



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

**21 December 2007**  
**[9-07]**

## **INITIAL ASSESSMENT REPORT**

### **APPLICATION A609**

## **ADDITION OF GOS, LONG CHAIN INULIN TO INFANT FORMULA PRODUCTS & INFANT FOOD**

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 22 February 2008**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE**

**WILL NOT BE CONSIDERED**

*(See 'Invitation for Public Submissions' for details)*

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

## **EXECUTIVE SUMMARY**

Food Standards Australia New Zealand (FSANZ) has received a paid Application from Nutricia Australia Pty Limited (Nutricia) to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the addition of galacto-oligosaccharides (GOS) and long chain inulin<sup>1</sup> as ingredients to infant formula products and infant foods. The Applicant is seeking to add GOS and long chain inulin in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively.

There is currently no express permission in the Code for the addition of GOS and long chain inulin to infant formula products and infant foods. The Applicant has stated that this Application is needed to provide clarity for all stakeholders regarding GOS and long chain inulin in infant formula products and infant foods by providing a defined upper limit and permission for the addition of GOS and long chain inulin in a ratio of 9:1. However, a separate proposal (Proposal P306 – Addition of Inulin/FOS and GOS to Food) is currently seeking to confirm the regulatory position for the food industry of these substances in the general food supply and more specifically in foods for infants and young children. Proposal P306 provides greater detail for some issues that relate to this Application, particularly the risk assessment. FSANZ has therefore released concurrently its invitations for public submissions for this Application A609, and Proposal P306. FSANZ suggests this Initial Assessment Report should be read and considered together with Proposal P306.

The Applicant has stated a range of potential health benefits arising from the consumption by infants of GOS and long chain inulin in a ratio of 9:1 and at the proposed maximum levels. However, in the absence of Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) policy guidance that would apply to this Application, FSANZ will, in accordance with its primary statutory objective, only describe the physiological effects compared with breastfed infants and assess the safety aspects of the addition of these substances to infant formula products and infant foods – potential health benefits will not be assessed.

### **Purpose**

The purpose of this Initial Assessment Report is to provide information, including relevant information supplied by the Applicant, to identify affected parties and to outline the relevant issues and FSANZ's proposed approach to evaluating the Application.

### **Reasons for Initial Assessment**

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) [in place before 1 July 2007], FSANZ has decided to accept the Application for the following reasons:

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<sup>1</sup> The Applicant uses the expression 'long chain fructo-oligosaccharides' to describe the substance to be added to infant formula products and infant foods. Based on the information available, FSANZ considers this substance to be a fraction of processed 'inulin' and as such refers to this substance as 'long chain inulin'. This is supported by the specifications for this substance provided in the Application.

- The Application seeks approval to add GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively. Such an approval, if granted, may require a variation to Standards 2.9.1 – Infant Formula Products and 2.9.2 – Foods for Infants.
- There is currently no express permission in the Code for the addition of GOS and long chain inulin to infant formula products and infant foods.
- The Application is not so similar to any previous Application that it ought not be accepted. However, as the Draft Assessment Report for Proposal P306 is being released for public consultation concurrently with this Application, it is likely to be completed before this Application. Because Proposal P306 deals with aspects of this Application it may satisfy in part, or as a whole, the requirements of this Application.
- Notwithstanding the pending completion of Proposal P306 prior to completion of Application A609, there are no other measures that would be more cost-effective than a variation to Standards 2.9.1 and 2.9.2 that could achieve the same end.
- At this stage no other relevant matters are apparent.

At Initial Assessment FSANZ is considering two options for addressing this Application:

**Option 1** – maintain the *status quo* by not amending the Code to permit the addition of GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively.

**Option 2** - amend Standards 2.9.1 and 2.9.2 to permit the addition of GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively.

FSANZ will undertake a full impact analysis at Draft Assessment however; preliminary consideration of the effects of these two options is included in Section 7 of this Initial Assessment Report.

## **Consultation**

This Initial Assessment Report is intended to elicit public comment to help FSANZ assess this Application and to seek early responses to a range of specific issues, including the likely regulatory impact of this Application. FSANZ has posed a number of questions in this Initial Assessment Report to facilitate consideration of Application A609 and would like public responses to these questions, the proposed regulatory options, and the report as a whole.

FSANZ will use responses to this Initial Assessment Report to develop the next stage of the Application assessment and prepare a Draft Assessment Report.

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## **INVITATION FOR PUBLIC SUBMISSIONS**

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles, safety assessment and for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as confidential commercial information. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand**  
**PO Box 7186**  
**Canberra BC ACT 2610**  
**AUSTRALIA**  
**Tel (02) 6271 2222**  
**[www.foodstandards.gov.au](http://www.foodstandards.gov.au)**

**Food Standards Australia New Zealand**  
**PO Box 10559**  
**The Terrace WELLINGTON 6036**  
**NEW ZEALAND**  
**Tel (04) 473 9942**  
**[www.foodstandards.govt.nz](http://www.foodstandards.govt.nz)**

This first public consultation period for this Application is extended to eight weeks (from the usual six weeks) to allow for the summer holiday break.

**Submissions need to be received by FSANZ by 6pm (Canberra time) 22 February 2008.**

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au).

## **GLOSSARY**

AI	adequate intake
AOAC	Association of Official Analytical Chemists
DP	degree of polymerisation
EFSA	European Food Safety Authority
FOS	fructo-oligosaccharides
FSANZ	Food Standards Australia New Zealand
GOS	galacto-oligosaccharides
GRAS	generally recognised as safe

## **INTRODUCTION**

Food Standards Australia New Zealand (FSANZ) received a paid Application from Nutricia Australia Pty Limited (Nutricia) on 27 July 2007. The Application seeks to amend Standard 2.9.1 – Infant Formula Products and 2.9.2 – Foods for Infants in the *Australia New Zealand Food Standards Code* (the Code) to permit the addition of galacto-oligosaccharide (GOS) and long chain inulin as ingredients in a ratio of 9:1 in infant formula products and infant foods at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively.

This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comments from stakeholders to assist FSANZ in making an assessment of this Application.

### **1. Background**

#### **1.1 Nature of the Application received by FSANZ**

The Applicant has proposed the addition of GOS and ‘long chain fructo-oligosaccharides’ to infant formula products and infant foods. The Applicant uses the expression ‘long chain fructo-oligosaccharides’ to describe the substance to be added to infant formula products and infant foods. Based on the information available, FSANZ considers this substance to be a fraction of processed ‘inulin’ and as such refers to this substance as long chain inulin (refer to section 1.4 for further details on terminology used in this Application). This is supported by the specifications for this substance provided in the Application.

The Applicant is seeking permission to add GOS and long chain inulin as ingredients, and more specifically to:

1. regulate levels of GOS and long chain inulin in a ratio of 9:1 for infant formula and foods for infants at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively in Australia and New Zealand; and
2. align such regulation with that already in place in the European Union.

With regard to the request to add these substances to infant formula products, it is not clear in the Application if Nutricia want to add GOS and long chain inulin to all types of infant formula product defined in Divisions 2 and 3 of Standard 2.9.1 (*i.e. Division 2 – Infant Formula and Follow-on Formula and Division 3 – Infant Formula Products for Special Dietary Use*). For the purpose of this Initial Assessment Report, FSANZ will assume that the request applies to all three types of infant formula described in Divisions 2 and 3 of Standard 2.9.1.

The Applicant has stated that this Application is needed to provide clarity for all stakeholders regarding GOS and long chain inulin in infant formula products and infant foods by providing a defined upper limit and permission for the addition of GOS and long chain inulin in a ratio of 9:1.

Additionally, the Applicant has claimed that consumption by infants of GOS and long chain inulin (in a ratio of 9:1 at a maximum of 0.8 g/ 100 mL) has been shown to promote the following benefits:

- *Stimulation and growth of naturally occurring beneficial bacteria in the gut of formula fed infants, resembling microflora profiles found in breastfed infants;*
- *Promoting softer, more frequent stools, similar to breastfed infants;*
- *Reduction in atopic dermatitis in formula fed babies at risk of allergy; and*
- *Reduction of infection in formula fed babies, reduced diarrhoea and recurrent upper respiratory tract infections.*

## **1.2 Other related FSANZ work**

In addition to this Initial Assessment Report, FSANZ has prepared Proposal P306 – Addition of Inulin/FOS & GOS to Food to confirm the regulatory position for the food industry of inulin-derived substances and fructo-oligosaccharides (FOS) when added to the general food supply, and to consider permissions for the addition of inulin-derived substances, FOS and GOS when added to infant and follow-on formula, infant foods and formulated supplementary foods for young children. Proposal P306 covers some of the key issues associated with the assessment of Application A609. Invitations for public submissions for this Initial Assessment Report for Application A609 and the Draft Assessment Report for Proposal P306 are being requested concurrently. Submitters to this Application are encouraged to consider Proposal P306 in their submissions to Application A609.

FSANZ has also received Application A598 – Addition of Prebiotic Oligosaccharides in Infant Formula Products from Heinz Wattie’s. Application A598 seeks to permit the addition of prebiotic oligosaccharides, namely GOS and FOS<sup>2</sup> as nutritive substances in infant formula products up to a maximum concentration of approximately 0.8 g/100 mL of GOS and 0.3 g/100 mL of FOS. The assessment of Application A598 is due to commence in the first quarter of 2008.

As Proposal P306 deals with aspects of both this Application and Application A598, it may ultimately satisfy in part, or whole, the requirements of these Applications.

## **1.3 Terminology**

FSANZ acknowledges that there are diverse opinions within industry groups regarding the description of inulin-derived substances and FOS and that a number of different terms and expressions are used to describe these substances in published literature. To ensure clarity in this Initial Assessment Report, the following terminology accords with the terms that have been applied at Draft Assessment for Proposal P306.

### *1.3.1 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.

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<sup>2</sup> No specifications were provided for these substances, hence until processing of Application A598 begins, FSANZ is uncertain of the specific substances being requested.



While the disaccharide lactose is present in GOS mixtures, it is not regarded as a GOS. GOS is produced from lactose by enzymatic action and is also referred to as ‘trans-GOS’.

### 1.3.2 Long chain inulin and other related substances

Fructans<sup>3</sup> are characterised by the range of the degree of polymerisation<sup>4</sup> (DP), and/or 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 in this Report have been described on the basis of the average DP (see Attachment 2 of Proposal P306 for more information on the DP ranges for particular substances).

Throughout this report the term ‘**long chain inulin**’ is used to describe the processed inulin fraction that is proposed to be added to infant formula products and infant foods by the Applicant. The terms **inulin**, **oligofructose** and **fructo-oligosaccharides** (all defined below) will be used where appropriate; the term ‘**inulin-derived substances**’ is used to collectively refer to inulin, long chain inulin and oligofructose.

- The term ‘**inulin**’ means those fructans, with  $\beta$  (2→1) fructosyl-fructose linkages, where the average DP is equal to or greater than ten;
  - the term ‘**long chain inulin**’ means those fructans with  $\beta$  (2→1) fructosyl-fructose linkages, where the average DP is equal to or greater than 23;
- the term ‘**oligofructose**’ means those fructans, with  $\beta$  (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**’ means those fructose polymers with  $\beta$  (2→1) fructosyl-fructose linkages, where the average DP is less than four and is typically produced from enzymic condensation of sucrose.

FSANZ acknowledges that sometimes oligofructose and inulin are referred to as ‘FOS’ and sometimes ‘FOS’ is 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, this Report uses the highlighted terms described above to ensure clarity in the FSANZ assessment process and related consultations.

### 1.3.3 Other terms 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.

**Infant formula products and foods for infants** are defined in Section 1.6.

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<sup>3</sup> Polymers of fructose.

<sup>4</sup> Degree of polymerisation is the number of fructose or saccharide units.

**Note to submitters:**

**The terminology in this Initial Assessment Report has been based on that described in Proposal P306. If submitters have comment on these descriptions, they should do so through Proposal P306.**

#### **1.4 Food technology aspects**

FSANZ is unaware of any food technology basis for the addition of GOS or inulin-derived substances such as long chain inulin to infant formula products or infant foods. For this reason, FSANZ is not proposing to assess the food technology aspects of the addition of GOS and long chain inulin to infant formula products or infant foods.

#### **1.5 Ministerial Policy Guidelines**

When developing and varying food standards, FSANZ must have regard to any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). The Ministerial Council is currently developing a policy guideline on the addition of substances other than vitamins and minerals to foods. However, preliminary indications suggest that the policy will not apply to special purpose foods such as infant formula products.

In the absence of policy guidance that would apply to this Application, FSANZ will describe the physiological effects compared with breastfed infants and assess the safety aspects of the addition of these substances to infant formula products and infant foods, however, potential health benefits will not be assessed for this Application.

#### **1.6 Domestic and international regulations**

##### *1.6.1 Domestic regulations*

The Standards in the Code relevant to this Application are:

**Standard 2.9.1 – Infant Formula Products** regulates the compositional and labelling requirements for infant formula products. There are a number of clauses in Standard 2.9.1 which permit specific substances, such as lactic acid cultures, to be added to infant formula products. There is currently no express permission in Standard 2.9.1 for the addition of GOS and long chain inulin. The term infant formula product includes infant formula, follow-on formula and infant formula products for special dietary use. Infant formula products for special dietary use includes:

- (a) Infant formula products formulated for premature or low birthweight infants;
- (b) Infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions; and
- (c) Infant formula products for specific dietary use based upon protein substitutes.

Relevant definitions from Standard 2.9.1 are:

*infant formula product* means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

*infant formula* means an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.

*follow-on formula* means an infant formula product represented as either a breast milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months.

**Standard 2.9.2 – Foods for Infants** regulates the compositional and labelling requirements of foods intended and/or represented for use as food for infants. Foods in this Standard are intended to be fed to infants in addition to human milk and/or infant formula products. Clause 2 in Standard 2.9.2 provides permissions for specific substances which may be added, but currently no express permission exists for the addition of GOS and long chain inulin to infant foods.

Relevant definitions from Standard 2.9.2 are:

*Food for infants* means a food that is intended and/or represented for use as a source of nourishment for infants, but does not include –

- (a) infant formula products; and
- (b) formulated meal replacements; and
- (c) formulated supplementary foods; and
- (d) unprocessed fruit and vegetables.

*Infant* means a person up to the age of 12 months.

## 1.6.2 International regulations

There are international regulations relating to the addition of GOS and long chain inulin to infant formula products and infant foods. The relevant international regulations of which FSANZ is aware of are outlined below.

### 1.6.2.1 Codex Alimentarius

The recently adopted revised Codex Standard for infant formula and formulas for special medical purposes intended for infants<sup>5</sup> does not specifically recognise GOS and long chain inulin but allows the addition of *optional ingredients* to infant formula. Optional ingredients, may be added *in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breast-fed babies.*

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<sup>5</sup> Codex Alimentarius Commission. Standard for infant formula and formulas for special medical purposes intended for infants (2007). Formerly CAC/RS 72-1972. Adopted as a world-wide Standard 1981, Amended 1983, 1985, 1987. Revision 2007.

The revised Standard also states 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.*

The Codex Standards for Canned Baby Foods<sup>6</sup> also does not contain express permissions for GOS and long chain inulin but 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.* Similarly, the Codex Standard for Processed Cereal-based Foods for Infants and Young Children<sup>7</sup> allows the addition of *other ingredients suitable for infants who are more than six months of age and for young children.*

#### 1.6.2.2 United States of America (USA)

Inulin from the root of the chicory plant (*Cichorium intybus*) is ‘generally recognized as safe’ (GRAS) for use in food as a bulking agent<sup>8</sup>. Of the 43 food categories that are permitted to contain added inulin in varying levels, baby foods and beverages are included, but infant formula is excluded. Based on these food categories, dietary intakes of inulin in the U.S. at the 90<sup>th</sup> percentile level are estimated to be approximately 6 g per day for infants less than one year of age, approximately 15 g per day for infants older than one year of age, and approximately 20 g per day for the general population (i.e. two years of age and older).

FOS is GRAS for use as a bulking agent in specific foods<sup>9,10</sup>. Infant foods (0-12 months) and toddler foods (12-24 months) are included in the permitted range of foods but infant formula is explicitly excluded.

#### 1.6.2.3 European Union

In December 2006, the European Commission published Commission Directive 2006/141/EC on infant formulae and follow-on formulae<sup>11</sup>. The previous directive, Commission Directive 91/321/EEC<sup>12</sup>, will be repealed with effect from 1 January 2008.

Infant formula products and follow-on formula products containing added oligosaccharides have been marketed in the European Union for several years. Commission Directive 91/321/EEC provides a general provision for the addition of *other food ingredients* to infant formula and follow-on formula; this includes oligosaccharides<sup>13</sup>.

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<sup>6</sup> Codex Standards for Canned Baby Foods. Codex Stan 71-1981.

<sup>7</sup> Codex Standard for Processed Cereal-based Foods for Infants and Young Children. Codex Stan 074-1981, Rev 1-2006.

<sup>8</sup> US Food and Drug Administration. Agency Response Letter GRAS Notice No. GRN 000118, 5 May 2003. Available at: <http://www.cfsan.fda.gov/~rdb/opa-g118.html>

<sup>9</sup> US Food and Drug Administration. Agency Response Letter GRAS Notice No. GRN 000044, 22 November 2000. Available at: <http://www.cfsan.fda.gov/~rdb/opa-g044.html>

<sup>10</sup> US Food and Drug Administration. Agency Additional Correspondence Letter GRAS Notice No. GRN 000044, 1 June 2007. Available at: <http://www.cfsan.fda.gov/~rdb/opag044a.html>

<sup>11</sup> 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/I, 30/12/2006.*

<sup>12</sup> Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae. *Official Journal of the European Union, L 175, 04/07/1991.*

<sup>13</sup> Personal communication – Health and Consumer Protection Directorate-General, European Commission, June 2007.

However, at the request of Member States, the European Commission asked the Scientific Committee on Food<sup>14</sup> (SCF) to comment on *the suitability and safety of the resistant short chain carbohydrates, FOS and GOS, in infant formula and follow-on formula.*

The SCF released two statements on the above matter in 2001<sup>15,16</sup>. The statements concluded that there were no major concerns about the combination of 90% GOS and 10% *high molecular weight oligofructosyl-saccharose*<sup>17</sup> in infant formula and follow-on formula in total concentrations up to 0.8 g/ 100 mL in the product ready for consumption.

Subsequently, as part of a review of the essential requirements of infant formula and follow-on formula, the SCF was requested to address the content of FOS and GOS in these products. In April 2003, the SCF released a report<sup>18</sup> that reaffirmed their previous statement of December 2001. In addition, the SCF concluded that *fructans other than [high molecular weight] oligofructosyl-saccharose should not be included in infant formulae and follow-on formulae*, based on available data at that time.

In 2003, the European Commission requested the European Food Safety Authority (EFSA) to provide a scientific opinion on the safety and suitability for particular nutritional use by infants of oligofructose (referred to as fructo-oligosaccharides by EFSA) at conditions specified by a manufacturer of infant formula and follow-on formula. The conditions specified by the manufacturer were an infant formula supplemented with 1.5 or 3.0 g/L of oligofructose.

On 19 February 2004, the Scientific Panel on Dietetic Products, Nutrition and Allergies of EFSA concluded that *there is no evidence of benefits to infants from the addition of fructo-oligosaccharides to infant formula at the conditions specified by the manufacturer while there are reasons for safety concerns.* This conclusion was based on *an increased prevalence of adverse effects, including loose stools, in infants fed formula with added fructooligosaccharides. As no measures were made to demonstrate satisfactory water balance, the possibility of increased risk of dehydration can not be excluded, raising concerns with respect to the safety of such formulae.*

On 22 December 2006, the European Commission issued a revised Directive on infant formulae and follow-on formulae (Commission Directive 2006/141/EC). In relation to infant formula, this Directive states that:

*Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formulae. 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.*

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<sup>14</sup> Scientific Committee on Food is now known as the European Food Safety Authority (EFSA).

<sup>15</sup> Scientific Committee on Food. Statement on the use of resistant short chain carbohydrates (oligofructose and oligogalactose) in infant formulae and in follow-on formulae, expressed on 26 September 2001.

<sup>16</sup> Scientific Committee on Food. Additional statement on the use of resistant short chain carbohydrates (oligofructosyl-saccharose and oligogalactosyl-lactose) in infant formulae and in follow-on formulae, expressed on 13 December 2001.

<sup>17</sup> *High molecular weight oligofructosyl-saccharose* is referred to as 'long chain inulin' in this report.

<sup>18</sup> Scientific Committee on Food. Report of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae, adopted on 4 April 2003.

Article 5 states that:

*Infant formulae 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. This Directive must be adopted by Member States by 31 December 2007.

#### 1.6.2.4 United Kingdom

The European Commission Directive 2006/141/EC will be implemented by respective regulation in England, Wales, Scotland and Northern Ireland. For example, in England the *Infant Formula and Follow-on Formula (England) Regulations 2007* will implement the Commission Directive 2006/141/EC, and will revoke and replace, in England, the existing *Infant Formula and Follow-on Formula Regulations 1995*.

The Food Standards Agency will develop Guidance Notes to assist stakeholders interpret the provisions of the new Regulations before 1 January 2008.

#### 1.6.2.5 Asian countries

Infant formula products with added inulin, oligofructose and GOS have been marketed in many Asian countries for a number of years. It appears that these countries do not prohibit the addition of these substances to infant formula products. However, many Asian countries require products to be registered before they are permitted to be imported into the respective country. In some instances, product registration requires the product to be compliant with the food regulations of the country of origin.

In August 2007, the New Zealand Food Safety Authority published an exemption from the requirements of the Code, in relation to the use of oligosaccharides in the manufacture of dairy based infant formula products for export to specified countries, including China, Malaysia, Indonesia and Republic of Korea<sup>19</sup>.

In Japan, oligosaccharides have ‘foods of specified health use’ (FOSHU) status, relating to a *health function* as a food to *modify gastrointestinal conditions*<sup>20</sup>.

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<sup>19</sup> New Zealand Food Safety Authority. Animal Products (Exemption from New Zealand Standards – Oligosaccharides in Infant Formula Products) Notice 2007 (3 August 2007). Available at: <http://www.nzfsa.govt.nz/dairy/publications/specifications/fos-gos-60b-exemption-notice-2007.pdf>

<sup>20</sup> Ministry of Health, Labour and Welfare. Available at: <http://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html>

## **1.7 Current use**

### *1.7.1 Presence in food*

Inulin occurs naturally in many plant foods including wheat, bananas, onions, garlic, Jerusalem artichoke and chicory<sup>21</sup>. GOS is found in some dairy products, such as lactose-reduced milk and yoghurt.

### *1.7.2 Added to foods for infants and young children – internationally*

Infant formula products containing long chain inulin and GOS has been available in the United Kingdom and Ireland for several years.

As mentioned previously, infant formula and follow-on formula containing added oligosaccharides have been marketed in the European Union for several years (see Section 1.6.2.3).

Many Asian countries also sell infant formula and toddler formula products containing inulin, oligofructose and GOS.

## **2. The Issue**

The Applicant is seeking to regulate the addition of GOS and long chain inulin as ingredients to infant formula products and infant foods. Currently the Code does not provide express permission to add these substances to infant formula products and infant foods. The Applicant is proposing a specific ratio of GOS and long chain inulin of 9:1, and a defined upper limit of 0.8 g/100 mL or 0.8 g/100 g which they consider will provide clarity for all stakeholders. Permission for the addition of GOS and long chain inulin at the proposed levels and ratio will depend on demonstration of their safety.

## **3. Objectives**

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

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<sup>21</sup> The reference for this information describes inulin with a DP ranging from 2 to 60 or more and oligofructose with a DP from 2 to 20, which is different to the terminology for added substances referred to in this report.

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

#### **4. Key Risk Assessment Questions**

The key risk assessment questions listed below will be addressed in full at Draft Assessment:

1. Are GOS and long chain inulin *present in breast milk*? If so:
  - at what levels; and
  - how do these compare with the levels proposed for infant formula products and infant foods?
2. What are the *physiological effects* in infants of consuming GOS and long chain inulin in a 9:1 ratio?
3. How do the identified physiological effects compare with those in similarly aged breastfed infants?
4. What are the *potential risks* to infants consuming formula products and infant foods containing added GOS and long chain inulin in a 9:1 ratio up to 0.8 g/100 mL and 0.8g/100 g, respectively?
5. How much GOS and long chain inulin do infants already consume and how much additional inulin-derived substances and GOS would infants consume if these substances were added to infant formula products and infant foods in the amounts sought?

**Question to submitters:**

**Do submitters consider that any further questions should be addressed as part of the risk assessment for this application?**

### **RISK ASSESSMENT**

The risk assessment for this Application will require information on the oligosaccharide content in milks fed to infants; the physiological effects of GOS and long chain inulin such as microbiological function and stool consistency and frequency, stool pH and faecal short chain fatty acid profile; the safety aspects of the addition of these substances; and the current and estimated additional intakes of GOS and long chain inulin. The risk assessment for this Application will be addressed in full at Draft Assessment.



A risk assessment of the addition of inulin-derived substances including GOS and long chain inulin to infant formula products and infant foods has been described in detail in Proposal P306. In early December 2007, FSANZ discussed the risk assessment of Proposal P306 with the recently established Infant and Young Child Scientific Advisory Group (ICSAG)<sup>22</sup>. FSANZ convened this Group to provide scientific advice on any issues relating to Standards 2.9.1, 2.9.2 and 2.9.3. Their input relates to the health, nutritional status and safety of infants and young children consuming food products with added inulin/FOS and GOS. This Group may also be called upon to provide input on the risk assessment as it relates specifically to this Application.

## **RISK MANAGEMENT**

### **5. Identification of risk management issues**

At Initial Assessment potential risk management issues for Application A609 have been identified. FSANZ will consider the management of these issues and any further risks identified at Draft Assessment of this Application. This will include consideration of submitter comments received during the public consultation period.

#### **5.1 Safety, Levels of Addition and Proposed Ratio of GOS to Long Chain Inulin**

At Draft Assessment, FSANZ will consider the need to manage any identified safety issues arising from the risk assessment of the addition of GOS and long chain inulin to infant formula products and infant foods in a ratio of 9:1 and to a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively as specifically requested in this Application.

It is noted that the Applicant states in Application A609 that *Numico*<sup>23</sup> presently holds an intellectual property position, including patents, in relation to the use of prebiotics GOS and long chain FOS (high molecular weight) in a ratio of 9:1. Other manufacturers will need to consider this position and make their own enquiries if formulating infant formula products with added GOS and long chain inulin.

#### **5.2 Specifications for GOS and Long Chain Inulin for Addition to Infant Formula Products and Infant Foods**

Standard 1.3.4 – Identity and Purity requires that substances added to foods must comply with this Standard, where applicable. These requirements include specifications for certain substances.

The Applicant has provided specifications for GOS and long chain inulin that are proposed to be added to infant formula products and infant foods. FSANZ will consider whether these specifications or variations to them should be included in Standard 1.3.4.

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<sup>22</sup> ICSAG is an expert scientific advisory group who advise FSANZ on any matters relating to infant and young child foods. Details of the ICSAG and a list of its members will be available on the FSANZ website in the near future.

<sup>23</sup> Numico is an international food manufacturer of specialised food products including the Nutricia brand of infant formula products and infant foods.

### **5.3 Labelling Requirements for Infant Formula Products**

Specific labelling and packaging requirements for infant formula products are prescribed in Standard 2.9.1 – Infant Formula Products. In addition, the general labelling requirements under Part 1.2 of the Code, including Standard 1.2.4 – Labelling of Ingredients, also apply to these products, subject to any specified exemptions. If GOS and long chain inulin are permitted to be added to infant formula products in a 9:1 ratio, a specific declaration of these ingredients will be required in the statement of ingredients.

Clause 20 of Standard 2.9.1 prohibits claims on infant formula and follow-on formula in reference to the presence of any nutrient or nutritive substance, except where the reference is in the statement of ingredients or a nutrition information statement (exceptions apply also to information relating to lactose and infant formula products for specific medical conditions). FSANZ is currently considering a revised approach to nutrition, health and related claims. It is proposed in draft Standard 1.2.7 – Nutrition, Health and Related Claims that the above approach will be maintained. Therefore, claims on infant formula and follow-on formula that relate to the presence of any nutrient or nutritive substance will remain prohibited. FSANZ will further consider at Draft Assessment the need for additional labelling specific to the addition of GOS and inulin-derived substances to infant formula products.

### **5.4 Labelling Requirements for Infant Foods**

If permitted in infant foods, GOS and long chain inulin would have to be declared in the ingredient list in accordance with the requirements in Standard 1.2.4.

Under existing Code requirements, Standard 1.2.4 applies to infant foods as regulated in Standard 2.9.2 – Foods for Infants, with the exception of the requirement to declare compound ingredients.

General labelling requirements prescribed in Standard 1.2.8 – Nutrition Information Labelling apply to infant foods, notwithstanding specific claim criteria for nutrition claims relating to ‘no added sugar’ and ‘sweetened’ in clause 5 of Standard 2.9.2 and exemptions for specific provisions in Standard 1.2.8 that are listed in clause 9 of Standard 2.9.2. Where there is a direct inconsistency between nutrition labelling requirements in Standard 1.2.8 and in Standard 2.9.2, the latter would prevail to the extent of the inconsistency.

Standard 1.2.8 also includes general claim provisions applicable to infant foods. These provisions would apply to the specific forms of GOS and long chain inulin proposed for addition in this Application.

Currently infant foods are prohibited from carrying health claims under existing requirements in the Code. However, provisions for nutrition and health claims are currently being considered under Proposal P293 – Nutrition, Health and Related Claims, including provisions applicable to infant foods.

FSANZ will consider further at Draft Assessment labelling issues specific to the addition of GOS and inulin-derived substances to infant foods.

## 5.5 Compliance and enforcement

The Applicant has proposed specific maximum amounts of GOS and long chain inulin in infant formula products and infant foods. If these limits were approved, there would need to be a mechanism available to determine compliance with these limits.

FSANZ considers that suitable methods exist for compliance purposes and these methods have been published, including by the Association of Official Analytical Chemists<sup>24</sup>.

### Question to submitters:

**FSANZ invites comment on whether these methods are suitable for regulatory purposes and in particular whether they are suitable for monitoring compliance with the Applicant's proposed limits for GOS and long chain inulin in infant formula products and infant foods.**

## 6. Regulatory Options

At Initial Assessment, FSANZ is considering two regulatory options for Application A609:

- 1. Option 1** – maintain the *status quo* by not amending the Code to permit the addition of GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively.
- 2. Option 2** - amend Standards 2.9.1 and 2.9.2 to permit the addition of GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively.

## 7. Impact Analysis

### 7.1 Affected Parties

The parties likely to be affected by this Application are:

- infants who consume infant formula products and infant foods with added GOS and long chain inulin (**consumers**);
- **carers** of infants consuming infant formula products and infant foods;
- manufacturers and/or marketers of specialty ingredients (GOS and long chain inulin) for application in infant formula products and infant foods (**industry**);
- manufacturers, importers and exporters of infant formula products and infant foods with added GOS and long chain inulin (**industry**); and
- the **Governments** of Australia and New Zealand.

<sup>24</sup> Current methods in the Code for determining fructans as dietary fibre are listed in the Table to subclause clause 18(1) of Standard 1.2.8 – Nutrition Information Requirements: Inulin and fructo-oligosaccharide - Section 997.08 of the AOAC, 17th Edition (2000); Inulin - Section 999.03 of the AOAC, 17th Edition (2000).

## 7.2 Benefit Cost Analysis

Impacts on the interested parties have been considered in the Draft Assessment Report for Proposal P306 and it is likely that impacts will be similar for Application A609. However, further benefit cost analysis specific to Application 609 will be undertaken at Draft Assessment.

### 7.2.1 Consumers / Carers

Maintaining the *status quo* is unlikely to have a significant impact on consumers and their carers since appropriate infant formula products and infant foods would continue to be available for infants.

**Option 2** would provide consumers and their carers with an additional choice and enable infants to receive any potential benefit that may be provided by the addition of GOS and long chain inulin in a ratio of 9:1. Option 2 would also ensure the safety of these products and is likely to maintain consumer confidence. The manufacture of products with added GOS and long chain inulin may incur additional costs which may potentially be passed onto infant carers who chose to purchase these products.

### 7.2.2 Industry

Maintaining the *status quo* could limit innovation in product development as currently there are no expressed permissions for the addition of GOS and long chain inulin in the Code. This may then also limit the option to manufacture products suitable for both the local and overseas market as regulations would not harmonise with some international regulations, such as the European Union. This could affect economies of scale in the production of these products with possible increased manufacturing costs.

The *status quo* may also impact on trade opportunities by restricting the ability to export products to some countries that permit the addition of GOS and long chain inulin but require compliance with the country of origin, for example some Asian countries. This may result in lost markets for some manufacturers.

**Option 2** would confirm the regulatory position for manufacturers and for suppliers of GOS and long chain inulin by permitting the addition of these substances as ingredients, with limits to infant formula products and infant foods.

Alignment with international regulations could potentially allow for the single formulation and manufacture of products for both local and overseas markets maximising production costs. Option 2 is likely to reduce barriers to trade for those manufacturers wishing to export products with added GOS and long chain inulin to countries that require products to comply with regulations of the country of origin.

**Option 2** could potentially support product innovation for manufacturers of infant formula products and infant foods. However, when developing new products manufacturers would need to consider and make enquiries regarding the intellectual property position held by Numico (see Section 5.1), including patents in relation to a specified ratio, as this may impact on potential innovation.

### 7.2.3 Government

It is expected that there would be minimal impact for Government for either regulatory option.

#### **Question to Submitters:**

**Are there other likely impacts on consumers, industry and government from maintaining the *status quo*?**

**Are there other likely impacts on consumers, industry and government from permitting the addition of GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively?**

### 7.3 Comparison of Options

At this Initial Assessment stage, no comparison of the cost and potential benefits of the identified regulatory options has been undertaken for this Application. Further information on the risk assessment and risk management aspects of these Applications will be considered, including information received by submitters, before such a comparison is made. A comparison of options will therefore be provided at Draft Assessment.

## **COMMUNICATION AND CONSULTATION STRATEGY**

### 8. Communication

At Initial Assessment, FSANZ does not intend to undertake specific communication and consultation work outside of the two statutory public consultation periods. FSANZ will review the nature of the feedback received from submitters to the Initial Assessment, and determine whether additional communication strategies are required for Draft and Final Assessments.

### 9. Consultation

This Initial Assessment Report is intended to seek input into the likely regulatory impact of Application A609. At this stage FSANZ is seeking public comment to assist in assessing this Application and is particularly interested in any information on the questions posed in this Initial Assessment Report.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application assessment and the preparation of a Draft Assessment Report.

#### 9.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international Standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the Agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements. This will enable other WTO member countries to comment on proposed changes to Standards where they may have a significant impact on them.

## **CONCLUSION**

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act (in place before 1 July 2007), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to add GOS and long chain inulin as ingredients to infant formula products and infant foods in a ratio of 9:1 and at a maximum level of 0.8 g/100 mL and 0.8 g/100 g, respectively. Such an approval, if granted, may require a variation to Standards 2.9.1 – Infant Formula Products and 2.9.2 – Foods for Infants.
- There is currently no express permission in the Code for the addition of GOS and long chain inulin to infant formula products and infant foods.
- The Application is not so similar to any previous Application that it ought not be accepted. However, as the Draft Assessment Report for Proposal P306 is being released for public consultation concurrently with this Application, it is likely to be completed before this Application. Because Proposal P306 deals with aspects of this Application it may satisfy in part, or as a whole, the requirements of this Application.
- Notwithstanding the pending completion of Proposal P306 prior to completion of Application A609, there are no other measures that would be more cost-effective than a variation to Standards 2.9.1 and 2.9.2 that could achieve the same end.
- At this stage no other relevant matters are apparent.

### **Question to submitters:**

**Is there any further relevant information that FSANZ will need for the assessment of Application A609 other than that which has been collected for Proposal P306?**