANZ's response to each of the issues raised is discussed in detail below.

6.1 Consistency with the objectives of the legislation that establishes FSANZ

6.1.1 Provision of regulatory certainty when adding these substances to infant formula products

6.1.1.1 The Review Request states that regulatory certainty is not provided if the nutritive status of inulin-derived substances and GOS, when added to infant formula products, is not acknowledged

FSANZ acknowledges that the proposed amendments to the Code reflect an **interim regulatory response** but provide the required regulatory certainty at this time.

The proposed draft variations to Standard 2.9.1, 2.9.2 and 2.9.3, provide express permissions for the addition of inulin-derived substances and GOS to special purpose foods for infants and young children, such as infant formula products. This approach confirms the regulatory position (i.e. express permission based on pre-market safety assessment) for the food industry as well as providing certainty for enforcement agencies. The regulatory certainty of this permission is not dependent on deeming inulin-derived substances and GOS to be 'nutritive substances'.

FSANZ also notes that it is outside the scope of this section 36 Proposal to give consideration to broader issues such as the nutritive status of these substances but has indicated that it will undertake a review of the definition of 'nutritive substance' in Standard 1.1.1 and its application in the Code at a later date. Preliminary work has begun on FSANZ's response to the Ministerial Council's Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals. This work will include a review of the definition of 'nutritive substance'. In addition, Application A613, to be commenced soon, will also consider the issues raised by this definition.

Therefore, FSANZ reaffirms its decision at Final Assessment, to retain clause 9A in Standard 2.9.1 which provides express permissions to add inulin-derived substances and GOS to infant formula products. This clause does not indicate the nutritive status of these substances but, as indicated above, this decision may be reviewed at a later date.

6.1.2 Interim approach sets a precedent for other non-nutritive substances to be added to infant formula products

6.1.2.1 The Review Request states that because the substances have not been declared to be either nutritive or non-nutritive this sets a precedent for other non-nutritive substances to be added to infant formula products in the future without requiring pre-market approval

FSANZ agrees that this **interim regulatory response** for inulin-derived substances and GOS does not provide the regulatory certainty for substances that do not meet the definition of substances requiring pre-market approval (such as nutritive substances).

However, currently all substances not considered to be ingredients require express permission in Standard 2.9.1, irrespective of their nutritive status; other standards cross-referenced in Standard 2.9.1 provide additional guidance in relation to the addition of food additives as well as microbiological limits. This situation will remain following the gazettal of the draft variations to the Code.

FSANZ acknowledges, however, that what is regarded as an ingredient[3] in an infant formula product is open to interpretation as this has not been explicitly defined in Standard 2.9.1. However, this anomaly is expected to be addressed in the proposed future review of the infant formula Standard following development of a Policy Guideline for Infant Formula Products. (see Section 6.1.3 for further information on the development of the Policy Guideline).

6.1.3 Lack of relevant policy guidance at present

6.1.3.1 The Review Request states that the absence of Ministerial policy guidance is resulting in piecemeal interim regulatory responses that do not provide long term regulatory certainty for any stakeholder. In light of this uncertainty, policy guidance should not be pre-empted

FSANZ affirms that **interim regulatory responses** are sometimes necessary to address situations that raise uncertainty for the food industry. Thus, FSANZ undertook this work to provide short term regulatory certainty for general food manufacturers who have for some years been adding inulin and oligofructose to a range of foods for a variety of technical and nutritional reasons in Australia and New Zealand. The interim regulatory response also provides short term certainty to infant formula manufacturers seeking to market products containing inulin-derived substances in Australia and New Zealand.

A Policy Guideline for Infant Formula Products is currently being developed by a Food Regulation Standing Committee (FRSC) Working Group on Infant Formula Products. The development of the Policy Guideline has been precipitated by recent applications and proposals seeking to amend Standard 2.9.1 and the range of issues arising from this work, in particular the vulnerability of infants and that infant formula may be the sole source of nutrition for an infant. The three current Applications[4] received by FSANZ that relate to these issues can only be delayed, pending policy advice, with agreement from the applicants.

An indicative timeframe for completion of the Policy Guideline is late 2009. As a result of this proposed timeframe, FSANZ considers it appropriate to progress Proposal P306 as quickly as possible and will reconsider the implications of the Policy Guideline on the infant formula standard (Standard 2.9.1) when it becomes available.

[3] An ingredient is not defined generically in the Code, but only in Standard 1.2.4 for the purposes of labelling.
[4] Applications A598, A609 and A613.

6.1.4 'Urgent' standards should only address the presenting problem

6.1.4.1 The Review Request states that 'urgent' standards, particularly for vulnerable populations such as infants, should not be used to do anything other than address the presenting problem and provide a regulatory response which is consistent with international permissions and which has been demonstrated to protect public health and safety

This Proposal was not prepared under the urgency provisions contained in what was section 24 (declaration of urgency) of the FSANZ Act (as was in force prior to 1 July 2007), but rather was prepared as a section 36 Proposal (FSANZ may simplify proposal procedure).

In the interest of dealing with this regulatory matter in a timely and responsive manner, FSANZ decided, pursuant to section 36 of the FSANZ Act (as was in force prior to 1 July 2007), to omit to one round of public consultation. Consequently one round of public consultation was not called for prior to making the Draft Assessment. FSANZ remains satisfied that omitting one round of public consultation prior to making the Draft Assessment does not have significant adverse effects on the interests of anyone – one of the criteria for using this provision of the FSANZ Act. By adopting this course of action, all relevant issues have been addressed. Manufacturers, consumers, health care providers and government agencies that have an interest in ensuring the health and safety of a vulnerable population group have had opportunity to provide comment and engage with the relevant agencies.

It should also be noted that had this Proposal been prepared after 1 October 2007, it would have had only one round of public consultation in accordance with the General Category provisions of the amended FSANZ Act.

6.2 Protection of public health and safety

6.2.1 Maximum level of inulin-derived substances proposed to be permitted to be added to infant formula products

6.2.1.1 The Review Request states that the increase in the proposed maximum amount of inulin-derived substances permitted to be added to infant formula products from 3 g/L at Draft Assessment to 8 g/L at Final Assessment was based on one study with a questionable methodology

The conclusions reached by FSANZ on the safety of inulin-derived substances and GOS, including the proposed maximum concentration of 8 g/L to be added to infant formula, do not rely on any one study or piece of evidence. FSANZ has used a weight-of-evidence approach, underpinned by the following considerations:

- Similar to naturally-occurring human milk oligosaccharides (HMOs), inulin-derived substances and GOS are undigested in the small intestine. When they reach the large intestine, mostly intact, there is a small beneficial increase in osmotic potential in the colon. This increase in osmotic potential from inulin-derived substances and GOS is similar to that observed from HMOs and therefore no more likely to cause dehydration.

- Data from clinical trials that have provided formulas supplemented with up to 10 g/L of inulin-derived substances and GOS to infants for various durations were without evidence of harm.

- Evidence that inulin-derived substances and GOS are fermented by colonic microflora to a similar or greater extent than HMOs.

- Evidence that addition of inulin-derived substances and GOS and inulin-derived substances alone up to 10 g/L, added to infant formula products result in similar physiological effects i.e. softer stool consistency and lower pH of stools; and microbiological effects i.e. selective growth stimulation of intestinal *Bifidobacterium* to those of breastfed infants.

- Approximately 1-2% of human breast milk comprises HMOs, with a large variation in their concentration among individual women. The natural levels of HMOs in colostrum (25 g/L) and mature breast milk (15 g/L) are safe for newborn and older infants.

- While there are fewer data in older infants and young children, older children are much less sensitive to potential dehydration because their kidneys are more developed, and have the ability to concentrate urine. Further, infant foods and toddler formula do not represent the sole source of nutrition in this group. It follows that if inulin-derived substances and GOS are safe for newborns and young infants, they will be equally safe for older infants and young children.

Following Draft Assessment, FSANZ received an unpublished supplementary study by Veereman-Wauters *et al.* (2008), also referred to as the Beneo study, which examined the effect of 4 g/L or 8 g/L of inulin-derived substances, or formula containing 8 g/L of 9:1 GOS to long-chain inulin in newborn infants. The Review Request questioned the suitability of this study in terms of its sample size, duration, statistical power and whether it could 'fully assess the effects of the substances on infant health, growth and development'.

The study of Veereman-Wauters *et al.* (2008) was evaluated by FSANZ based on its scientific merits (see Attachments 7 and 8 in the Final Assessment Report). The study examined approximately 20 infants per group for 28 days in a randomised, blinded design. The study analysed a number of independent indicators of infant health, growth and development including length, weight, food intake, stool frequency and consistency, faecal microbe analysis, crying, regurgitation and vomiting. The study found no adverse effects on any of these parameters. The group size and duration of 20 and 28 days, respectively, were not limitations to the interpretation of the study. It is noteworthy that the interpretation of any study is not based solely on statistical analysis, but more importantly, on biological relevance, which is underpinned by sound scientific judgement and comparisons with other studies in the scientific database. The group size and study duration are consistent with a range of clinical studies conducted in variously aged infants up to 6 months of age.

The Review Request raised the issue of infants as a vulnerable population group and the need to take a conservative approach. It is important to recall that soluble oligosaccharides, like naturally occurring HMOs, are not digested to any great extent in the small intestine, and reach the large intestine intact where they are also fermented by colonic bacteria to short-chain volatile fatty acids and carbon dioxide.

There is virtually no systemic exposure to these intact oligosaccharides and therefore the only possible adverse effect identified in infants was an increased osmotic potential within the colon due to the excretion of unchanged oligosaccharides, potentially leading to increased water loss and dehydration. This effect is more likely in very young infants because they lack a fully developed renal system and may not have full colonisation of the colon with bacteria capable of breaking down added oligosaccharides.

However, in comparison to breastfed infants, where the HMO concentration is up to 15 g/L, the levels of undigested oligosaccharides in the colon of infants fed infant formula containing inulin-derived substances and GOS will be about half those of breastfed infants. Therefore, it is unlikely that there is any risk to these very young infants from the presence of inulin-derived substances and GOS in infant formula at the levels suggested. This is supported by evidence that inulin-derived substances and GOS are fermented by colonic microflora to a similar or greater extent than HMOs.

To reiterate, FSANZ views the supplementary study by Veereman-Wauters *et al.* (2008) as supporting rather than pivotal evidence for the safety of the proposed maximum concentration. Therefore, FSANZ's assessment of the maximum permitted levels is based on the totality of evidence available, and has used the levels that have been shown to be safe in clinical studies to recommend maximum levels of inulin and GOS in infant formula products. No new data have been found to alter this conclusion after a comprehensive search of the published scientific literature, covering the period since the completion of the Final Assessment Report.

6.2.2 Established safety of the 9:1 ratio of GOS to long chain inulin compared with other ratios

6.2.2.1 The Review Request raised concerns that the majority of studies used in FSANZ's risk assessment have been conducted on the 9:1 of GOS to long chain inulin, while the proposed permissions are to add inulin-derived substances and GOS alone and in combination in any ratio. Thus, there is a stronger case for the safety of this level and ratio compared with other ratios, particularly when either substance is added alone to infant formula products.

FSANZ's safety assessment was informed by studies involving the addition of GOS and inulin-derived substances alone or in combination, to infant formula products, infant food, and toddler formula, and includes studies using concentrations of 4, 8 and 10 g/L. Although the majority of studies used the 9:1 ratio at a maximum level of 8 g/L, other studies have been undertaken with GOS or inulin-derived substances alone. At least one study was conducted with the 9:1 ratio at a level of 10 g/L. Based on the available evidence, FSANZ concluded that addition of a total level of 8 g/L of inulin-derived substances and GOS, alone or combined, at any ratio in infant formula products is unlikely to pose a risk to young infants.

This conclusion is based on data from clinical trials which have provided formulas supplemented with up to 10 g/L of inulin-derived substances and GOS to infants without evidence of harm. Data also indicated that these oligosaccharides are fermented to a similar or greater extent than HMOs. The safety of this level (8 g/L) is further supported by the presence of higher levels of HMOs (up to 25 g/L) in colostrum and (up to 15 g/L) in mature breast milk.

On the basis of the above considerations, FSANZ concludes that there are no safety concerns with regard to the addition of inulin-derived substances and/or GOS to infant and follow-on formula, infant foods and toddler formula, singularly or combined, in any ratio, up to 8 g/L.

6.2.3 Views of external experts regarding the conclusions of the safety assessment

6.2.3.1 The Review Request states that there was not consensus among experts on FSANZ's Infant and Child Health Scientific Advisory Group (ICSAG) regarding the increase in the maximum amount of inulin-derived substances permitted to be added to infant formula products from 3 g/L to 8 g/L

FSANZ established the ICSAG to provide scientific advice to FSANZ on matters relating to infant and child health. ICSAG comprises six members in addition to the FSANZ Chair[5] ICSAG met for the first time in December 2007. As this is an Advisory Group, minutes were not taken at this meeting, but outcome notes were provided to members following the meeting. The outcome notes indicated ICSAG members' agreement with FSANZ's proposed maximum level of inulin-derived substances added to infant formula products of 3 g/L although concerns were raised about the quality of the studies at the time.

Prior to completion of the Final Assessment, FSANZ sought additional comment from ICSAG members on the proposed increase in the maximum amount of inulin-derived substances from 3 g/L to 8 g/L permitted to be added to infant formula products. In response, three of the six external members provided comment. FSANZ did not expect a response from all members, as not all members have expertise in infant carbohydrate nutrition. Of those that did respond, two members were generally supportive of increasing the maximum amount of inulin-derived substances added to infant formula products from 3 g/L to 8 g/L based only on the additional evidence in the Veereman-Wauters *et al.* (2008) study referred to above in Section 6.2.1. Similar to the issues raised in the Review Request, the third member was not supportive of the increase on the basis that the study was not large enough to identify statistically significant differences (there were 20 infants in each treatment group), the short duration of the study (28 days post birth and up to five days old) and the categories of crying behaviour, vomiting and regurgitation were not sufficiently sensitive to detect differences.

Because of the lack of agreement among ICSAG members, FSANZ also sought advice from Professor Cummings[6] who considered that the additional evidence did provide reassurance of the safety of 8 g/L of inulin-derived substances in infant formula. His conclusion was based on no significant differences in terms of growth, weight gain and food intake between infants fed either 8 g/L of inulin-derived substances or those fed 8 g/L of GOS and inulin-derived substances in a ratio of 9:1. He also noted that stool frequency was well below that of the breastfed infants indicating that infants fed this formula were not at risk of dehydration. FSANZ did not contact Professor Gibson[7] again because he had concurred with FSANZ's risk assessment conclusions at Draft Assessment that 8 g/L in any combination of GOS, oligofructose and inulin, either alone or combined, was safe.

[5] ICSAG's membership is located at the following FSANZ website http://www.foodstandards.gov.au/aboutfsanz/scientificcapabilities/infantandyoungchilds3960.cfm.

[6] Professor John Cummings is Emeritus Professor of Experimental Gastroenterology, University of Dundee, Scotland and has expertise in dietary fibre and carbohydrates.

[7] Professor Glenn Gibson is Head of Food Microbial Sciences, University of Reading, England and has expertise in prebiotics.

Thus, FSANZ acknowledges that there was not complete agreement among all members of ICSAG. FSANZ has, however, maintained its conclusion that a maximum of 8 g/L of inulin-derived substances added to infant formula products is unlikely to pose a risk to the growth and development of infants fed this formula from birth onwards. This conclusion accords with the majority of reviewers including the international experts consulted.

6.3 Consistency with international food standards

6.3.1 Use of the term 'inulin-derived substances'

6.3.1.1 The Review Request states that the terminology, in particular the term inulin-derived substances, is not consistent with international terminology used for these substances. The Australian and New Zealand food regulatory system should strive for consistency between our food standards and international food standards, especially where international standards clearly protect public health and safety.

FSANZ has outlined its response to the safety concerns of these substances, particularly inulin-derived substances, when added to infant formula products in Section 6.2 above.

FSANZ considers that there are no international standards permitting the addition inulin-derived substances and GOS to infant formula products. FSANZ, has however, acknowledged the one overseas standard, the EC Directive on infant formula and follow-on formula (see Section 6.3.3 below) in its consideration of this Proposal.

In regard to terminology, FSANZ has consistently noted the use of a variety of terms used to describe inulin-derived substances in Australia, New Zealand and internationally. There are also no relevant Codex Alimentarius Commission standards that define inulin-derived substances. As a result there is confusion and misunderstanding when various terms are used. FSANZ has attempted to resolve this confusion by using the generic term 'inulin-derived substances' which includes oligofructose, inulin and long chain inulin, but not FOS.

As such, the proposed draft variations to Standards 2.9.1, 2.9.2 and 2.9.3 use the term inulin-derived substances and GOS to clarify the compositional permissions (which are inclusive of, but broader than, the EC regulations) but do not prescribe the terms to be used in labelling. For example, infant formula manufacturers could use other names, such as 'long chain FOS', in labelling to describe the addition of long chain inulin to their products, provided that these names describe the true nature of these substances. This approach provides flexibility for manufacturers to name inulin-derived substances to reflect the relevant and different target audiences for all the foods that may contain inulin-derived substances. This approach also allows the current differing terminology to continue to be used in the different contexts and therefore promotes consistency with the varying international terms used to describe inulin-derived substances.

6.3.2 Oligofructose as an inulin-derived substance

6.3.2.1 The Review Request queries why FSANZ is recommending the use of oligofructose as an inulin-derived substance but not FOS when oligofructose has an average chain length of less than ten but whose degree of polymerisation (DP) can vary from two to ten

Fructose polymers (fructans) are characterised by the range of the Degree of Polymerisation (DP), including the average DP. The DP is a measure of the number of fructose molecules or saccharide units in the substance. The DP ranges for the different fructans can vary with these ranges overlapping for the different substances. For this reason, the terms used to describe fructans in the Final Assessment Report have been described on the basis of the DP as well as their source (see Attachment 4 – Chemical and Technological Uses Assessment Report – of the Final Assessment Report for more information on the average DP, DP ranges and sources for particular substances).

The Final Assessment Report stated that inulin-derived substances includes 'oligofructose' that is produced from the partial enzymatic hydrolysis of inulin, typically with a DP in the range of 2-8, although a range of 3-9 has also been quoted. For the purpose of the Final Assessment Report, FOS was regarded as mixtures of fructose polymers produced from the enzymatic condensation of sucrose and they have a more narrow degree of polymerisation range (DP 3-5) than inulin-derived substances.

FOS, as described in the Final Assessment Report, has not been sufficiently studied in infants and young children to allow any conclusions about their physiological effects to be made. Therefore, there is insufficient data to support their addition to infant formula and special purpose foods for young children.

Based on this insufficiency of data, the draft variations needed to be worded so that fructose polymers produced from the enzymatic condensation of sucrose (i.e. FOS) were not permitted in infant formula products, infant foods and FSFYC. This was achieved by limiting the definition of 'inulin-derived substances' to inulin as the source. This excluded FOS from the definition of inulin-derived substances, removed the need to define FOS, and simplified the definitions in the draft variations by allowing them to be consolidated into two general terms.

In addition, FSANZ is not aware of the use of FOS in the general food supply in Australia or New Zealand, so their exclusion from the term inulin-derived substances is not seen as problematic.

6.3.3 Recommendation to permit the addition of inulin-derived substances to infant formula products and not restrict this to long chain inulin

6.3.3.1 The Review Request queries why FSANZ is recommending the addition of GOS and inulin-derived substances when the European Commission Directive recommends GOS and 'long chain inulin' and this appears to be the substances commonly added to infant formula products?

Independent risk assessments are an integral part of FSANZ's approach to developing food standards for Australia and New Zealand. In this context, FSANZ considers, but is not bound by, relevant international regulations.

However, FSANZ has acknowledged the EC Directive 2006/141/EC on infant formula and follow-on formula[8] published in December 2006. In relation to infant formula, this Directive states that:

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formula. In that case their content shall not exceed: 0.8 g/100 mL in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Article 5.

As noted in Attachment 2, 'oligogalactosyl-lactose' is the same substance as GOS and 'high molecular weight oligofructosyl-saccharose' is the same substance as long chain inulin.

Article 5 states that:

Infant formula shall be manufactured from protein sources defined in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

Such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The Directive also states that similar amounts and ratios may be voluntarily added to follow-on formula.

Thus, while the Directive permits the addition of GOS and long chain inulin to infant and follow-on formula, it also indicates that other substances can be added subject to a systematic review of the available data. FSANZ undertook an independent systematic review of both the published and unpublished literature and documented these findings in the Microbiological, Nutrition and Safety Assessments (see Attachments 5, 6 and 7, respectively, in the Final Assessment Report). The clinical studies reported in the literature included the inulin-derived substances: oligofructose (Raftilose® P95 and Beneo® P95) and inulin (Frutafit IQ) in addition to long chain inulin (Raftiline® HP and Synergy 1®).

The Assessments did not consider potential health benefit but the Microbiological and Nutrition Assessments compared the amounts of these and similar substances in breast milk, and whether they result in similar microbiological and physiological effects to breastfed infants. FSANZ indicated at Final Assessment that it will await the outcomes of the Policy Guideline on Infant Formula Products before considering potential health benefit in greater detail than has been considered in this interim regulatory response.

Thus, FSANZ considers that is has adequately met the systematic review process outlined in the EC Directive regarding the amounts and ratios of inulin-derived substances and GOS which can be safely added to infant formula products.

[8] 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.*

6.4 Enforcement and compliance

6.4.1 Analysis of inulin-derived substances and GOS in foods

6.4.1.1 The Review Request states that there is 'no reliable or agreed methodology' for the analysis of inulin-derived substances or GOS

Under the outcomes based approach to developing the Code, FSANZ does not prescribe analytical methods. While this approach is consistent with the philosophy engendered in the move to the Code, the issue of analytical methods has been raised in the context of a number of standards and by a range of stakeholders. It appears to be an issue that is best considered by the Implementation Sub-Committee (ISC) or FRSC as the appropriate bodies to determine what, if any, action should be taken to resolve this broader issue. If FSANZ received guidance or a request from the Ministerial Council to move to a more prescriptive approach in developing standards, a proposal would be raised to consider this issue and to provide opportunities for interested parties to provide input to this process.

In the absence of ISC consideration or Ministerial Council policy guidance, FSANZ considers that it is the role of laboratories or enforcement agencies to develop analytical capability for monitoring inulin-derived substances and GOS in foods. FSANZ cannot develop this capability on their behalf because method development and validation must be undertaken by appointed analysts to reflect their individual capability, their available analytical facilities and their commercial priorities. In addition, enforcement agencies can collaborate or develop agreements among themselves as to which methods they consider suitable for monitoring compliance. FSANZ considers that this is the most appropriate means for enforcement agencies to agree on methods suitable for monitoring enforcement.

Thus, methods of analysis for inulin-derived substances and GOS have not been prescribed to allow enforcement agencies and their appointed analysts to develop and agree on their own means of monitoring enforcement and thereby reduce the costs of developing suitable capability.

6.4.2 Cost of the methods of analysis

6.4.2.1 The Review Request states that there are 'considerable costs' to develop and verify methods but does not include information on these costs

In the Final Assessment Report, FSANZ acknowledged that published methods may need to be modified to be suitable for enforcement monitoring purposes. Depending on the analytical facility, method modification or validation may result in costs to enforcement agencies that have analytical facilities.

FSANZ has noted that methods for inulin-derived substances are already used for dietary fibre analysis and therefore capability for this analysis should already exist. On this basis, there should be no costs to enforcement agencies associated with the analysis of inulin-derived substances in food as the costs associated with developing this capability should already have been incurred.

As acknowledged at Final Assessment, costs for developing capability for GOS analysis may result in costs for enforcement agencies that have analytical facilities.

The Association of Official Analytical Chemists published method for GOS analysis has not been prescribed in the draft variations to assist enforcement agencies and their appointed analysts in developing alternative appropriate methods and therefore to reduce their costs for developing enforcement capability.

The potential costs to jurisdictions have not been itemised because this information was not provided to FSANZ. However, FSANZ expects any additional costs to be not significant given that most enforcement agencies would have this capability at least for inulin-derived substances. In any case, the costs for developing or validating methods would be unlikely to outweigh the benefits associated with this Proposal.

Moreover in accordance with Best Practice Regulation guidelines, FSANZ undertook a preliminary assessment that indicated negligible compliance costs for this Proposal. This assessment was forwarded to the Office of Best Practice Regulation (OBPR) the government's central body to promote and monitor the effectiveness and efficiency of regulation. The OBPR have cleared the Regulatory Impact Statement, including the impact analysis as adequate.

7. Proposed amendments to the draft variations

7.1 Maximum amount of inulin-derived substances permitted to be added to infant formula products

As indicated above in Sections 6.2.1 and 6.2.2, FSANZ's assessment of the maximum permitted level based on the totality of evidence re-affirms that 8 g/L of inulin-derived substances added to infant formula products is unlikely to pose a risk to the growth and development of infants fed this formula from birth onwards.

However, FSANZ notes that infant formula manufacturers[9] are not seeking permissions to add up to 8 g/L of inulin-derived substances to infant formula products at this time.

FSANZ also acknowledges that work on the Ministerial Council's Policy Guideline on the regulation of infant formula products has commenced. Once this policy guidance is received FSANZ intends to review Standard 2.9.1. Also, as noted above (see Section 6.1.4), FSANZ has undertaken this Proposal in accordance with section 36 of the FSANZ Act so that the immediate problem is addressed and regulatory certainty is provided in a timely and responsive manner.

Therefore at First Review, in noting the interim nature of the regulatory response and the levels being sought for use by the infant formula industry, FSANZ is proposing to amend the maximum level of inulin-derived substances permitted to be added to infant formula products from 8 g/L proposed at Final Assessment to 3 g/L as proposed at Draft Assessment.

8. Review options

Three options were considered in this Review:

[9] FSANZ has received two Applications seeking to add inulin-derived substances to infant formula products. Application A609 from Nutricia Australia Pty Limited is seeking permission to add GOS and long chain inulin up to 8 g/L in a ratio of 9:1. Application A598 from Heinz Wattie's Limited is seeking permission to add GOS alone up to 8 g/L or FOS alone up to 3 g/L. The specification for FOS has yet to be clarified with Heinz.

1. re-affirm approval of the draft variations to the Code as notified to the Ministerial Council;

2. re-affirm approval of the draft variations to the Code subject to any amendments FSANZ considers necessary; or

3. withdraw approval of the draft variations to the Code as notified to the Ministerial Council.

9. Conclusion

The First Review concludes that the preferred option is Option 2 – re-affirm approval of the draft variations to the Code subject to any amendments FSANZ considers necessary (at Attachment 1).

References

Veereman-Wauters, G., Staelens, S., Vandebroek, H., Plaskie, K. *et al.* (2008) Study of the effects of prebiotics on the intestinal flora of the neonate. Unpublished Report.

Attachments

Draft variations to the Australia New Zealand Food Standards Code.
Terminology

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunsetting.

To commence: on gazettal

[1] ***Standard 1.1.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in clause 2 –*

galacto-oligosaccharides means a mixture of those substances produced from lactose by enzymatic action, comprised of between two and eight saccharide units, with one of these units being a terminal glucose and the remaining saccharide units being galactose, and disaccharides comprised of two units of galactose.

inulin-derived substances 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.

[1.2] *inserting after clause 9 –*

9A Certain substances not nutritive substances

Inulin-derived substances are taken not to be nutritive substances.

[2] ***Standard 2.9.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *inserting after clause 9 –*

9A Permitted inulin-derived substances and galacto-oligosaccharides

(1) Infant formula product may contain no more than –

(a) 110 mg per 100 kJ of inulin-derived substances; or
(b) 290 mg per 100 kJ of galacto-oligosaccharides; or
(c) 290 mg per 100 kJ of combined inulin-derived substances and galacto-oligosaccharides, where the inulin-derived substances is no more than 110 mg per 100 kJ.

(2) For subclause (1) the maximum permitted amount only applies when the substances are added. In that case the maximum permitted amount then applies to the sum of the naturally occurring and the added substances.

[2.2] *omitting paragraph 16(1)(c), substituting –*

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

(d) when added, the average amount of –

(i) a combination of inulin-derived substances and galacto-oligosaccharides; or
(ii) inulin-derived substances; or
(iii) galacto-oligosaccharides

expressed in weight per 100 mL.

[2.3] *omitting paragraph 16(2)(d), substituting –*

(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 inulin-derived substances and galacto-oligosaccharides; or
(ii) inulin-derived substances; or
(iii) galacto-oligosaccharides

expressed in weight per 100 mL.

[2.4] *omitting clause 20, substituting –*

(1) The label on a package of infant formula product must not contain –

(a) a picture of an infant; or
(b) a picture that idealises the use of infant formula product; or
(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or
(d) words claiming that the formula is suitable for all infants; or
(e) information relating to the nutritional content of human milk; or
(f) subject to clause 28, a reference to the presence of any nutrient or nutritive substance, except for a reference to a nutrient or nutritive substance in –

(i) clause 30 – claims relating to lactose free formula or low lactose formula; or
(ii) Standard 1.2.4 – labelling of ingredients; or
(iii) clause 16-declaration of nutrition information; or

(g) subject to Division 3, a representation that the food is suitable for a particular condition, disease or disorder.

(2) Subject to clause 28, the label on a package of infant formula product must not contain a reference to inulin-derived substances or galacto-oligosaccharides except for a reference to either substances in –

(a) a statement of ingredients; or
(b) the nutrition information statement.

[2.5] *omitting the* Nutrition Information *table in the* Guidelines for Infant Formula Products, *substituting* –

NUTRITION INFORMATION

	Average amount per 100 mL made up formula *1	**Average amount per 100 g of powder (or per 100 mL for liquid concentrate) *2**
Energy	kJ	kJ
Protein	g	g
Fat	g	g
Carbohydrate	g	g
Vitamin A	µg	µg
Vitamin B_6	µg	µg
Vitamin B_{12}	µg	µg
Vitamin C	mg	mg
Vitamin D	µg	µg
Vitamin E	µg	µg
Vitamin K	µg	µg
Biotin	µg	µg
Niacin	mg	mg
Folate	µg	µg
Pantothenic acid	µg	µg
Riboflavin	µg	µg
Thiamin	µg	µg
Calcium	mg	mg
Copper	µg	µg
Iodine	µg	µg
Iron	mg	mg
Magnesium	mg	mg
Manganese	µg	µg
Phosphorus	mg	mg
Selenium	µg	µg
Zinc	mg	mg
Chloride	mg	mg
Potassium	mg	mg
Sodium	mg	mg
(insert any other nutritive substance or inulin-derived substances and galacto-oligosaccharides to be declared)	g, mg, µg	g, mg, µg

***1** – Delete the words 'made up formula' in the case of formulas sold in 'ready to drink' form.
***2** – Delete this column in the case of formulas sold in 'ready to drink' form.

[2.6] *deleting the* Note *at the end of the* Nutrition Information *table in the* Guidelines for Infant Formula Products

[3] ***Standard 2.9.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[3.1] *omitting paragraph 2(2)(b) substituting –*

(b) lactic acid producing cultures; and
(c) either singularly or in combination, no more than 0.8g/ 100 g of inulin-derived substances and galacto-oligosaccharides, as consumed.

(3) For paragraph 2(2)(c) the maximum permitted amount only applies when the substances are added. In that case the maximum permitted amount then applies to the sum of the naturally occurring and the added substances.

[3.2] *omitting subclause 2(3) and the heading to the* Table to paragraph 2(3)(c)*, substituting –*

(4) Food for infants must not contain –

(a) more than 50 mg/100 g of total iron in cereal-based food on a moisture free basis; or
(b) honey, unless it has been treated to inactivate *Clostridium botulinum* spores; or
(c) more than the total quantity of sodium set out in column 2 of the Table to this paragraph for each particular type of food for infants; or
(d) added salt, in the case of ready-to-eat fruit-based foods, fruit drink and vegetable juice.

Table to paragraph 2(4)(c)

[3.3] *omitting subclause 2(4)* and the Editorial note, *substituting –*

(5) Food for infants intended for infants under the age of 6 months must be formulated and manufactured to a consistency that minimises the risk of choking.

Editorial note:

The intent of subclause (5) is to ensure that the food, except in the case of rusks, should have a texture that is soft and free of lumps.

[4] ***Standard 2.9.3*** *of the Australia New Zealand Food Standards Code is varied by –*

[4.1] *inserting in clause 6 –*

(4) Formulated supplementary foods for young children may contain singularly or in combination, no more than 1.6 g of inulin-derived substances and galacto-oligosaccharides per serving.

(5) For subclause 6(4) the maximum permitted amount only applies when the substances are added. In that case the maximum permitted amount then applies to the sum of the naturally-occurring and the added substances.

Attachment 2

Terminology

1. Inulin-derived substances and fructo-oligosaccharides

Given the differences in the terminology currently in use, FSANZ developed terminology for fructose polymers to ensure there was clarity about these terms in assessing or considering the assessments for Proposal P306. FSANZ acknowledges that there are diverse opinions regarding the description of inulin-derived substances and that a number of different terms and expressions are used to describe these substances. To ensure that there is clarity about the terminology and identity of these substances, the following terms are used:

- The term '**inulin-derived substances**' is used to collectively describe inulin, long-chain inulin and oligofructose. This term does not include those fructose polymers derived from sucrose;

- the term 'inulin' is used to describe those fructans[10], with β (2→1) fructosyl-fructose linkages, where the average degree of polymerisation[11] (DP) is equal to or greater than ten:

  - the term '**long-chain inulin'** is used to describe those fructans with β (2→1) fructosyl-fructose linkages, where the average DP is equal to or greater than 23;

- the term 'oligofructose' is used to describe those fructans, with β (2→1) fructosyl-fructose linkages, where the average DP is less than ten but greater than or equal to four. Oligofructose is derived from inulin. Chicory inulin, for example, contains about 30% oligofructose; and

- the term 'fructo-oligosaccharides' is used to describe those fructose polymers with β (2→1) fructosyl-fructose linkages, where the average DP is less than four and is typically produced from enzymic condensation of sucrose.

FSANZ also acknowledges that sometimes oligofructose and inulin are referred to as 'FOS' and FOS is sometimes referred to as 'oligofructosyl-saccharose'. In addition, the terms oligofructose and FOS are sometimes used interchangeably. Given the differences in the terminology currently in use, the terms described above have been used to ensure clarity in the FSANZ assessment process and related consultations.

Fructans are characterised by the range of the DP, including the average DP. The DP is a measure of the number of fructose molecules or saccharide units in the substance. The DP ranges can vary for the different fructans with these ranges overlapping for the different substances. For this reason, the terms used above have been described on the basis of the average DP.

[10] Polymers of fructose.
[11] Degree of polymerisation is the number of fructose or saccharide units.

The term '**long-chain inulin'** is used to describe the processed inulin fraction that is currently added to infant formula, follow-on formula, infant foods and FSFYC internationally. The terms **inulin**, **oligofructose** and **FOS** is used where appropriate.

2. Galacto-oligosaccharides

The term '**galacto-oligosaccharides'** (sometimes referred to as oligogalactosyl-lactose) is used consistently to describe those substances comprised of between two and eight saccharide units with one of these units being a terminal glucose and the remaining saccharide units being galactose and disaccharides comprised of two molecules of galactose. While disaccharide lactose is present in GOS mixtures, it is not regarded as a galacto-oligosaccharide. GOS is produced from lactose by enzymatic action and is also referred to as 'trans-GOS'.

3. Oligosaccharides and polysaccharides

The terms oligosaccharides and polysaccharides are used throughout this Report.

Oligosaccharides refer to component sugars with a DP range 3-10.

Polysaccharides contain several simple sugars (DP > 10) linked together and are often referred to as complex carbohydrates.

Human milk oligosaccharides (HMOs) is a collective term used to refer to the oligosaccharide and polysaccharide content of human breast milk.