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[08-13]

Approval Report – Application A1055

Short Chain Fructo-oligosaccharides

Food Standards Australia New Zealand (FSANZ) has assessed an Application from GTC Nutrition d/b/a Corn Products International, Inc (GTC Nutrition). The Application sought permission for the optional addition of short chain fructo-oligosaccharides produced from sucrose by enzymatic action (short chain FOS_{sucrose}) as an alternative to inulin-derived substances to: infant formula products, foods for infants and formulated supplementary foods for young children. The Application also sought permission to use the enzyme β -fructofuranosidase (EC 3.2.1.26) from *Aspergillus niger* as a processing aid.

On 17 December 2012, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 15 submissions.

FSANZ approved the draft variation on 9 May 2013. The COAG Legislative and Governance Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 21 May 2013.

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

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents used to prepare this report are available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1055shor4991.cfm>

- SD1 Risk and Technical Assessment Report
- SD2 Assessment of the Application in relation to Specific Policy Principles for the Regulation of Infant Formula Products

1. Executive summary

The Application

GTC Nutrition (the Applicant) lodged an Application which sought to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the optional addition of short chain fructo-oligosaccharides produced from sucrose by enzymatic action (short chain FOS_{sucrose}) to infant formula products, foods for infants and formulated supplementary foods for young children (FSFYC).

The Code currently permits 'inulin-derived substances' (IDS), alone or in combination with galacto-oligosaccharides (GOS), to be added to these food categories up to a maximum amount. The current definition in the Code for IDS incorporates short chain FOS derived from inulin (short chain FOS_{inulin}) but specifically excludes short chain FOS_{sucrose}. The Applicant proposed short chain FOS_{sucrose} be used as an alternative to IDS in these food categories up to the same maximum levels.

The Application also sought approval for the use of a new microbial source of the enzyme β -fructofuranosidase (EC 3.2.1.26) from a strain of the fungus *Aspergillus niger* as a processing aid to be used in the production of short chain FOS_{sucrose}.

Conclusions of the risk and technical assessment

Food Standards Australia New Zealand's (FSANZ's) risk and technical assessment (at SD1) concluded that:

- scFOS_{sucrose} is technologically suited to its proposed use and complies with international specifications.
- No public health and safety issues were identified with the proposed use of β -fructofuranosidase from *A. niger* as a processing aid in the production of scFOS_{sucrose}. An acceptable daily intake (ADI) "not specified" is considered appropriate.
- Results of laboratory animal studies confirmed that scFOS_{sucrose} has no identifiable hazard at concentrations likely to be encountered under Good Manufacturing Practice.
- The digestion of scFOS_{sucrose} was equivalent to IDS in an *in vitro* model of human colonic fermentation, producing comparable levels of short-chain fatty acids (SCFAs) and gas.
- No adverse effects on growth, hydration status, nutrient intake, frequency and nature of adverse events, gastrointestinal intolerance, stool consistency and frequency, or faecal flora, were observed in studies conducted in healthy infants or young children at amounts of scFOS_{inulin}, or scFOS_{sucrose} up to 3.0 g/L for periods ranging from 1 week to approximately 3 months.

The decision

FSANZ decided to amend the Code to permit the optional addition of short chain FOS_{sucrose} to infant formula products, foods for infants and FSFYC, up to the same maximum amounts currently permitted for IDS or IDS and GOS in combination. The term IDS in the Code is replaced by a new term 'inulin-type fructans'. The definition is broadened to incorporate both short chain FOS_{sucrose} and IDS. FSANZ defined 'inulin-type fructans' (ITF) as:

Inulin-type fructans means mixtures of saccharide chains that have β -D-(2 \rightarrow 1) fructosyl-fructose linkages with or without a terminal α -D-(1 \rightarrow 2) glucosyl-fructose linked glucose unit.

Substances falling within this broadened definition would not be regarded as nutritive substances, thus also permitting the addition of short chain FOS_{sucrose} to general purpose foods. In addition, the Code is amended to permit the enzyme β -fructofuranosidase from *A. niger* as a processing aid.

No regulatory impact statement was required for this Application as it sought permission for the optional (as opposed to mandatory) addition of an ingredient (RIS Exemption ID: 12065). However, FSANZ undertook an analysis of potential impacts of the changes on key stakeholder groups which indicated that the amendments to the Code provide the greatest net benefit to the community.

Reasons for decision

FSANZ considered that the approved variations meet the requirements of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). The assessment, based on the best available evidence, concluded that the use of ITF at the same prescribed maximum permitted amounts currently applying to IDS, or IDS and GOS combined, is unlikely to pose a risk to the health and safety of infants and young children or the community more generally.

FSANZ had regard to the relevant Ministerial Policy Guidelines and considers that the approved variations are consistent with these Guidelines. The variations improve consumer choice; support cost-effective manufacturing consistent with overseas regulations; support innovation; and provide clarity for manufacturers and enforcement agencies in Australia and New Zealand.

2. Introduction

2.1 The Applicant

The Applicant, GTC Nutrition d/b/a Corn Products International, Inc (GTC Nutrition) is a global ingredient provider to the food and beverage industry, with a particular focus on functional food ingredients.

2.2 The Application

Application A1055 – Short Chain Fructo-oligosaccharides was accepted on 23 September 2010 and commenced on 22 November 2010. The Application sought permission for the optional addition of short chain fructo-oligosaccharide (FOS) produced from sucrose by enzymatic action (short chain FOS_{sucrose}) to infant formula products, foods for infants and formulated supplementary foods for young children (FSFYC) in the *Australia New Zealand Food Standards Code* (the Code). The Applicant proposed that short chain FOS_{sucrose} is an alternative to inulin-derived substances (IDS) and that it be permitted addition to the same maximum levels as IDS.

The Application also sought permission for the use of a new microbial source of the enzyme β -fructofuranosidase (also called invertase) (EC 3.2.1.26) from a natural strain of the fungus *Aspergillus niger* as a processing aid. This enzyme is used in the production of short chain FOS_{sucrose}.

2.3 Current provisions in the Code

2.3.1 Short chain FOS

- Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions
Clause 1 of Standard 1.1.1 defines IDS and galacto-oligosaccharides (GOS). The definition of IDS specifically excludes those polymers of fructose produced from sucrose by enzymatic action.

Clause 9A states that IDS are taken not to be ‘nutritive substances’ which is also defined in Standard 1.1.1.
- Standard 2.9.1 – Infant Formula Products
Standard 2.9.1 sets the compositional and labelling requirements for infant formula products. An infant is defined as a person under the age of 12 months.

Clause 9A requires that, if added, infant formula products contain no more than 110 mg per 100 kJ of IDS, either alone or combined with GOS.
- Standard 2.9.2 – Foods for Infants
Standard 2.9.2 sets the compositional and labelling requirements for foods intended or represented for use as food for infants.

Paragraph 2(2)(c) states that food for infants may contain, either alone or in combination, a maximum of 0.8 g/100 g of IDS and GOS, as consumed.

- Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods
Division 4 – Formulated supplementary foods for young children sets the compositional and labelling requirements for FSFYC which are foods specifically designed as a supplement to the normal diet for children aged one to three years.

Subclause 6(4) states that FSFYC may contain, alone or in combination, a maximum of 1.6 g per serving of IDS and GOS. The maximum permitted amount only applies when the substances are added, as stated in subclause 6(5). When the substances are added, the maximum permitted amount applies to the sum of the naturally-occurring and added substances.

2.3.2 *Aspergillus niger* as a processing aid

Use of processing aids in food manufacture is prohibited unless there is a specific permission within Standard 1.3.3 – Processing Aids. The Table to clause 17 lists permitted enzymes of microbial origin. Currently, only invertase (EC 3.2.1.26) sourced from *Saccharomyces cerevisiae* is permitted as a processing aid.

2.3.3 Relevant international and overseas regulations

2.3.3.1 Short chain FOS

Codex Alimentarius has no specific provisions for short chain FOS in infant formula products, canned or cereal foods for infants, or follow-up formula (6-36 months). However, there are general provisions permitting optional ingredients providing that their safety and suitability are scientifically demonstrated.

In the European Union, fructo-oligosaccharides and GOS may be added to infant formula and follow-up formula (6-12 months) to a set maximum and in a prescribed ratio. Other combinations and maximum levels of oligosaccharides are permitted, providing their suitability is established by generally accepted scientific data. In Japan, short chain FOS has been used in infant formula since 1987. Infant formula with short chain FOS is also marketed in Pakistan, China, Vietnam and Taiwan. In the United States, the Food and Drug Administration has designated short chain FOS to be Generally Regarded As Safe (GRAS). It is used in infant foods and infant formula products. In New Zealand, the Ministry for Primary Industries published an exemption from the requirements of the Code² in relation to the use of oligosaccharides, including fructo-oligosaccharide, in the manufacture of dairy-based infant formula products for export to: China, The Customs Union of Belarus, Kazakhstan and Russia, the European Union, Malaysia, Indonesia and Republic of Korea.

2.3.3.2 *Aspergillus niger* as a processing aid

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

² New Zealand Ministry of Primary Industry Animal Products (Dairy Based Infant Formula products – Food Standards Exemption) Notice 2011 <http://www.foodsafety.govt.nz/industry/exporting/introduction/infant-formula.htm> accessed 19 October 2012

2.4 Reasons for accepting the Application

The Application was accepted for assessment because

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

The draft variation as proposed following assessment was approved with amendments (the original draft variation).

The approved variation, as varied after submissions were received, is at Attachment A and the corresponding Explanatory Statement at Attachment B.

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

3. Summary of the findings

In this report, the following terminology is used:

Table 1: Terminology

Short chain FOS	Short chain FOS is a mixture of unbranched polysaccharides consisting of a sucrose molecule joined to additional fructose molecules via a β (2 \rightarrow 1) linkage. Short chain FOS can be produced by enzymatically degrading inulin or by synthesising it from sucrose also via an enzyme-catalysed process. An analysis of a short chain FOS preparation should have no less than 85.0% (w/w) short chain FOS with at least 30.0% trimer, 45.0% tetramer, and 5.0% pentamer and larger, with the remainder being glucose, fructose, and sucrose, on a dried basis (Food Chemicals Codex, 8 th ed, 2012).
Short chain FOS _{sucrose} Short chain FOS _{inulin}	For the purpose of describing their <i>in vitro</i> mode of production, short chain FOS preparations synthesized from sucrose are designated short chain FOS _{sucrose} whereas preparations derived from randomly cut fragments of inulin are designated short chain FOS _{inulin} .
Inulin-derived substances (IDS)	Mixtures of polymers of fructose with predominantly β (2 \rightarrow 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.
Inulin-type fructans (ITF)	Mixtures of saccharide chains that have β -D-(2 \rightarrow 1) fructosyl-fructose linkages with or without a terminal α -D-(1 \rightarrow 2) glucosyl-fructose linked glucose unit. It includes substances described as FOS, short-chain FOS, oligofructose and inulin.

3.1 Risk and technical assessment

The full risk and technical assessment report is provided as SD1.

A summary of the conclusions is provided below.

Short chain fructo-oligosaccharides (scFOS) can be produced by two discrete methods: enzymatic degradation of inulin or enzymatic condensation from sucrose. The Food Chemicals Codex has established specifications for scFOS that indicate analysis of the respective scFOS preparations should yield no less than 85.0% (w/w) scFOS with at least 30.0% trimer, 45.0% tetramer, and 5.0% pentamer and larger, with the remainder being glucose, fructose and sucrose on a dried basis. Inulin-derived substances (IDS) (including inulin-derived scFOS resulting from enzymatic degradation) are already a permitted addition to infant formula products, infant foods and formulated supplementary foods for young children (FSFYC) alone or in combination with galacto-oligosaccharides (GOS).

These oligosaccharide preparations are added to purposely better align the stool characteristics of formula-fed infants with the softer stools typically associated with breastfed infants. Despite having the same chemical specifications as inulin-derived scFOS (scFOS_{inulin}), sucrose-derived scFOS (scFOS_{sucrose}) is currently not permitted to be added to infant formula products, infant foods and FSFYC on the basis of its method of manufacture.

As part of an Application to amend the Australia New Zealand Foods Standards Code, to permit the use of scFOS_{sucrose}, this risk assessment was undertaken for the purpose of evaluating the technological suitability, safety and benefit of the proposed addition of scFOS_{sucrose} to infant formula products, infant foods and FSFYC as an alternative to already permitted IDS. Additionally, an amendment to Standard 1.3.3 was sought for the enzyme β -fructofuranosidase produced by *Aspergillus niger* to be used as a food processing aid in the production of scFOS_{sucrose}.

The conclusions of this risk assessment are summarised as follows:

- scFOS_{sucrose} is technologically suited to its proposed use and complies with international specifications.
- No public health and safety issues were identified with the proposed use of β -fructofuranosidase from *A. niger* as a processing aid in the production of scFOS_{sucrose}. An acceptable daily intake (ADI) “not specified” is considered appropriate.
- Results of laboratory animal studies confirmed that scFOS_{sucrose} has no identifiable hazard at concentrations likely to be encountered under Good Manufacturing Practice.
- The digestion of scFOS_{sucrose} was equivalent to IDS in an *in vitro* model of human colonic fermentation, producing comparable levels of short-chain fatty acids (SCFAs) and gas.
- No adverse effects on growth, hydration status, nutrient intake, frequency and nature of adverse events, gastrointestinal intolerance, stool consistency and frequency, or faecal flora, were observed in studies conducted in healthy infants or young children at amounts of scFOS_{inulin}, or scFOS_{sucrose} up to 3.0 g/L for periods ranging from 1 week to approximately 3 months.

On the basis of the above considerations, it is concluded that scFOS_{sucrose} produced by β -fructofuranosidase-catalysed condensation of sucrose is technologically justified and is as safe as IDS already permitted to be added to foods generally, and infant formula products, infant foods and FSFYC alone or in combination with IDS and/or GOS up to the currently permitted maximum amounts.

Additionally, scFOS_{inulin} and scFOS_{sucrose} have the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered beneficial effects.

3.2 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Public submissions were invited on the draft variation setting out amendments to Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3 between 17 December 2012 and 11 February 2013. Fifteen submissions were received from: jurisdictions; infant formula product manufacturers and industry representative groups; health professional organisations; advocacy groups and an individual.

In general, industry stakeholders supported the proposed amendments to the Code but were concerned about the proposed terminology and possible subsequent labelling implications. Jurisdictions, advocacy groups and health professional associations identified a variety of concerns with the proposed amendments to permit short chain FOS_{sucrose} in infant formula products. Most submitters were supportive of or remained silent on the proposed change to permit β -fructofuranosidase as a processing aid. In addition, most submitters did not raise concerns with the proposed changes to the Code to permit the optional addition of short chain FOS_{sucrose} to foods for infants and FSFYC.

A more detailed summary of submitter comments along with FSANZ's response is outlined in Table 2.

3.3 Risk management

The following sections summarise the key issues considered as part of the risk management approach.

3.3.1 Protecting the health and safety of infants and young children

The risk and technical assessment concluded that short chain FOS_{sucrose} is as safe as IDS already permitted to be added to general purpose foods, infant formula products, foods for infants and FSFYC, up to the current permitted maximum amounts. FSANZ has considered the safety concerns raised by submitters, reviewed the literature and consulted with our Infant and Child Health Scientific Advisory Committee (ICHSAAG) to reach this conclusion.

A potential beneficial effect resulting from the addition of short chain FOS_{sucrose} to infant formula products is the potential to soften stools of formula-fed infants and reduce the incidence of constipation.

Some submitters considered that infants and young children who may experience functional gastrointestinal disorders would be harmed should short chain FOS_{sucrose} be permitted as an optional substance in infant formula products, foods for infants and FSFYC. As IDS are already permitted addition to these products, FSANZ considers that there is no greater risk of harm to infants and young children who may experience functional gastrointestinal disorders from consumption of formulas containing added short chain FOS_{sucrose}.

ITF added to products must be declared in the ingredient list in the same manner as inulin-derived substances. This will assist carers of infants and young children to identify which products contain ITF. In addition, health professionals who are advising carers of formula-fed infants are best placed to provide information about potential gastrointestinal effects and their management.

3.3.2 Consistency with ministerial policy guidance

FSANZ has had regard to the relevant Ministerial Policy Guidelines under paragraph 18(2)(e) of the FSANZ Act.

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

- *Intent of Part 2.9 – Special Purpose Foods*
- *Regulation of Infant Formula Products.*

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

This Application is consistent with the Ministerial Policy Guideline on the *Intent of Part 2.9 – Special Purpose Foods*. The Application does not change the intended purpose of the food categories and FSANZ's assessment has taken into consideration the vulnerability of the relevant populations.

In relation to the addition of short chain FOS_{sucrose} to infant formula products, FSANZ considered that the assessment of this Application is consistent with the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*. The relevant specific policy principles relating to composition are (d), (e), (h), (i) and (j). A summary table of FSANZ's assessment of this Application against the specific policy principles is in Supporting Document 2 (SD2).

In brief, FSANZ has:

- Assessed the levels of oligosaccharides in breast milk as the primary reference. The permitted amounts of IDS and now ITF are well below the amount of oligosaccharides in breast milk.
- Noted that short chain FOS_{inulin} is already permitted in infant formula products in the Australian and New Zealand food supply.
- Determined that there are no public health and safety concerns associated with the optional addition of short chain FOS_{sucrose} to infant formula products.
- Noted that the addition of short chain FOS_{sucrose} has the potential to soften stools and may reduce the incidence of constipation both of which are considered beneficial effects. FSANZ considers that it has applied caution.

3.3.3 Labelling

A number of submitters commented on how the proposed term 'inulin-type fructans' would apply to labelling in the statement of ingredients, and when declared in the nutrition information statement for infant formula products, or in the nutrition information panel (NIP) for food for infants and FSFYC when a claim is made.

3.3.3.1 Ingredient labelling

At assessment, FSANZ noted ingredient labelling requirements that currently apply to IDS would be expected to apply to ITF.

That is, general labelling provisions in Standard 1.2.4 – Labelling of Ingredients would apply to infant formula products, foods for infants and FSFYC as well as general purpose food. Clause 4 of this Standard specifies in part that ingredients must be declared in the statement of ingredients using the common name of the ingredient; a name that describes the true nature of the ingredient; or where applicable, a generic name set out in the Table to clause 4. In this case, a food manufacturer adding ITF to a product is required to declare an appropriate common or descriptive name of ITF in the statement of ingredients.

3.3.3.2 Nutrition information labelling and claims

The approach for nutrition information labelling, including the Nutrition Information Panel (NIP) where it applies, would be similar to the approach taken for IDS through Proposal P306 – Addition of Inulin/FOS & GOS to Food³. That is, where a food manufacturer makes a claim about any of the substances captured by the definition of ITF on the label of foods for infants or FSFYC, the content of these substances would need to be declared in the NIP according to the requirements in the Code. When added to infant formula products, there is a mandatory requirement to declare any of the substances captured by the definition of ITF in the nutrition information statement.

As noted in the assessment, specific conditions relating to the nutrition information format required under subclause 9(2) of Standard 2.9.2 prevail if a nutrition content claim about dietary fibre is made on a food for infants. General labelling provisions for claims in Standard 1.2.7 – Nutrition, Health and Related Claims and Standard 1.2.8 – Nutrition Information Requirements would apply for FSFYC where no conflict exists between Standards.

At assessment, FSANZ noted the current arrangements for nutrition and health claims for infant foods and FSFYC, including the existing prohibition on these claims for infant formula products, would apply to short chain FOS_{sucrose}, if permitted. Since that time, Standard 1.2.7 was gazetted on 18 January 2013. There is a three year transition period for manufacturers to meet the requirements of the new Standard.

In summary, Standard 1.2.7:

- continues to prohibit infant formula products from carrying nutrition content claims and health claims
- permits specific nutrition content claims and associated conditions currently within Standard 2.9.2 and Division 4 of Standard 2.9.3 to remain, and allows other nutrition content claims in accordance with Standard 1.2.7
- permits foods for infants and FSFYC to carry general level health claims which are either pre-approved (for example, Schedule 3 of Standard 1.2.7 includes a food-health relationship about dietary fibre and regular laxation) or self-substantiated according to the requirements in the Standard
- permits foods for infants and FSFYC to carry high level health claims about a serious disease, or a biomarker of a serious disease. All high level health claims need to be pre-approved and currently there are none in relation to IDS.

³ Page 34 of the Final Assessment Report for Proposal P306 – Addition of Inulin/FOS & GOS to Food, available from the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/proposals/proposalp306addition3639.cfm>

3.3.4 Operation of the Code

3.3.4.1 Definition of inulin-type fructans

To ensure regulatory clarity, the proposed variation included a definition of the term ‘inulin-type fructans’ which extended to include short chain FOS_{sucrose}. At assessment, FSANZ proposed the term:

Inulin-type fructans which means *mixtures of saccharide chains that have predominantly β (2→1) fructosyl-fructose linkages with or without a terminal glucose.*

Many submitters found this term confusing and inconsistent with international literature.

At approval, FSANZ amended the definition of ‘inulin-type fructans’ to the following:

Inulin-type fructans means mixtures of saccharide chains that have *β -D-(2→1) fructosyl-fructose linkages with or without a terminal α -D-(1→2) glucosyl-fructose linked glucose unit.*

Many submitters suggested that reference in the definition to commonly used terms such as inulin, FOS, short chain FOS and oligofructose could clarify that these substances were intended for inclusion in the definition of ITF. However, mention of specific substances could be interpreted that they were the only ones intended to be defined. FSANZ has therefore set out in the explanatory statement attached to the approved variation that the Code’s definition of ITF includes short chain FOS, FOS, oligofructose and inulin. This information will also be put on the FSANZ website. In addition, to provide clarity, the term ‘predominantly’ was removed from the definition.

3.3.4.2 Applicability of the definition of nutritive substances

The effect of the approved variation is to regard ITF as not a nutritive substance. This is consistent with the current approach for IDS which was adopted as an interim regulatory measure pending Ministerial policy guidance on infant formula products and Part 2.9 – Special Purpose Foods, the review of the definition of nutritive substances, and the review of Standard 2.9.1. The reviews of the definition of nutritive substances and Standard 2.9.1 are underway so these issues remain outstanding. For this reason, the current approach has been extended.

3.3.4.3 Terminology for β -fructofuranosidase

Invertase is also known as β -fructofuranosidase. Invertase from *Saccharomyces cerevisiae* is already permitted as a processing aid in the Code. The Application sought permission for a new microbial source of invertase from *A niger*. At assessment, FSANZ proposed amending the Code to permit invertase from *A niger*. One submitter suggested that this more correct term, β -fructofuranosidase, should be used in the Code. As the International Union of Biochemistry and Molecular Biology (IUBMB) use the term β -fructofuranosidase, this amendment has been made.

Table 2: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Terminology		
<p>The removal of the term IDS from the Code may cause confusion. The term 'inulin-type fructans' is inconsistent with the terminology used in: P306, overseas regulations and by industry. Reference to common names of substances would provide clarification.</p>	<p>Nutricia, Pyx, Infant Nutrition Council (INC), New Zealand Food and Grocery Council (NZFGC), New Zealand Ministry of Primary Industry (MPI), Australian Food and Grocery Council (AFGC)</p>	<p>FSANZ is unaware of internationally standardised terminology to describe oligosaccharides. The term ITF has replaced IDS in Standard 1.1.1. ITF is a broad term that extends the range of substances currently covered by the IDS definition in the Code to include the short-chain FOS from sucrose.</p> <p>A clarifying statement outlining that short chain FOS, oligofructose, inulin and FOS are included in ITF has been added to the explanatory statement, a legal document associated with the variation. This information will also be provided on the FSANZ website.</p>
<p>The term ITF is confusing as it can be interpreted as having to be from inulin or similar to inulin.</p>	<p>Beneo GmbH, AFGC, MPI, INC</p>	<p>Fructan is a general term to describe any polymer of fructose in which one or more fructosyl-fructose links constitute the majority of osidic bonds. They are further characterised according to the type of linkages between the fructosyl residues. Inulin-type fructans are characterised by β (2→1) linkages, levan-type fructans are characterised by β (2→6) fructosyl linkages. Therefore the definition ITF describes the β (2→1) fructosyl – fructose bonds predominant in inulin. There is no requirement for the substance to be sourced from inulin.</p>
<p>Clarify the term 'predominantly' in proposed definition</p>	<p>MPI</p>	<p>The term 'predominantly' has been removed in the revised definition of 'inulin-type fructans' to provide clarity.</p>
Labelling		
<p>Consider that food manufacturers may be affected by the proposed definition changes. Clarification is sought that the term ITF is for definitional purposes only and not intended for labelling purposes.</p>	<p>Nutricia, Pyx, INC, NZFGC, AFGC</p>	<p>Similar to IDS, ITF has been defined to clarify compositional permissions. Current labelling requirements that apply to IDS will apply to ITF. The change in definition should not result in the need to use the term ITF on the label or in additional costs for manufacturers.</p> <p>Refer to Section 3.3.3 of this report for further information on labelling implications.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Needs a risk management strategy that includes clear labelling so people with functional gastrointestinal disorder (FGID) can avoid if required.	Victorian Departments of Health and Primary Industry, and Dairy Food Safety Victoria (VIC Health)	FSANZ considered that the scientific understanding of this disorder is still evolving and the prevalence across the population and the extent of risk to affected individuals is unknown. Substances captured by the definition of ITF that are added to the infant formula products, infant foods or FSFYC, will be declared on the ingredient list.
Prohibit claims that indicate short chain FOS _{sucrose} will provide similar benefits to breast milk.	Women's Health Action	<p>Claims purporting to convey a message that the infant formula product is similar to breast milk are currently prohibited on the label of infant formula products under subclause 20(1) of Standard 2.9.1. The prohibition extends to short chain FOS_{sucrose} voluntarily added to infant formula products.</p> <p>Also, the label on a package of infant formula product must not refer to IDS or GOS (or ITF) except under limited circumstances.</p> <p>In addition, clause 3 of Standard 1.2.7 expressly prohibits nutrition content claims and health claims to be made about an infant formula product.</p>
Does not support any claim that prebiotics offer any clinical benefit.	Dietitians New Zealand	Health claims are not permitted on infant formula products, however they would be permitted for foods for infants and FSFYC if all of the relevant requirements in Standard 1.2.7 are met.
Concerns with risk and technical assessment		
<p>Equivalence of short chain FOS_{inulin} and short chain FOS_{sucrose}</p> <ul style="list-style-type: none"> • Chemical structure of short chain FOS_{sucrose} (DP2-4) is sufficiently different to short chain FOS_{inulin} (DP2-9) to warrant individual assessment. • Literature supports that FOS of different chain lengths appear to exert different physiological effects. 	<p>VIC Health, Department of Health and Human Services Tasmania (Tas Health), QLD Health, Dietitians Association of Australia (DAA)</p> <p>VIC Health, Tas Health, MPI, DAA</p>	<p>Chemical characterisation plays a critical role in risk assessment. Analytical methods are important to define the nature of the added substance, including isomeric composition and chemical purity. This chemically defined material is used in studies of hazard identification, characterisation and tolerance studies.</p> <p>Standard 1.3.4 specifies that substances added to food must meet standards of identity and purity as described in a primary source listed under clause 2 – Substances with specifications in primary sources – which states that a substance must comply with a relevant monograph published in one of the following:</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<ul style="list-style-type: none"> Studies used to support equivalence are in vitro, use adults and do not support conclusions. 	VIC Health, Tas Health, DAA	<p>(a) The schedule to this Standard, or</p> <p>(b) Combined compendium of Food Additive Specifications FAO JECFA Monographs; or</p> <p>(c) Food Chemicals Codex (8th edition) published by United States Pharmacopoeia (2012).</p> <p>The Food Chemicals Codex defines short chain FOS as being indigestible carbohydrates synthesized from sucrose and fructose through an enzymatic process or from inulin by partial enzymatic hydrolysis. Short chain FOS is described as a mixture of unbranched polysaccharides consisting of a sucrose molecule joined to additional fructose molecules via a β (2→1) linkage. An analysis of a short chain FOS preparation should have no less than 85.0% (w/w) short chain FOS with at least 30.0% trimer, 45.0% tetramer, and 5.0% pentamer and larger, with the remainder being glucose, fructose, and sucrose, on a dried basis (Food Chemicals Codex 2012).</p> <p>The substance that is the subject of this Application has the following distribution: trimer (GF2)=36.2%, tetramer (GF3)=49.1%, pentamer (GF4)=10.7%. This fructo-oligosaccharide distribution conforms to that specified for a short chain FOS preparation. Further information is provided in SD1.</p>
<p>Concern with the assessment</p> <ul style="list-style-type: none"> The risk assessment methodology and strength of evidence base are not clearly reported. There is limited discussion of methodology or limitations in order to make an assessment of the quality of the studies. No systematic review of the literature is presented. 	VIC Health	An additional section has been added to SD1 (Section 4.2 Evaluation) that outlines the risk assessment methodology.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Limitations of the evidence base</p> <ul style="list-style-type: none"> • Concern with the quality of studies. • Use of unpublished works (not peer reviewed). • It is not clear which type of short chain FOS is used in most of the studies considered as evidence in the risk assessment. • Studies designed to assess toxicity vs benefit. • Crying behaviours and colic not assessed, which were identified in P306 and by ICHSAG as potential significant adverse effects. 	<p>VIC Health, QLD Health, DAA, Tas Health</p>	<p>The assessment strategy used by FSANZ to determine the safety and tolerance of infant formula containing short chain FOS is consistent with that used for similar types of applications wishing to amend the Code. The process is consistent with the principles espoused by the Codex Alimentarius Commission. A weight-of-evidence approach is used where the scientific merits of individual studies are evaluated. Studies that do not meet basic principles of scientific integrity and value-add to the database are not included in a safety assessment.</p> <p>The risk and technical assessment prepared in relation to this Application relies on both published and unpublished studies. FSANZ has independently evaluated (i.e. by peer review) the unpublished studies provided by the applicant, which included a thorough examination of all methodological details and unmodified (raw) experimental data. FSANZ also included a systematic review of the published scientific literature as outlined in Section 4.2 of SD1.</p> <p>Studies evaluated by FSANZ and included in SD1 were designed to assess either safety or benefit, however, studies designed to assess benefit also made observations for safety (e.g. flatulence, spit-up, vomiting etc).</p>
<p>Methodological limitations of studies</p> <ul style="list-style-type: none"> • Small sample sizes. • Short treatment duration inconsistent with US guidelines recommending clinical studies of 3-4 months duration. • Concerns regarding the assessment of hydration status. 	<p>VIC Health, DAA, QLD Health</p>	<p>The sample size within studies was discussed by the ICHSAG in relation to the assessment of a potential beneficial effect of short chain FOS on normal infant growth and development (which is variable). The group sizes of the evaluated studies ranged from 24-139 subjects per treatment-group. The duration of consumption of short chain FOS ranged from 1-12 weeks in healthy term infants and from up to 11 days to 16 weeks in toddlers/children. The longer terms studies, which cover ~50% of the maximum timeframe over which infant formula is likely to be exclusively consumed (i.e. 6 months), are considered to be of sufficient duration to have detected any relevant adverse effects.</p> <p>A discussion, including conclusions of the ICHSAG, regarding infant hydration is provided in Section 4.4 in SD1.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
		It was concluded that that there were no adverse effects on infants' hydration status as assessed by the measurement of urine specific gravity, bodyweight gain, the occurrence of diarrhoea, expert clinical examination and formula intake. ICHSAG noted that in a clinical setting, hydration status is more accurately assessed via recent changes in bodyweight gain. In all studies, bodyweight was consistent between short chain FOS-fed and control infants suggesting no effect on hydration status.
<p>Conclusion of the risk assessment</p> <ul style="list-style-type: none"> Disagree with conclusion that short chain FOS has potential beneficial effect to soften stools and reduce constipation. 	DAA	FSANZ has reviewed the best available scientific evidence, and consulted with external experts in paediatrics and gastroenterology to develop the conclusion.
Clinical issues		
Short chain FOS are part of the FODMAP (FOLFAP) group implicated in functional bowel disorders. To date there is no data on the incidence for infants. The potential clinical implications of more rapidly fermented oligosaccharides have not been considered in this assessment.	QLD Health, DAA, Tas Health, VIC Health	<p>The risk assessment outlines that short chain FOS sucrose would behave no differently to already permitted fructans in infant formula.</p> <p>FSANZ considers that infants who experience functional gastrointestinal disorders that are associated with fermented oligosaccharides are best managed by health professionals. Should short chain FOS_{sucrose} be added to infant formula, it must be declared on the label in the ingredient list, which will provide health professionals and carers with adequate information to make an informed decision on their choice of infant formula products.</p>
Recommend FSANZ considers if addition of short chain FOS is the best solution to manage constipation.	Women's Health Action, Lianne Mather	Short chain FOS was considered as an optional ingredient in infant formula products, and not as an intervention to manage constipation. Health professionals are best placed to advise parents and caregivers on clinical issues.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Suitability of the Mean Rank Stool Consistency (MRSC) measure for determining constipation	Comments received from jurisdictions at a follow-up teleconference.	<p>ICHSAG members commented that MRSC is a socially acceptable, qualitative measure of infant gastrointestinal health and advised FSANZ that the use of the descriptor “watery” was not equivalent to diarrhoea.</p> <p>With regard to the relationship between stool consistency or frequency and infant well-being, the ICHSAG advised that there is a relationship between severe constipation and reduced infant well-being. However it would be difficult to identify such a relationship within what is the normal range of stool consistency and frequency in infants, including less severe constipation.</p>
Policy Guideline		
As there is no FOS in breast milk an appropriate primary reference has not been used. Plant base prebiotics are not equivalent to prebiotics in breast milk.	VIC Health, Dietitians NZ	<p>Breast milk contains a range of non-digestible oligosaccharides (human milk oligosaccharides (HMO)) at concentrations that are maximal soon after birth (~25g/L) and decline to around 15g/L by around three months.</p> <p>IDS and short chain FOS_{sucrose} are purposely added to infant formula products to better align the stool characteristics of formula-fed infants with the softer stools typically associated with breastfed infants. The assessment for the addition of short chain FOS to infant formula products has considered the functional equivalence of fructooligosaccharides to IDS and HMOs. Short chain FOS is degraded like HMOs in the infant digestive tract. That is, it is fermented by intestinal microflora to produce short chain fatty acids and gas</p>
Physiological benefit – notes that the evidence reviewed identifies a small benefit shown at one time point. Other studies used older infants or contained Raftilose95. If exclude Raftilose studies query whether it meets policy principle j	MPI	<p>FSANZ has given regard to all of the Section 18(2) objectives, including the Policy Guideline on the <i>Regulation of Infant Formula Products</i>.</p> <p>The risk and technical assessment concluded that short chain FOS has the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered beneficial effects. These beneficial effects which are evident from fortifying infant formula with short chain FOS will be observed irrespective of its mode of production.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Other issues		
<p>Clarify IDS and GOS classified as non-nutritive substances was an interim regulatory response in P306 pending the outcome of Ministerial policy guideline development, reviews of the definition of nutritive substance and future review of Standard 2.9.1.</p>	<p>MPI</p>	<p>The review of nutritive substances and novel foods and the review of Standard 2.9.1 are currently underway. As these issues remain outstanding, the current approach has been extended.</p>
<p>Fructo-oligosaccharides with a lower DP have a higher level of sweetness, thus permitting short chain FOS may increase the sweetness of the product.</p>	<p>MPI</p>	<p>SD1 outlines that short chain FOS in solution has a similar sweetness to IDS which is 30-50% of sucrose. The shorter DP the more sweet the substance is, i.e. shorter chain FOS is closer to the 50% end of the range rather than the 30% end of the range. Infant formula products are only permitted to have a maximum of 0.3% short chain FOS which is significantly less than other sweet flavouring substances such as sucrose or lactose which make up about 7% of infant formula products. FSANZ therefore considers that there is unlikely to be any additional sweet flavouring from the addition of this amount of short chain FOS to infant formula products. This issue was also discussed with the ICHSAG who agreed that the addition of scFOS_{sucrose} is unlikely to increase the sweetness of infant formula products relative to oligosaccharides already permitted to be added to infant formula products.</p>
<p>Believes that the intent of P306 was to exclude all fructooligosaccharides with a DP≤4 as these were not able to be assessed. Seeks clarification of the review of these.</p>	<p>MPI</p>	<p>At P306, FSANZ identified that it is not practical to exclude all fructo-oligosaccharides with a DP≤4, as long chain inulin will still include some short chain FOS. The approved variation permits short chain FOS from inulin to be added.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Dietary Fibre		
Need to clarify current regulatory status of short chain FOS as a source of dietary fibre. Can it already be added as dietary fibre to Std 2.9.2 and 2.9.3 foods?	MPI	FSANZ has broadened the definition and permissions related to IDS to include short chain FOS _{sucrose} . The new definition for ITF provides regulatory certainty about the substances permitted for addition. The definition of dietary fibre as it applies to Standard 1.2.8 includes oligosaccharides with a DP >2. Both AOAC 997.08 and AOAC 999.03 methods listed in the Code can <u>detect</u> short chain FOS derived from sucrose. The methods can detect short chain FOS with DP >2.
International regulations		
GRAS notification for infant formula	Pyx Ltd	Relevant section updated (see section 2.3.3.1)
Need to be clear about which short chain FOS are permitted in international regulations. Notes that in the US GRAS status has only been approved for short chain FOS with DP ≥ 4. Also EU only permits high molecular weight FOS.	MPI, Tas Health, VIC Health	FSANZ noted that infant formula with short chain FOS _{sucrose} has GRAS status and is available in the US. The EU permits other oligosaccharides, providing their suitability is established by generally accepted scientific data. Infant formula containing short chain FOS is available in some European countries . Infant formula containing short chain FOS has been available in Japan since 1987, It has also been available in Pakistan, China, Vietnam and Taiwan.
Consider updating name of “invertase” to β-Fructofuranosidase	MPI	Amended – the approved variation refers to β-Fructofuranosidase rather than invertase.

3.4 Risk communication

FSANZ applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions were evaluated and addressed in this report.

The variation approved by the FSANZ Board takes into account public comments received from the assessment.

The FSANZ Board decision has been notified to the Forum. If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

4. Reasons for decision

The draft variation setting out amendments to Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3 was approved subject to further amendment on the basis of the available evidence and for reasons summarised as follows:

- In terms of public health and safety, FSANZ's assessment determined that the optional addition of short chain FOS_{sucrose} is as safe as the already permitted IDS in infant formula products, foods for infants and FSFYC. Similarly, no public health and safety risks were identified with the use of β -fructofuranosidase as a processing aid.
- The optional addition of short chain FOS_{sucrose} to infant formula products has the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered beneficial effects.
- The permitted amounts are well below the amount of oligosaccharides found in breast milk. The assessment also concluded that the consumption of short chain FOS-supplemented formula supports normal growth in infants.
- The optional permission provides choice to carers of consumers of these products; promotes fair trade; and provides an overall net benefit to the community.
- The approved variation is consistent with the relevant Ministerial policy guidelines, supports cost-effective manufacturing through consistency with overseas regulations, supports innovation, and provides clarity for manufacturers and enforcement agencies in Australia and New Zealand.

4.1 Addressing section 29 of the FSANZ Act

In assessing the Application, FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

Affected parties include carers and consumers, food industry and government enforcement agencies.

No regulatory impact statement was required for this Application as it sought permission for the optional addition of an ingredient (RIS Exemption ID: 12065). However, FSANZ undertook a basic cost benefit analysis as outlined in the Assessment report.

The analysis of potential impacts on key stakeholder groups indicates that the approved variation provides an overall net benefit to the community. In addition, FSANZ concluded that there were no measures other than the approved variation that would achieve the same result. There are no relevant New Zealand standards that apply, and there are no other relevant matters other than those considered in this report.

4.2 Addressing FSANZ’s objectives for standards-setting

FSANZ had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

FSANZ has undertaken a risk and technical assessment based on the best available scientific evidence (see SD1). The assessment concluded that short chain FOS_{sucrose} is as safe as IDS. IDS are already permitted to be added to general purpose foods, and to infant formula products, foods for infants and FSFYC alone or in combination with GOS up to the currently permitted maximum amounts. Likewise, no public health and safety issues were identified with the proposed use of β -fructofuranosidase from *A. niger* as a processing aid in the production of short chain FOS_{sucrose} including for use in foods generally.

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

The current labelling requirements for IDS in the Code will also apply to ITF. There is no change to the level or type of information that is required and available to carers when compared to the current labelling requirements for IDS (see section 3.3.3 above).

4.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

4.2.4 Subsection 18(2) considerations

FSANZ also had regard to the objectives set out in subsection 18(2):

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

The best available scientific evidence was used as the basis of the assessment of this Application, as described in section 3.1 and SD1.

The promotion of consistency between domestic and international food standards

FSANZ has reviewed the relevant international and overseas regulations for the relevant special purpose foods. The approved variation to the Code is in line with international guidelines and permissions and will promote consistency between domestic and international food standards.

The desirability of an efficient and internationally competitive food industry

Manufacturers can choose whether to add short chain FOS_{sucrose} to their products, including general purpose foods, allowing for innovation and potentially the use of the same formulation for multiple markets. This approach therefore supports an internationally competitive food industry.

The promotion of fair trading in food

Short chain FOS_{inulin} is already permitted as an optional ingredient in general purpose foods, infant formula products, foods for infants and FSFYC. Extending the permission for use of short chain FOS_{sucrose} as an alternative to short chain FOS_{inulin}, allows manufacturers to use alternative formulations that promote fair trade.

Any written policy guidelines formulated by the Ministerial Council

FSANZ had regard to the relevant Ministerial policy guidelines and considered that the Application is consistent with the Ministerial Policy Guidelines on the *Intent of Part 2.9 – Special Purpose Foods and Regulation of Infant Formula Products*, as discussed in section 3.3.2.

A summary of FSANZ's consideration of this Application in relation to infant formula products against the specific policy principles in the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* is at SD2.

Attachments

- A. Approved variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code*

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



Food Standards (Application A1055 – Short-chain Fructo-oligosaccharides) Variation

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

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1055 – Short-chain Fructo-oligosaccharides) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

These variations commence on gazettal.

SCHEDULE

[1] Standard 1.1.1 is varied by

[1.1] omitting from clause 2 the definition of “inulin-derived substances” and substituting

“**inulin-type fructans** means mixtures of saccharide chains that have β -D-(2→1) fructosyl-fructose linkages with or without a terminal α -D-(1→2) glucosyl-fructose linked glucose unit.”

[1.2] omitting from clause 9A “Inulin-derived substances” and substituting “Inulin-type fructans”

[2] Standard 1.3.3 is varied by

[2.1] omitting from the Table to clause 17

“

Invertase
EC 3.2.1.26

Saccharomyces cerevisiae

”

[2.2] inserting in alphabetical order in the Table to clause 17

“

β -Fructofuranosidase
EC 3.2.1.26

Aspergillus niger
Saccharomyces cerevisiae

”

[3] Standard 2.9.1 is varied by

[3.1] omitting “inulin-derived substances” wherever occurring and substituting “inulin-type fructans”

[3.2] updating the Table of Provisions to reflect these variations

[4] Standard 2.9.2 is varied by omitting from paragraph 2(2)(c) “inulin-derived substances” and substituting “inulin-type fructans”

[5] Standard 2.9.3 is varied by omitting from subclause 6(4) “inulin-derived substances” and substituting “inulin-type fructans”

Attachment B –Explanatory Statement

1. Authority

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

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

FSANZ accepted Application A1055, in which the Applicant seeks amendments to the Code to permit the optional addition of short chain FOS produced from sucrose by enzymatic action (short chain FOS_{sucrose}) to Infant Formula Products (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Formulated Supplementary Foods for Young Children (Standard 2.9.3 Division 4).

The Code currently permits 'inulin-derived substances' (IDS), alone or in combination with galacto-oligosaccharides (GOS), to be added to these food categories up to a maximum amount. The definition of IDS in the Code incorporates short chain FOS derived from inulin (short chain FOS_{inulin}). The Applicant proposes short chain FOS_{sucrose} be used as an alternative to IDS at the same levels as currently permitted.

The Applicant also requested amending Standard 1.3.3 to permit the use of a new microbial source of β -fructofuranosidase (also called invertase) (EC 3.2.1.26) enzyme from a strain of the fungus *Aspergillus niger* (*A. niger*) as a processing aid (enzyme) to be used in the production of short chain FOS_{sucrose}.

The Authority considered Application A1055 in accordance with Division 1 of Part 3 and has approved a draft variation setting out amendments to Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation⁴, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft standard or draft variation of a standard.

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

2. Purpose and operation

The purpose of the draft variation is to amend the following Standards in the Code:

- Standard 1.1.1;
- Standard 1.3.3; and
- Standards 2.9.1 to 2.9.3.

⁴ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

The proposed amendments are as follows:

- replacing the term 'inulin-derived substances' (IDS) and its definition with a new term 'inulin-type fructans' (ITF) and its definition (Standard 1.1.1);
- replacing references to IDS with the new term ITF throughout the Code (Standards 1.1.1, 2.9.1 to 2.9.3); and
- adding *Aspergillus niger* as an additional source of the enzyme β -fructofuranosidase (EC3.2.1.26) (Table to clause 17 in Standard 1.3.3).

Replacing the reference to IDS with ITF in Standards 2.9.1, 2.9.2 and 2.9.3 would enable both short chain FOS_{sucrose} and IDS, alone or in combination with each other and/or GOS, to be added to infant formula products, infant foods and formulated supplementary foods for young children.

In addition, the Code currently states that IDS are taken not to be nutritive substances. This principle would apply to the new term, ITF. This means that the use of ITF, including short chain FOS_{sucrose}, would not be prohibited in general foods.

Amending Standard 1.3.3 – Processing Aids, would enable manufacturers to produce short chain FOS_{sucrose} using the invertase enzyme from a natural, genetically unmodified strain of the fungus *A. niger* as a processing aid.

3. Documents incorporated by reference

The variation to food regulatory measures does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1055 included one round of public consultation following an assessment of A1055, the preparation of a draft variation setting out amendments to Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3 and associated report. Submissions were called for in December 2012 for an eight-week consultation period. As a result of submissions received, some amendments were made to the draft variation.

An expert group, the Infant and Child Health Scientific Advisory Group (ICHSAG), was established with representatives from the fields of paediatrics, child nutrition research, gastroenterology and clinical nutrition to provide advice to the Authority throughout the standard development process. The ICHSAG contributed a broad spectrum of knowledge and expertise in the field of infant and young children's nutrition.

A Regulation Impact Statement (RIS) was not required because the proposed variation provides only for the optional, as opposed to mandatory, addition of an ingredient and is unlikely to have a major impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variations

Subitem [1.1]

Subitem [1.1] amends clause 2 of Standard 1.1.1 to replace the current term IDS and its definition with the new term ITF and its definition. Although not specified in the definition itself, the mixtures referred to in the definition of 'inulin-type fructans' would include but is not limited to substances described as -

- (a) FOS; or
- (b) short-chain FOS; or
- (c) oligofructose; or
- (d) inulin.

Subitem [1.2]

Subitem [1.2] amends clause 9A of Standard 1.1.1 to replace the reference to IDS with a reference to ITF. This amendment means that ITF would be taken not to be nutritive substances and, consequently, the use of ITF in general foods would not be prohibited.

Subitem [2.1]

Subitem [2.1] amends the Table to clause 17 of Standard 1.3.3 to omit the invertase enzyme (EC3.2.1.26) sourced from *Saccharomyces cerevisiae* from the list of permitted enzymes of microbial origin that may be used as a processing aid.

Subitem [2.2]

Subitem [2.2] amends the Table to clause 17 of Standard 1.3.3 by inserting a reference to the enzyme β -fructofuranosidase (EC3.2.1.26) sourced from both *Saccharomyces cerevisiae* and *A. niger* into the list of permitted enzymes of microbial origin that may be used as a processing aid.

Subitem [3.1] and items [4] and [5]

Subitem [3.1] and items [4] and [5] amend Standards 2.9.1, 2.9.2 and 2.9.3 respectively to replace the term IDS wherever this term occurs within those Standards with the term ITF. This is in line with the amendments made to Standard 1.1.1 above. These amendments permit ITF, which includes short chain FOS_{sucrose}, to be added to infant formula products, infant foods and formulated supplementary foods for young children, alone or in combination with each other and/or GOS, at the maximum amounts currently prescribed in relation to IDS or IDS and GOS in these Standards.

Subitem [3.2]

Subitem [3.2] amends the Table of contents of Standard 2.9.1 so that clause 9A, which is currently not in the Table of contents, will be added to it with the new heading "Permitted inulin-type fructans and galacto-oligosaccharides."

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1055 – Short-chain Fructo-oligosaccharides) Variation

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

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1055 – Short-chain Fructo-oligosaccharides) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

These variations commence on gazettal.

SCHEDULE

[1] Standard 1.1.1 is varied by

[1.1] omitting from clause 2 the definition of inulin-derived substances and substituting -

“**inulin-type fructans** means mixtures of saccharide chains that have predominantly $\beta(2\rightarrow1)$ fructosyl-fructose linkages with or without a terminal glucose.”

[1.2] omitting from clause 9A “Inulin-derived substances” and substituting “Inulin-type fructans”

[2] Standard 1.3.3 is varied by omitting from the Table to clause 17

“

Invertase
EC 3.2.1.26

Saccharomyces cerevisiae

”

and substituting –

“

Invertase
EC 3.2.1.26

Aspergillus niger
Saccharomyces cerevisiae

”

[3] Standard 2.9.1 is varied by

[3.1] omitting “inulin-derived substances” wherever occurring and substituting “inulin-type fructans”

[3.2] updating the Table of Provisions to reflect these variations

[4] Standard 2.9.2 is varied by omitting from paragraph 2(2)(c) “inulin-derived substances” and substituting “inulin-type fructans”

[5] Standard 2.9.3 is varied by omitting from subclause 6(4) “inulin-derived substances” and substituting “inulin-type fructans”