

17 December 2012
[29-12]

Call for submissions – Application A1055

Short Chain Fructo-oligosaccharides

FSANZ has assessed an Application made by GTC Nutrition 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 (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Formulated Supplementary Foods for Young Children (Standard 2.9.3 Division 4), and has prepared a draft food regulatory measure. The Applicant proposes short chain FOS be permitted to be added to these special purpose food categories in the same quantities but as an alternative to, those currently set for 'inulin-derived substances' (IDS). The definition of IDS in the Code incorporates short chain FOS derived from inulin (short chain FOS_{inulin}). The Application is also requesting modification of Standard 1.3.3 to permit the use of a new microbial source of invertase (EC 3.2.1.26) enzyme from a strain of the fungus *Aspergillus niger* as a processing aid (enzyme). This enzyme is to be used in the production of short chain FOS.

Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 11 February 2013

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1055shor4991.cfm>

- SD1 Risk and technical assessment report
- SD2 Background and risk management report

1. Executive summary

GTC Nutrition (the Applicant) lodged an Application seeking amendments to 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 (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Formulated Supplementary Foods for Young Children (FSFYC) (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 Code's current definition of IDS incorporates short chain FOS derived from inulin (short chain FOS_{inulin}) and specifically excludes short chain FOS_{sucrose}. The Applicant proposes short chain FOS_{sucrose} be used as an alternative to IDS up to the same maximum levels as currently permitted.

The Applicant also seeks approval for the use of a new microbial source of 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}. Short chain FOS_{sucrose} is permitted and used in some overseas infant formula products, infant foods and FSFYC.

FSANZ's Risk and technical assessment (at SD1) concludes that short chain FOS_{sucrose} produced by invertase-catalysed condensation of sucrose is technologically justified and is as safe as IDS already permitted to be added to foods generally, and to infant formula products, infant foods and FSFYC, alone or in combination with IDS and/or galacto-oligosaccharides (GOS) up to the currently permitted maximum amounts. Additionally, short chain FOS_{sucrose} has the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered to be beneficial effects. In addition, the Risk and technical assessment identified no public health and safety issues with the proposed use of invertase from *A. niger* as a processing aid in the production of short chain FOS_{sucrose}. *A.niger* is internationally recognised as a safe organism and suitable for the manufacture of enzyme preparations.

The preferred regulatory approach is to amend special purpose Standards 2.9.1, 2.9.2 and 2.9.3 to permit the optional addition of short chain FOS_{sucrose} to infant formula products, infant foods and FSFYC respectively, up to the same maximum amounts currently permitted for IDS or IDS and GOS. This approach also includes a revised definition in Standard 1.1.1 that covers both short chain FOS_{sucrose} and IDS (see section 3.2.6.1 below). IDS substances falling within this broadened definition would also be taken not to be nutritive substances which means that the addition of short chain FOS_{sucrose} to foods generally would not be prohibited. In addition, an amendment to Standard 1.3.3 would permit invertase from *A. niger* as a processing aid to be used to produce short chain FOS_{sucrose}.

To achieve the above, FSANZ proposes that the term 'inulin-derived substances' be replaced by the inclusive term 'inulin-type fructan' (ITF) defined as:

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

No regulatory impact statement is required for this Application as it is seeking permission for the optional (as opposed to mandatory) addition of an ingredient (RIS Exemption ID: 12065). However, FSANZ undertook an analysis of the regulatory options and potential impacts on key stakeholder groups. That analysis, in conjunction with the safety assessment, indicates that FSANZ's preferred option provides the greatest net benefit to the community.

FSANZ considers the preferred option meets the requirements of the FSANZ Act. The assessment, based on the best available evidence at this time, concludes that the use of inulin-type fructans, with the same prescribed maximum permitted amount currently applying to IDS or IDS and GOS, is unlikely to pose a risk to the health and safety of infants and young children.

FSANZ also considers that the preferred approach meets the relevant Ministerial Policy Guidelines, allows consumers choice, provides options for manufacturers, reduces potential barriers to trade, supports cost-effective manufacturing through harmonisation with overseas regulations, supports innovation, and provides clarity for manufacturers and enforcement agencies in Australia and New Zealand.

2. Introduction

2.1 The Applicant

GTC Nutrition lodged an Application on 23 September 2010.

2.2 The Application

The Applicant seeks amendments to the Code to permit the optional addition of short chain fructo-oligosaccharide (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 (FSFYC) (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 Code's current definition of IDS incorporates short chain FOS derived from inulin (short chain FOS_{inulin}) and specifically excludes short chain FOS_{sucrose}. The Applicant proposes short chain FOS_{sucrose} be used as an alternative to IDS up to the same maximum levels as currently permitted. The Applicant does not seek the addition of short chain FOS_{sucrose} as a nutritive substance nor as a novel food.

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

2.3 The current Standards

2.3.1 Domestic Standards

2.3.1.1 Short chain FOS

- Standard 1.1.1 – *Preliminary provisions – Application, Interpretation and General Prohibitions*

Clause 1 defines IDS and 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.

- Standard 2.9.1 – *Infant Formula Products*

Standard 2.9.1 sets out the compositional and labelling requirements for infant formula products i.e. foods intended or represented for use as a substitute for breast milk.

Clause 9A requires that infant formula products contain no more than 110 mg of IDS per 100 kJ either alone or combined with GOS.

- Standard 2.9.2 – *Foods for Infants*

Standard 2.9.2 sets out the compositional and labelling requirements of foods intended or represented for use as foods for infants.

Subclause 2(2) states that the maximum permitted amount of IDS and GOS that can be voluntarily added, either alone or in combination, is 0.8 g/100 g as prepared for consumption.

- Standard 2.9.3 – *Formulated Meal Replacements and Formulated Supplementary Foods*

Division 4 (FSFYC) –sets out compositional and labelling requirements for FSFYC 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.

2.3.1.2 *Aspergillus niger*

- Standard 1.3.3 – *Processing Aids*

The Table to clause 17 lists invertase (EC 3.2.1.26) sourced from *Saccharomyces cerevisiae* as a permitted processing aid.

2.3.2 International regulations

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 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 to a set maximum and in a prescribed ratio. Other oligosaccharides are also permitted, providing their suitability is established by generally accepted scientific data. In the United States, infant formula products containing short chain FOS are available. Fructo-oligosaccharides with fructose units from two to four are designated as Generally Recognised as Safe (GRAS) by the USFDA in infant foods. Infant formula products are excluded from this GRAS notice.

International regulations relevant to both short chain FOS and *A. niger* are described in more detail in SD2.

2.4 Applicable Ministerial Policy Guidelines

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.

2.5 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.

2.6 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk and technical assessment

Short chain FOS are mixtures of short unbranched polymers of ≤ 9 fructose monomers. They have identical chemical linkages to IDS. Short chain FOS are produced by enzymatically degrading inulin (short chain FOS_{inulin}) or by synthesising it from sucrose also via an enzyme-catalysed process (short chain FOS_{sucrose}). These substances are added to infant formula products to purposely better align the stool characteristics of formula-fed infants with the softer stools typically associated with breastfed infants. Despite its equivalence with short chain FOS_{inulin}, short chain FOS_{sucrose} is currently not permitted to be added to infant formula products, infant foods and FSFYC on the basis of its method of manufacture.

The conclusions of the Risk and technical assessment are summarised as follows:

- Short chain FOS_{sucrose} is technologically suited to its proposed use and complies with international specifications.
- Results of laboratory animal studies confirmed that short chain FOS_{sucrose} has no identifiable hazard at concentrations likely to be encountered under Good Manufacturing Practice.
- The digestion of short chain FOS_{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 short chain FOS_{sucrose} up to 3.0 g/L for periods ranging from 1 week to approximately 3 months.
- Short chain FOS_{sucrose} has the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered beneficial effects.
- The use of short chain FOS_{sucrose} in the general food supply would be as safe as IDS.
- No public health and safety issues were identified with the proposed use of invertase from *A. niger* as a processing aid in the production of short chain FOS_{sucrose}. An acceptable daily intake (ADI) 'not specified' is considered appropriate for this substance.

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

3.2 Risk management

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in 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
- 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.

3.2.1 Regulatory options

Based on consideration of the above matters, the totality of available evidence, and the Risk and technical assessment conclusions, there are two regulatory options in relation to Application A1055.

Option 1: Prepare a draft variation to amend Standards 2.9.1, 2.9.2 and 2.9.3 to permit the optional addition of short chain FOS_{sucrose} to infant formula products, infant foods and FSFYC respectively, up to the same maximum amounts currently permitted for IDS and GOS. This option would create a revised definition in Standard 1.1.1 that covers both short chain FOS_{sucrose} and IDS (see Section 3.2.6.1 below), and also would permit invertase from *A. niger* as a processing aid. The broadened definition would continue to be taken not to be a nutritive substance. This means that short chain FOS_{sucrose} would not be a nutritive substance and, consequently, its use in general foods would not be prohibited.

Option 2: Reject the Application i.e. do not amend Standard 2.9.1, 2.9.2 and 2.9.3, and maintain the current definitions in Standard 1.1.1. Under this Option, invertase from *A. niger* would also not be permitted as a processing aid.

3.2.2 Cost/benefit analysis

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

No regulatory impact statement is required for this Application as it is seeking a permission for the optional addition of an ingredient (RIS Exemption ID: 12065). However, FSANZ undertook a basic cost analysis summarised as follows.

The analysis of potential impacts on key stakeholder groups indicates that an overall net benefit is achieved through Option 1.

The potential impacts of each of the above regulatory options on the key stakeholder groups are considered in detail in SD2. This assessment is not intended to be an exhaustive, quantitative economic analysis. Rather, it summarises the likely qualitative impacts of each option.

3.2.3 Other more cost-effective measures (whether available to FSANZ or not)

There are no other measures which could achieve the same level of cost effectiveness other than amendments to Standard 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3.

3.2.4 Any relevant New Zealand standards

These standards apply to New Zealand and there are no relevant New Zealand only Standards.

3.2.5 Any other relevant matters

When developing risk management options, the following issues were also considered:

1. What (if any) are the risks to infants associated with adding short chain FOS_{sucrose}, either singularly or in combination with IDS and/or GOS to infant formula products, infant foods and FSFYC? What (if any) are the risks to the community associated with adding short chain FOS_{sucrose} to foods generally?
2. What (if any) are the benefits to infants consuming infant formula products containing short chain FOS_{sucrose}?
3. What risk management options and strategies are available?
4. What impacts would the available options have on the different stakeholder groups?
5. How would the regulatory options be included in the Code?
6. Do the options/strategies provide regulatory clarity? Can they be enforced/measured/monitored/evaluated?
7. How do the regulatory options meet relevant Ministerial Policy Guidelines?
8. Which option will provide the greatest net benefit to the community?
9. What are the consequential effects of the preferred regulatory measure?

SD2 discusses these and other risk management considerations, including overseas regulations, implications for trade, definitions and terminology. These risk management considerations informed the development of the regulatory options and risk management strategies proposed for this Application.

3.2.6 Preferred regulatory approach

The cost/benefit analysis indicated that an overall net benefit is achieved through Option 1.

3.2.6.1 Terminology and definitions in the Code

There is a need to define substances in the Code to ensure regulatory clarity, particularly for manufacturers and enforcement agencies.

FSANZ has considered the range of terms used in the scientific literature and how those could be adopted in the Code. Given that short chain FOS_{inulin} and short chain FOS_{sucrose} are equivalent and that there are no concerns with respect to their use with IDS and GOS, FSANZ considers there is no reason to differentiate the terms in regulation.

FSANZ proposes that the term 'inulin-derived substances' be replaced by the inclusive term 'inulin-type fructan' (ITF) defined as:

mixtures of saccharide chains that have predominantly β (2→1) fructosyl-fructose linkages with or without a terminal glucose

See the draft variation at Attachment A.

This term incorporates the previously described IDS and the substances described in this Application as short chain FOS_{sucrose}. A clear definition will provide clarity in the Code for both manufacturers and enforcement agencies.

3.2.6.2 Nutritive substances

The Code states that IDS are taken not to be nutritive substances. This principle will apply to the new term ITF. This means that short chain FOS_{sucrose} would not be a nutritive substance and, consequently, its use in general foods would not be prohibited. The risk assessment concludes that short chain FOS is as safe as already-permitted IDS.

3.2.6.3 Labelling requirements

Ingredient and nutrition information labelling requirements that currently apply to IDS would apply to ITF. Refer to SD2 for details of these labelling requirements.

Questions for submitters

1. Are there any other costs or benefits that should be considered in the impact analysis?
2. Are there any other parties you think the proposed variation to the relevant Standards may affect?
3. Does the proposed terminology and definition provide appropriate clarity and consistency?

3.2.7 Addressing FSANZ's objectives for standards-setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of the Application.

3.2.7.1 Protection of public health and safety

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

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

The current provisions within the Code relating to the inclusion of IDS in the ingredient list on labels of infant formula products, infant foods and FSFYC would also apply to ITF (including short chain FOS_{sucrose}). Therefore, there would be no change to the level or type of information that would be required and available to carers when compared to the current labelling requirements for IDS (including short chain FOS_{inulin}) (see section 3.2.6.3 above).

3.2.7.3 The prevention of misleading or deceptive conduct

Current labelling requirements, which aim to prevent misleading or deceptive conduct, would apply to the proposed amendments to the Code.

3.2.8 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

- 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
- any written policy guidelines formulated by the Ministerial Council¹.

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

The best available evidence has been 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 overseas regulations for the relevant special purpose foods, which are summarised in section 2.3.2 and SD2. The proposed regulatory approach for this Application 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

The preferred option is to permit the optional addition of short chain FOS_{sucrose}. This permission would be available to all manufacturers, allow for innovation, and is generally in line with international regulations. FSANZ proposed approach will not require manufacturers to produce products specifically for the small Australia New Zealand market, so does not create barriers to trade. 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 foods generally, and in infant formula products, infant foods and FSFYC. Extending the permission to include short chain FOS_{sucrose} will be equitable, and allow different manufacturers to use alternative formulations that will continue to promote fair trade.

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

Any written policy guidelines formulated by the Ministerial Council

The Ministerial Policy Guidelines that apply to this Application are:

¹ Now known as the COAG Legislative and Governance Forum on Food Regulation

- Intent of Part 2.9 of the Code
- Regulation of infant formula products.

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

FSANZ considers that the Ministerial Policy Guideline on the Regulation of Infant Formula Products has been met if short chain FOS_{sucrose} were to be permitted in infant formula products as requested by the Applicant. The particularly relevant specific policy principles for composition are (d), (e) (h) (i) and (j). Specific policy principles (a), (b), (f) and (g) are not applicable to this Application.

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

3.3. Risk communication

The communication strategy for A1055 – Short chain FOS aims to ensure relevant industry players, carers, health professionals and jurisdictions are aware of any changes to the Code which may result from this Application.

This Call for submissions report including the supporting documents and the proposed variation to the Code is provided on the FSANZ website for public consultation on this Application.

Following this consultation period, FSANZ will review the nature of the feedback received from submitters and determine whether additional communication or consultation is required to develop the final Approval Report for the FSANZ Board.

All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the *Food Standards News*. Subscribers and interested parties are also notified about the availability of reports for public comment.

3.3.1 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged 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.

There are relevant international standards in place for special purpose foods and amending the Code to permit the optional addition of short chain FOS_{sucrose} to infant formula products, infant foods and FSFYC is unlikely to have a significant effect on international trade as the permissions are in line with the international guidelines and overseas regulations.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variation

The draft variation is at Attachment A.

4.1. Implementation

The variation takes effect on gazettal.

Attachments

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

Attachment A – 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 *Saccharomyces cerevisiae*
EC 3.2.1.26”

and substituting –

“
Invertase *Aspergillus niger*
EC 3.2.1.26 *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 – Draft 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 invertase (also called β -fructofuranosidase) (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 the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

2. Purpose and operation

The Authority has prepared a draft variation of the following Standards in the Code:

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

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 *A.niger* as an additional source of the invertase enzyme (EC3.2.1.26) in the Table to clause 17 (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 2 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1055 includes one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for in December 2012 for an eight-week consultation period.

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

Item [1.1]

The amendment to clause 1 of Standard 1.1.1 replaces the current term IDS and its definition with the new term ITF and its definition. ITF is a broader term and includes both IDS and short chain FOS_{sucrose}.

Item [1.2]

The amendment to clause 9A of Standard 1.1.1 replaces 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.

Item [2]

The amendment to the Table to clause 17 of Standard 1.3.3 adds *A. niger* as an additional source of the invertase enzyme (EC3.2.1.26) to the list of permitted enzymes of microbial origin that may be used as a processing aid.

Items [3], [4] and [5]

These amendments replace the term IDS wherever this term occurs within Standards 2.9.1, 2.9.2 and 2.9.3, 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.