
**Application to amend the
Australia New Zealand Food Standards Code – General**

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| PART 1 GENERAL INFORMATION |
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1.1 Applicant

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(d) Orafti is the leading manufacturer of inulin and oligofructose worldwide

1.2 Nature of application

The intent of this application is:

- (a) to vary the following Standards of the Australia New Zealand Food Standards Code (the Code):

- 1.1.1 Preliminary Provisions - Application, Interpretation and General Prohibitions

- 2.9.1 Infant Formula Products

- 2.9.2 Foods for Infants

- (b) the application is made on behalf of the Orafti Group
- (c) there are no co-applicants

PART 2 SPECIFIC INFORMATION

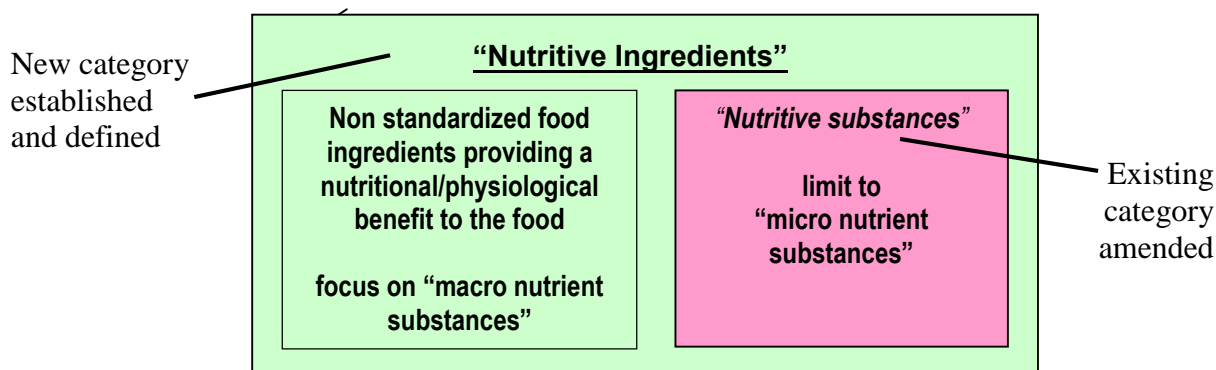
2.1 Details of the application

(a) The application seeks to amend the Code to:

- (i) vary the definition of *nutritive substance* in Clause 2 Interpretation of Standard 1.1.1 to clarify that it applies to micro nutrient substances only and does not apply to macro nutrient ingredients such as inulin and oligofructose (FOS);
- (ii) to include a definition for new category of *nutritive ingredient* in Clause 2 Interpretation of Standard 1.1.1 that applies to both micro nutrients substances (ie nutritive substances) and to macro nutrient ingredients.

These amendments are illustrated in Figure 1 below. The proposed draft amendments to the Code in these respects are included in [Annex 1](#).

Figure 1. “Nutritive Ingredient” illustrating the 2 subsets



- (iii) to replace the current prohibitions in the Code on the addition of a nutritive *substance* without express permission applying to special purpose foods standardised in standards 2.9.1 – Infant Formula Products and 2.9.2 – Food for Infants with a new prohibition on the addition of a nutritive *ingredient* without express permission to those foods. The proposed draft amendments to the Code in these respects are included in [Annex 2](#).
- (b) This application affects the use of micro nutrient substances (such as vitamins, minerals, amino acids, electrolytes and nucleotides) and macro nutrient food ingredients (such as inulin, oligofructose (FOS) as dietary fibres, fats, proteins, and oligosaccharides) in:
- (i) foods in general, and
 - (ii) in particular, in foods intended for consumption by infants.

Annex 3 lists substances which are currently classified as nutritive substances and included in the Code under the classification “nutritive substances” or “substances” or a similar classification.

2.2 Purpose and efficacy of the proposed variation/Standard

The purpose of this application is:

- (a) to provide regulatory certainty for existing uses of inulin and oligofructose (FOS) in foods in general by confirming that they are non-standardised food ingredients and are not nutritive substances

[This status is consistent with classifications expressed in the documents in **Annex 7** and the assessment and outcome of A277 which confirmed the status of inulin and oligofructose as both a food ingredient and a macro nutrient].

- (b) to enable stricter control of the use of both nutritive substances and food ingredients in special purpose foods intended for consumption by infants by creating a new category of “nutritive ingredient”.

"Nutritive ingredients" would incorporate both “nutritive substances” and food ingredients with an additional (nutritional/physiological) value. This new category would be substituted into those clauses in the Code that currently prohibit the addition of “nutritive substances” without specific approval in 2.9.1 Infant Formula Products and 2.9.2 Foods for Infants.

2.3 Justification for the application

There is currently significant debate about meaning of the definition of “nutritive substance” in Standard 1.1.1, Division 1, Clause 2 interpretation, particularly with regard to the application of the definition to “macro nutrient food ingredients” and the legal classification of ingredients such as inulin and oligofructose (FOS).

In particular this debate arises from an interpretation that these ingredients should be regarded as “nutritive substances” when added to provide dietary fibre or a prebiotic effect to foods intended for infants notwithstanding that they are unstandardised foods when added for technical purposes or as fibre or prebiotics to foods in general.

Since June 2007 a number of food regulatory and enforcement agencies in Australia and New Zealand have made public written and verbal statements to the effect that in seeking to control and regulate the use of inulin, oligofructose (FOS) and other “macro nutrient ingredients” in foods intended for infants, it is not their intention to restrict the current use of inulin and oligofructose (FOS) within the broader food supply.

Leaving aside the question of whether the interpretation of the regulatory and enforcement agencies is correct, this distinction is not recognised by the wording of the Code. The

purpose of the amendments are to clarify the interpretation of the provisions and to embody approach above and to give it regulatory backing.

At present there is no provision within the Code that would allow a differential interpretation that a substance is or is not a nutritive substance based solely upon the food to which it is added. Such an inconsistent interpretation would be contrary to the normal rules of statutory interpretation. As a result there is increasing concern within the broader food manufacturing industry that the interpretation currently advocated by a number of food regulatory and enforcement agencies in Australia and New Zealand in the context of foods intended for infants could in time come to have broader application. There is concern that it should not be applied to all foods in general to which inulin and oligofructose (FOS) are currently added as food ingredients, to other non-standardised foods used as ingredients to provide an additional (nutritional/physiological) value to foods *and* to new food uses of these ingredients thereby limiting innovation in the food supply.

The amendments proposed in this application if adopted are an effective way of maintaining confidence in the Code together with food regulation and enforcement generally. Adoption of the amendments will provide certainty for all stakeholders, including food regulatory and enforcement agencies and food manufacturers by establishing 2 tiers of definition that will allow the *status quo* to be maintained for inulin and oligofructose (FOS) in foods in general, enable stricter control of food ingredients for certain types of special purpose foods for infants and implement the differential interpretations of the meaning “nutritive substance” advocated by food regulatory and enforcement agencies.

2.4 Establish need for the application

Orafti is of the view that inulin and oligofructose (FOS) do not fall within the current definition of nutritive substance within the Code. In this respect, its views are consistent with and it also relies upon the previous views expressed the Australian food regulatory agencies referred to in [Annex 7](#).

In circumstances where food regulatory and enforcement agencies are now of a different view, clarification of the status of these ingredients and the meaning to be given to "nutritive substances" is needed. This is particularly the case in circumstances where it is not clear to industry stakeholders why food regulatory and enforcement agencies have not given reasons for their departure from the previous approach of the Code.

There are a number of legal means available by which the meaning of the Code could be clarified, including by way of this application to amend it. Orafti is aware that there are proceedings before the New South Wales Supreme Court which will involve consideration of the question of whether inulin and oligofructose (FOS) are nutritive substances. However, it is not a party to those proceedings. In lodging this application, Orafti is seeking a process that is open and transparent and will take into account the views of all stakeholders. Orafti seeks regulations which are clear in their meaning and sees it preferable for the Code to be amended.

Assuming good faith on the part of all stakeholders, the current debate indicates that the wording of the Code with respect to the definition of “nutritive substances” could be unclear and a variety of interpretations are possible. While Orafti is of the view that the current definition can and should be construed so as to exclude inulin and oligofructose (FOS), for the avoidance of doubt it proposes the amendments to the Code in this application.

The recent interpretation of food regulatory and enforcement agencies that inulin and oligofructose (FOS) should be regarded as “nutritive substances” was released without consultation and discussion with affected parties and stakeholders generally. This has resulted in the following problems, many of which we expect were unintended:

For the consumer:

- The publicity associated with the withdrawal of certain foods intended for infants has resulted in at best confusion and puzzlement in the minds of caregivers and at worse real concern due to conflicting information being available in the media;
- Infants have been required to change their diets due to the withdrawal of their usual, well tolerated formula products;
- The reputation of certain foods intended for infants and of inulin and oligofructose (FOS) has been thrown into question.

For the food companies directly involved:

- Nutricia, the manufacturer of formula products intended for infants is being prosecuted by the NSW Food Authority in the New South Wales Supreme Court.
- This manufacturer has also be required to conduct a voluntary withdrawal of the foods (see *Nutricia Australia Pty Ltd v NSW Food Authority* [2007] NSWSC 861) with a consequent loss of sales and market share.
- Its Karicare products have been subject to speculation and adverse commentary in the media
- Concerns have been expressed to Orafti about the legal status of its ingredients and if this issue is not clarified, we anticipate it will result in a dramatic negative impact on sales
- Commercial damage will be done to the Australian and New Zealand suppliers of inulin and oligofructose (FOS), Mandura and Invita (see [Annex 4](#))

For the whole AUS/NZ food industry:

- Manufacturers of foods generally which use inulin and oligofructose (FOS) as ingredients are concerned about the legality of doing so given the general prohibition in clause 9 of standard 1.1.1 and are concerned that may be in breach in the Code, may be prosecuted and/or may need to change the composition and packaging of their food products at short notice in the future
- Food companies are questioning FSANZ standing as a regulator and its decision making process both domestically in Australia and New Zealand and internationally. In circumstances where FSANZ has not provided reasons for the change in its interpretation of the relevant provision, there is a loss of confidence in the certainty and continuity of FSANZ guidance on regulatory issues

- There is some loss in faith in the joint regulatory regime generally and the Code as concerns about its drafting are raised and increasing bewilderment generally as news of the new interpretation becomes known overseas in North America and in Europe.

2.5 Nutritional implications

The granting of the application would allow the *status quo* to be maintained with regard to the use of inulin, oligofructose (FOS) and other non-standardised food ingredients in foods in general whilst enabling stricter regulatory control to be exercised over the nutritional composition and value of foods for infants.

2.6 Dietary implications

The granting of the application is not expected to have any significant net impact on diet other than to enable stricter regulatory control to be exercised over the nutritional composition and value of foods for infants.

Australians and New Zealanders have been consuming a wide range of inulin and oligofructose containing products since 1993/1994. These foods include products as diverse as cereals, bakery products, dairy products, sweet deserts. Inulin is added for a number of purposes (nutritional ones: prebiotic dietary fibre effects; technological ones: improved texture, sensory). Whether the dietary fibre or fibre/prebiotic attributes of the food ingredient are highlighted by the manufacturer of such foods, it is present in a wide range of foods. If the present status quo is not preserved by the granting of this application, the removal of these ingredients from foods in the marketplace would remove a significant intake of useful dietary fibre in the population.

2.7 Advantages to the consumer

The adoption of the amendments proposed by this application will preserve the status quo and the ability of consumers to continue to choose and consume foods that contain inulin, oligofructose (FOS) and other non-standardised food ingredients. At the same time, the granting of this application will also ensure that there is a high level of confidence that there is strict control over the composition of foods for infants.

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| PART 3 REGULATORY/LEGISLATIVE IMPLICATIONS |
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3.1 International standards

There are no Codex or international standards which include a classification comparable to that of "nutrient substance" in the Code.

In this respect, the Code is out of step with international regulation.

3.2 International legislation

Orafti is the leading manufacturer of inulin and oligofructose (FOS) internationally. Accordingly as part of our business we are aware of international legislation relating to these products. We are not aware of any legislative provisions internationally which treat inulin and oligofructose (FOS) differently from other macro nutrients. In most countries internationally, the status of inulin and oligofructose (FOS) as dietary fibre and therefore as a macro nutrient has been confirmed, the remaining jurisdictions internationally being silent as to its classification.

In a broad sense, the European Union's Foods for Particular Nutritional Uses ("PARNUTS") regulation (EU Directive 2001/15/EC (see [Annex 5](#))) has a related concept, that of "nutritional substances". This concept is different to that of "nutritive substance" in the Code. The term "nutritional substance" is not defined in the Directive. Further, inulin and oligofructose are not considered to fall under that classification.

PARNUTS includes a list of 112 vitamin and mineral substances, 22 amino acids, 2 carnitine substances, 4 choline substances, taurine, inositol and 10 nucleotides. Inulin and oligofructose (FOS) are not listed within those substances.

European law treats inulin and oligofructose differently. For example, the Directive on "Infant formulae and follow-on formulae" (2006/141/EC) as "fructo-oligosaccharides" that may be voluntary added to these products.

In the event that FSANZ were to treat inulin and oligofructose (FOS) as falling outside the definition of "nutritive substance" within the Code, doing so would be consistent with the approach adopted internationally.

3.3 Regulatory Impact Statement

Insofar as acceptance of this application would reflect the regulatory authorities' historical approach to the use of inulin and oligofructose (FOS) in foods generally and would restore the previous status quo, adoption of the proposed amendments is likely to have minimal impact.

There would be no need for consumers to change their diet nor would manufacturers of food products generally need to change the composition or packaging of products containing inulin and oligofructose.

Indeed, what impact it has is likely to be positive, that is, it would remove the current uncertainty about the interpretation of the Code and allow consistency in meaning in relation to nutritive substances and the treatment of inulin and oligofructose (FOS).

Adoption of the amendments would:

- give clarification and certainty to regulatory and enforcement authorities, suppliers, manufacturers and consumers.
- enable the continued use of inulin and oligofructose (FOS) in all foods generally.
- allow a valuable source of fibre and prebiotic to remain in foods generally.
- clarify the status of inulin and oligofructose (FOS) as a macro nutrient.
- establish a more stringent standard for the composition of infant formulae.

In the alternative, not granting the application is likely to have a far greater and widespread negative impact.

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| PART 4 | ANALYTICAL PROCEDURES |
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Having regarded the nature of this application a discussion of the analytical procedures is not necessary.

In any event, a past application (A277) concerned in part the appropriate analytical method for the determination of inulin and FOS as dietary fibre. The full assessment report as well as the inquiry report is available on the FSANZ homepage.

In the result, the AOAC method to determine the content of inulin and FOS as dietary fibres into the Food Code proposed by the A277 was gazetted by Amendment 55 (30/8/2001).

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| PART 5 | DETAILS OF REASONING |
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Inulin and oligofructose (FOS) should not be classified as nutritive substances but rather are non standardised food ingredients. Their dietary fibre and prebiotic characteristics mean they are macro-nutrients and not micro nutrients.

Structural classification of Inulin and oligofructose (FOS) ([Annex 6](#))

Inulin and oligofructose (FOS) are non-digestible carbohydrates belonging to the fructan family, found in many plants as a storage carbohydrate. Differences in chain length distributions and linearity in the various plant- fructans result in their having different characteristics.

Commercially, **inulin** is obtained mainly from chicory roots and today this source accounts for more than 95% of world-wide product availability. Inulin from chicory has a degree of polymerisation (DP) between 3 – 60, with an average between 10-12.

Oligofructose (FOS) is a fructan similar structure to inulin, but with a DP up to 10. This chain length range is also part of the inulin DP range, and as such chicory inulin contains about 30% oligofructose.

Long-chain inulin is a specific refinement of pure inulin, where the oligofructose (FOS) fraction (and residual smaller sugars) has been removed through crystallisation. As a result, the taste is completely neutral (no residual sweetness), and the average DP is increased from about 11 to ≥ 23 .

The use of inulin in foodstuffs

Both inulin and oligofructose (FOS) are well established as safe and suitable foods within the Australian and New Zealand food supply and contribute to a healthy diet. They are currently added as non-standardised food ingredients to over 40 foods, ranging from yoghurt to bread to beverages.

When added to these foods inulin and oligofructose (FOS) confer a range of significant technical and functional properties to them. They have been confirmed to be unstandardised foods meaning they may be added to any food that does not have specific compositional requirements including also “standardized foods” where the standard allows the addition of “other foods”, without any further regulatory process or approval being required.

This status was originally advised in Australia by the National Food Authority in 1993 ([Annex 7.1](#) and [Annex 7.2](#)) and in New Zealand by the Ministry of Health in 1994 ([Annex 7.3](#)).

This status was reaffirmed subsequently, through the acceptance of applications for permission to add inulin to standard G5 - table spreads, a standard for which prescriptive compositional standards existed (application A217, amendment 27 gazetted 1995) ([Annex 7.4](#)) and a second application for their recognition as dietary fibre (application A277, amendment 55 gazetted 2001) ([Annex 7.5](#) and [Annex 7.6](#)). Both of these amendments were endorsed by Ministers responsible for food in all Australian jurisdictions and in the case of application 277 by the New Zealand Minister as well. Furthermore, the affirmation of the

status of inulin and oligofructose (FOS) as foods was made in 2001, following the adoption of the new ANZ Code containing the definition of nutritive substance.

At no time has there been any consultation with Orafiti in relation to the release of a proposal to re-classify/define inulin or oligofructose (FOS) as “nutritive substances”. Nor has Orafiti been formally notified of FSANZ decision to treat inulin or oligofructose (FOS) as nutritive substances. Orafiti has also not been given any reasons for FSANZ's apparent decision to change the regulators previous consistent classification of these ingredients over many years and its prior interpretation of the Code.

There is current interest in marketing products for infants with added inulin and other food ingredients. It appears that a precautionary concern has been raised with regulatory and enforcement agencies that these ingredients have not undergone an appropriate pre-market assessment for use in these foods that are consumed by a vulnerable group within the community. This has led to shift in interpretation of the Code to the view that oligofructose (FOS) and inulin should be regarded as nutritive substances as defined in Standard 1.1.1 when used in these foods and that as a consequence specific permission is required for use.

However, this change in classification has implications for foods generally. There is currently no provision within the nutritive substance definition in the Code or otherwise that would allow a differential interpretation to be made based upon the food to which the substance is added, that is, foods in general or infant formula products and foods for infants.

Consequently this new interpretation is causing significant confusion amongst Orafiti's customers and more broadly within the food industry in Australia, New Zealand and overseas about the use of inulin and oligofructose (FOS) in the general food supply, despite their long history of use as non-standardised food ingredient.

Furthermore, if the interpretation as applied to inulin and oligofructose (FOS) were then applied consistently to other food ingredients a very large number of substances that are currently added to foods as non-standardised ingredients, with no requirement for express approval, become nutritive substances and are no longer permitted in food without specific approval. This potentially represents a significant change in regulatory policy in relation to the use of non-standardised food ingredients that has been introduced with little or no community consultation.

Inulin and oligofructose (FOS) are not “nutritive substances”

The definition of nutritive substance was included in Code at its adoption in December 2000.

Prior to the implementation of the Code, the term “food additive” was used in both Australia and New Zealand to describe any substance added to food for a technical or nutrient purpose. The Code harmonized the definition of “food additive” with international standards, attempting to limit it to substances added for a technological purpose (ie antioxidant, preservative, colour etc.).

The classification of “nutritive substance” was developed as a means to maintain control of vitamins, minerals and other micro nutrient substances that fell out of the food additive re-categorization. The relationship between unstandardised foods/food ingredients (also

sometimes called “other foods” or “foodstuffs”) and substances added to food for technical or nutrient purposes did not change in any way that affects the rulings, as indicated by comparison of the relevant clauses in the previous Code (Standard A3 clause 2) and the current Code (Standard 1.1.1 Clause 10).

However, given the different interpretations being advocated by various stakeholders, the definition of “nutritive substances” requires clarification.

There are a number of compelling reasons why the definition of "nutritive substance" does not and was never intended to apply to food ingredients such as inulin and oligofructose (FOS). “Nutritive substance” is defined in Standard 1.1.1 as:

a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides.

a) *a substance not normally consumed as a food in itself -*

The definition of "nutritive substance" is not directed at extracts of widely consumed foods (such as chicory, from which inulin and oligofructose (FOS) are extracted on an economical scale). Rather, the wording specifically limits the application of the definition to extracts, where the extract is obtained from a substance, where that substance is not normally consumed as a food (or ingredient). Therefore consideration needs to be given not to whether the extract is normally added to a food, but rather, whether the base ingredient used to manufacture the extract is normally consumed as a food (or ingredient). Within the definition, the word "after" is associated with “extraction and/or refinement, or synthesis” which implies it is directed not at the end product, but rather at the raw materials used.

The chicory root, which is the raw material for the extraction of inulin and oligofructose (FOS) – has also significant use in the production of a non-caffeinated alternative to coffee. During the manufacturing of that coffee substitute the chicory root is roasted and ground. The preparation of the hot drink is further similar to normal coffee - but without providing any caffeine. This product has a long tradition of use in various countries in North America, Europe and in Australia.

The chicory root is also commercially used as flour, after going through the simple process of washing, slicing, dehydration and grinding. This ingredient with a high content of inulin is particularly useful in improving consistency, texture and volume of baked products (breads, pastries, biscuits). It has had wide commercial use in Europe as such since the early 1920's. It can also be incorporated to improve sensory properties (taste, flavour, colour) in various beverages, sweets and savoury applications.

Further inulin-type fructans are present in many vegetables, fruits and cereals, including leek, onion, garlic, wheat, chicory itself, artichoke and banana (Van Loo

et al., 1995). All of these foods and vegetables are considered to be normally consumed as foods and as such, the fructans they contain must be considered substances normally consumed as food in itself.

b) *and not normally used as an ingredient of food -*

Both inulin and oligofructose (FOS) were previously confirmed to be unstandardised foods by regulators in Australia and New Zealand with the result that are being added to foods that do not have specific compositional requirements under the Code, without any further regulatory process or approval being required. This status was originally advised in Australia by the National Food Authority in 1993 and in New Zealand by the Ministry of Health in 1994.

This classification has been repeatedly reaffirmed, as discussed above, including since the adoption of the current Code (including as it does a definition of nutritive substance).

Unlike nutritive substances, however, when used as ingredients in food, ingredients such as inulin and oligofructose (FOS) make a range of contributions beyond nutritional enhancement. They may contribute to the physical properties of the food matrix, modify its organoleptic properties, increase the dietary fibre content, contribute to net energy and enhance the prebiotic properties. These contributions distinguish inulin and oligofructose (FOS), as foods, from added substances that are used merely to achieve a specific technological function (food additive) or a nutritional purpose (nutritive substance).

Inulin and oligofructose (FOS) are used currently and normally in many safe and suitable foods in Australia and New Zealand. Recent statements from both regulatory and food law enforcement agencies in Australia and New Zealand have reaffirmed the efficacy and safety of inulin and oligofructose (FOS) in the general food supply.

c) *added to a food to achieve a nutritional purpose –*

When added to a food, unlike micro nutrients (ie nutritive substances) which have very specific and limited functionality, food ingredients generally possess and bring to the food a range of technological, sensory and other properties that contribute to the overall nature of the food.

Inulin and oligofructose (FOS) make a range of contributions beyond mere nutritional enhancement. They affect the physical properties of the food matrix, modify its organoleptic properties, increase the dietary fibre content, contribute to net energy and enhance the prebiotic properties.

The purposes for which inulin and oligofructose (FOS) are added are both technological and physiological. Although inulin and oligofructose (FOS) make a contribution to the overall nutritional value of foods this is a direct consequence of their use as ingredients in foods.

d) *Consistency of interpretation -*

The wording *a substance not normally consumed as a food in itself and not normally used as an ingredient of food*, is found not only in the definition of nutritive substance but also appears in the purpose clause of Standard 1.3.1 Food Additives in relation to the description of a food additive.

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5.

Inulin and oligofructose (FOS)-have very effective fat and sugar replacement properties, for example in the retention of "mouth feel" in low fat and fat reduced foods. These are technological purposes that are consistent with those functions listed in schedule 5 of Standard 1.3.1. However, we do not understand that any stakeholder is suggesting that inulin/oligofructose (FOS) are food additives.

There are many food ingredients extracted from foods that exhibit some food additive like functions but which are not considered food additives specifically because they are recognised as either foods in their own right or food ingredients. Examples include:

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| Sugar | – preservative/bulking agent |
| Distilled vinegar | – preservative |
| Salt | – preservative |
| Lemon juice | – food acid, antioxidant |
| Starch | – thickener |

Consistency of interpretation across the Code is desirable. Inulin and oligofructose (FOS) are not considered to be food additives because they are *normally uses as ingredients in food*, despite displaying food additive like functions. Applying the same logic to the definition of nutritive substance i.e. inulin and oligofructose (FOS) are not nutritive substances because they are foods.

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| PART 6 MANUFACTURING AND PUBLIC HEALTH |
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6.1 Manufacturing process

Having regard to the nature of this application, a discussion of the manufacturing process is not applicable.

6.2 Public health and safety

As the intention of this application is to provide a technical regulatory solution, a discussion of public health and safety seems not to be required.

The safety of inulin and oligofructose (FOS) was recently been confirmed in public statements by the NSW Food Authority ([Annex 8](#)). Orafti considers that there can be no genuine concerns about the use of inulin and oligofructose food products generally outside (non-infant food) applications.

Further, we note that any concerns relating to public health or safety will be addressed in the contexts of the two separate applications - currently filed with FSANZ - by two interested infant food manufacturers.

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| PART 7 STATUTORY DECLARATION – AUSTRALIA |
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The information provided in Parts 1 to 3 must be attested to by a statutory declaration in some suitable form along the following lines:

STATUTORY DECLARATION

Statutory Declarations Act 1959

I, Anke Sentko, Head of Regulatory Affairs ORAFTI, 3300-Tienen, Belgium

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.



Declared at Tienen

on 21st

of August 2007

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| PART 7 STATUTORY DECLARATION – NEW ZEALAND |
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The information provided in Parts 1 to 3 must be attested to by a statutory declaration in some suitable form along the following lines:

STATUTORY DECLARATION

Oaths and Declarations Act 1957

I, Anke Sentko, Head of Regulatory Affairs ORAFT, B-3300 Tienen, Belgium
solemnly and sincerely declare that:

1. the information provided in this application fully sets out the matters required; and
2. the information is true to the best of my knowledge and belief; and
3. no information has been withheld which might prejudice this application to the best of my knowledge and belief.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the *Oaths and Declarations Act 1957*.

Declared at Tienen this 21st, August 2007

Signature 

Application to develop or vary the *Australia New Zealand Food Standards Code*

Checklist

| PART 1 General information | Data provided | Data Not provided | Omission explained |
|---|----------------------|--------------------------|---------------------------|
| 1.1 Applicant | √ | | |
| (a) Name | √ | | |
| (b) Address | √ | | |
| (c) Contact | √ | | |
| (d) Business | √ | | |
| 1.2 Nature of application | | | |
| (a) New or variation | √ | | |
| (b) Sole or joint | √ | | |
| (c) Co-applicants | √ | | |
| PART 2 Specific information | √ | | |
| 2.1 Details of application | √ | | |
| (a) Purpose | √ | | |
| (b) Type/s of food/s | √ | | |
| 2.2 Purpose and efficacy | √ | | |
| 2.3 Justification | √ | | |
| 2.4 Established need | √ | | |
| 2.5 Nutritional implications | √ | | |
| 2.6 Dietary implications | √ | | |
| 2.7 Advantage to consumer | √ | | |
| PART 3 Regulatory/legislative implications | √ | | |
| 3.1 Codex standards | √ | | |
| 3.2 International legislation | √ | | |
| 3.3 Regulatory Impact Statement | √ | | |
| PART 4 Analytical procedures | | | √ |
| PART 5 Details of reasoning | √ | | |
| PART 6 Manufacturing and public health | √ | | |
| 6.1 Manufacturing process | | | √ |
| (a) Method of manufacture | | | |
| (b) Quality assurance | | | |
| 6.2 Public health and safety | | | √ |
| PART 7 Statutory declaration | √ | | |

List of Annexes

- Annex 1** Suggested changes/amendments of the Standard:
Standard 1.1.1 Preliminary Provisions - Application, Interpretation and General Prohibitions
- Annex 2** Suggested changes/amendments of the Standards:
Standard 2.9.1 Infant Formula Products and
Standard 2.9.2 Foods for Infants
- Annex 3** Overview on examples appearing in the Code on the use or non-use of the classification “nutritive substances” for vitamins, minerals, amino acids, electrolytes and nucleotides
- Annex 4** **Confidential:** Commercial Information relating to Part 2.4
- Annex 5** Excerpt from the European Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (PARNUTS)
- Annex 6** Inulin and Oligofructose (FOS) and the definition of oligosaccharides in function of the chain length
- Annex 7** Statements from the authorities in Australia and New Zealand that confirm the food status of inulin and oligofructose (FOS):
- Annex 7.1 Letter of 1993 from the Australian National Food Authority confirming the food status of inulin
 - Annex 7.2 Letter of 1993 from the Australian National Food Authority confirming the food status of oligofructose
 - Annex 7.3 Letter of 1994 from the New Zealand Ministry of Health the confirming the food status of inulin
 - Annex 7.4 Excerpt from the Australian Food Standards Code of 1995 showing inulin included in the Standard G5 for table spreads
 - Annex 7.5 Full Assessment Report of 2001 from ANZFA to Application A277 on inulin as a dietary fibre
 - Annex 7.6 Letter of 2002 from FSANZ regarding Application A277
- Annex 8** Media release on 13 June 2007 of the New South Wales Food Authority (NSWFA)

Annex 1

Suggested changes/amendments of the definitions in the Code:

Standard 1.1.1

***Preliminary Provisions - Application, Interpretation and
General Prohibitions***

CHANGES / AMENDMENTS highlighted in grey

Standard 1.1.1

Preliminary Provisions - Application, Interpretation and General Prohibitions

Division 1

2. Interpretation

re (i), (ii) : CHANGE definition:

***nutritive substance** means a substance not normally consumed as a food in itself ~~and not normally used~~ or as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food (as a micro nutrient) to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides but does not include inulin and oligofructose (FOS).*

re (iii) : INSERT new definition:

nutritive ingredient means a ingredient not normally consumed as a food in itself but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional or physiological purpose, and includes nutritive substances and non-standardised food ingredients.

Annex 2

Suggested changes/amendments of the definitions in the Code:

Standard 2.9.1 Infant Formula Products
and
Standard 2.9.2 Foods for Infants

CHANGES / AMENDMENTS highlighted in grey

Standard 2.9.1 Infant Formula Products

Division 1 Subdivision 3 - General compositional requirements

Clause 6 Restrictions and prohibitions

(1) A ~~vitamin, mineral,~~ food additive or nutritive ~~substance-ingredient~~ must not be added to infant formula product unless -

(a) expressly permitted by this Code; or

(b) it is a protein ingredient essential to the true nature of the infant formula product

(c) it is naturally present in an ingredient of the infant formula product.

Standard 2.9.2 Foods for Infants

Clause 2 General compositional requirements

CHANGE / AMENDMENTS highlighted in grey

(1) Food for infants must not contain a food additive or nutritive ~~substance~~ ingredient unless -

(a) expressly permitted by this Code; or

(b) ~~the food additive or nutritive substance~~ is naturally present in an ingredient of the food for infants.

Annex 3

**Overview on examples appearing in the Code on the use or non-use of the
classification “nutritive substances”**

Overview on examples appearing in the Code on the use or non-use of the classification “nutritive substances” (**highlighted in blue**) for vitamins, minerals, amino acids, electrolytes and nucleotides:

Standard 2.9.1 Infant Formula Products

Table to Clause 7

| <i>Column 1</i> |
|-----------------------------------|
| Nutritive substance |
| <i>Choline</i> |
| <i>Inositol</i> |
| <i>Taurine</i> |
| <i>L-carnitine</i> |
| <i>Cytidine 5'-monophosphate</i> |
| <i>Uridine 5'-monophosphate</i> |
| <i>Adenosine 5'-monophosphate</i> |
| <i>Guanosine 5'-monophosphate</i> |
| <i>Inosine 5'-monophosphate</i> |

Standard 2.6.4 Formulated Caffeinated Beverages

Table to subclause 2(2)

| <i>Column 1</i> |
|-------------------------------|
| Substance |
| <i>Thiamin</i> |
| <i>Riboflavin</i> |
| <i>Niacin</i> |
| <i>Vitamin B₆</i> |
| <i>Vitamin B₁₂</i> |
| <i>Pantothenic acid</i> |
| <i>Taurine</i> |
| <i>Glucuronolactone</i> |
| <i>Inositol</i> |

STANDARD 2.9.4 Formulated supplementary sports foods

Table to Paragraph 2(a)

| <i>Column 1</i> |
|---|
| Micronutrient |
| <i>Vitamin A</i> |
| <i>Thiamin</i> |
| <i>Riboflavin</i> |
| <i>Niacin</i> |
| <i>Folate</i> |
| <i>Vitamin B₆</i> |
| <i>Vitamin B₁₂</i> |
| <i>Vitamin C</i> |
| <i>Vitamin D</i> |
| <i>Vitamin E</i> |
| <i>Biotin</i> |
| <i>Pantothenic acid</i> |
| <i>Calcium</i> |
| <i>Chromium : inorganic forms; organic forms</i> |
| <i>Copper: inorganic forms; organic forms</i> |
| <i>Iodine</i> |
| <i>Iron</i> |
| <i>Magnesium</i> |
| <i>Manganese: inorganic forms; organic forms</i> |
| <i>Molybdenum: inorganic forms; organic forms</i> |
| <i>Phosphorus</i> |
| <i>Selenium: inorganic forms organic forms</i> |
| <i>Zinc</i> |

Table to Paragraph 2(c)

| <i>Column 1</i> |
|--------------------|
| Ingredient |
| <i>L-carnitine</i> |
| <i>Choline</i> |
| <i>Inosine</i> |
| <i>Ubiquinones</i> |
| <i>Creatine</i> |

STANDARD 2.6.2 Non alcoholic Beverages and brewed soft drinks

Clause 6 Composition of **electrolyte** drinks and electrolyte drink bases

(3 An **electrolyte** drink, or an **electrolyte** drink base when made up, may contain:

- (a) calcium phosphates; and
- (b) potassium phosphates; and
- (c) calcium citrates; and
- (d) potassium citrates; and
- (e) sodium citrates; and
- (f) potassium carbonates, including potassium bicarbonate; and
- (g) potassium chloride; and
- (h) calcium chloride; and
- (i) sodium chloride; and
- (j) calcium lactate; and
- (k) magnesium lactate; and
- (l) magnesium sulphate.

- CONFIDENTIAL -

Annex 4

Commercial Confidential Information

Annex 5

**Excerpt from the European Commission Directive 2001/15/EC on
substances that may be added for specific nutritional purposes in foods for
particular nutritional uses (PARNUTS)**

Excerpt from the European Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (PARNUTS)

Category 1. Vitamins

VITAMIN A— retinol x— retinyl acetate x— retinyl palmitate x— beta-carotene x
VITAMIN D— cholecalciferol x— ergocalciferol x
VITAMIN E— D-alpha-tocopherol x— DL-alpha-tocopherol x— D-alpha-tocopheryl acetate x— DL-alpha-tocopheryl acetate x— D-alpha-tocopheryl acid succinate x
VITAMIN K— phyloquinone (phytomenadione) x
VITAMIN B1— thiamin hydrochloride x— thiamin mononitrate x
VITAMIN B2— riboflavin x— riboflavin 5'-phosphate, sodium x
NIACIN— nicotinic acid x— nicotinamide x
PANTOTHENIC ACID— D-pantothenate, calcium x— D-pantothenate, sodium x— dexpanthenol x
VITAMIN B6— pyridoxine hydrochloride x— pyridoxine 5'-phosphate x— pyridoxine dipalmitate x
FOLIC ACID— pteroylmonoglutamic acid x
VITAMIN B12— cyanocobalamin x— hydroxocobalamin
BIOTIN — D-biotin x
VITAMIN C — L-ascorbic acid x — sodium-L-ascorbate x — calcium-L-ascorbate x — potassium-L-ascorbate x— L-ascorbyl 6-palmitate x

Category 2. Minerals

CALCIUM — carbonate x — chloride x — salts of citric acid x — gluconate x — glycerophosphate x — lactate x — salts of orthophosphoric acid x — hydroxide x — oxide x — sulphate x
MAGNESIUM— acetate x — carbonate x — chloride x — salts of citric acid x — gluconate x — glycerophosphate x — salts of orthophosphoric acid x — lactate x — hydroxide x — oxide x — sulphate x
IRON — ferrous carbonate x — ferrous citrate x — ferric ammonium citrate x — ferrous gluconate x — ferrous fumarate x — ferric sodiumdiphosphate x — ferrous lactate x — ferrous sulphate x — ferric diphosphate (ferric pyrophosphate) x — ferric saccharate x — elemental
COPPER— cupric carbonate x — cupric citrate x — cupric gluconate x — cupric sulphate x — copper lysine complex x
IODINE— potassiumiodide x — potassiumiodate x — sodiumiodide x — sodiumiodate x
ZINC— acetate x — chloride x — citrate x — gluconate x — lactate x — oxide x— carbonate x — sulphate x
MANGANESE— carbonate x — chloride x — citrate x — gluconate x — glycerophosphate x — sulphate x
SODIUM— bicarbonate x — carbonate x — chloride x — citrate x — gluconate x — lactate x — hydroxide x — salts of orthophosphoric acid x
POTASSIUM— bicarbonate x — carbonate x — chloride x — citrate x — gluconate x — glycerophosphate x — lactate x — hydroxide x — salts of orthophosphoric acid
SELENIUM — sodiumselenate x — sodiumhydrogen selenite x — sodiumselenite x
CHROMIUM (III) and their hexahydrates — chloride x — sulphate x
MOLYBDENUM (VI) — ammonium molybdate x — sodium molybdate x
FLUORINE — potassiumfluoride x — sodiumfluoride x

Category 3. Amino acids

— L-alanine x
— L-arginine x
— L-aspartic acid x
— L-citrulline x
— L-cysteine x
— Cystine x
— L-histidine x
— L-glutamic acid x
— L-glutamine x

- glycine x
- L-isoleucine x
- L-leucine x
- L-lysine x
- L-lysine acetate x
- L-methionine x
- L-ornithine x
- L-phenylalanine x
- L-proline x
- L-threonine x
- L-tryptophan x
- L-tyrosine x
- L-valine x
- L-serine x
- L-arginine-L-aspartate x
- L-lysine-L-aspartate x
- L-lysine-L-glutamate x
- N-acetyl-L-cysteine x
- N-acetyl-L-methionine

Category 4. Carnitine and taurine

- L-carnitine x
- L-carnitine hydrochloride x
- taurine x
- L-carnitine-L-tartrate x

Category 5. Nucleotides

- adenosine 5'-phosphoric acid (AMP) x
- sodiumsalts of AMP x
- cytidine 5'-monophosphoric acid (CMP) x
- sodiumsalts of CMP x
- guanosine 5'-phosphoric acid (GMP) x
- sodiumsalts of GMP x
- inosine 5'-phosphoric acid (IMP) x
- sodimsalts of IMP x
- uridine 5'-phosphoric acid (UMP) x
- sodiumsalts of UMP x

Category 6. Choline and inositol

- choline x
- choline chloride x
- choline bitartrate x
- choline citrate x
- inositol

Annex 6

Inulin and Oligofructose (FOS) and the definition of oligosaccharides in function of the chain length



Inulin and Oligofructose (FOS) and the definition of oligosaccharides in function of the chain length

1. Nature and definitions of inulin and oligofructose.

1.1. Inulin

Inulin, a non-digestible carbohydrate belonging to the fructan family, is found in many plants as a storage carbohydrate (Van Laere et al., 2002). It has a mild sweet taste, and has been part of our daily diets for some centuries. Inulin-type fructans are present in many vegetables, fruits and cereals, including leek, onion, garlic, wheat, chicory, artichoke and banana (Van Loo et al., 1995). Not all inulin fructans have the same characteristics. Differences in chain length distributions and linearity in the various plant-sourced inulin-types result in their having different characteristics. Commercially, more than 95% of world-wide product is derived from chicory roots (Figure 1). Inulin is used as a functional food ingredient which offers beneficial nutritional properties and important technological attributes.

Inulin from chicory has a degree of polymerisation (DP) between 3 – 60, with an average of between 10 – 12, indicating a linear chain length of different numbers of fructose units, mostly ending with a glucose unit (GF_n-type: Figure 2). They are linked together through a β -(2-1) bond, which makes inulin resistant against digestion in the upper gastro-intestinal tract. As such it belongs to the family of dietary fibres. The exact composition and chain length distribution can be visualised by HPLC-Dionex analytical methodology, and a typical composition is shown in Figure 3.a.



1.2. Oligofructose (FOS)

Oligofructose (FOS) is a fructan similar to inulin, but with a DP up till 10. This chain length range is also part of the inulin definition, and as such chicory inulin already contains for about 30% of oligofructose.

Pure oligofructose (FOS) can be economically produced in 2 different ways:

- The first way is through a partial enzymatic hydrolysis of inulin (Norman et al., 1989), a process that also occurs in the chicory plant later in the season (Van den Ende et al., 1996). The more mature the chicory, the higher the oligofructose content. This process results in an oligofructose with a mixture of GF_n and Fn compounds (Figure 2) The DP is between 2 – 9, with an average of about 4. A typical composition is shown in Figure 3.b.

This production process is used by Orafti to produce oligofructose.

- The second method is an enzymatic process during which the chain length is increased by adding fructose units starting from sugar (sucrose, DP = 2) (Norman et al., 1989). The resulting FOS has a DP between 3 – 5, with an average of about 3,5. Such a product is sometimes referred to as short-chain FOS (scFOS) or synthetically derived FOS. Its composition contains GF₂, GF₃ and GF₄ type compounds (Figure 2). None or little of this product is marketed in Australia or New Zealand at present.

Synonyms for oligofructose include fructo-oligosaccharide (FOS) and oligofructosyl-saccharose.

1.3. Long-chain inulin

Long-chain inulin is a specific refinement of pure inulin, where the oligofructose (FOS) fraction (and residual smaller sugars) have been removed through crystallisation. As a result, the taste is completely neutral (no residual sweetness), and the average DP is increased from about 11 to ≥ 23 . A typical composition of long-chain inulin is shown in Figure 3.c. The ORAFTI brand name for this particular ingredient is BENETM HP.



All Orafti ingredient varieties consist of moieties that are part of inulin as it is present in the chicory root, and have been on the market for many years world-wide.

1.4. “Long-chain” FOS

Certain companies use in their scientific and consumer communications, and regulatory submissions the term “long-chain FOS”, or sometimes also “high-molecular weight oligofructosyl-saccharose” (e.g. Application to amend the Australian New Zealand Food Standards Code – Standards 2.9.1 and 2.9.2; submitted by Nutricia Australia). In this particular case, these terms have been used in relation to the mixture of GOS/FOS used in Infant formula, to specifically refer to the FOS part of the mixture.

However, this mixture consists of GOS in combination with the “long-chain” quality of inulin, where as explained above (2.3), the part of inulin which covers the typical FOS range, has been removed. This is a.o. evidenced by the inclusion in the Nutricia submission of the Product (specification) Sheet of BENEOTM HP, clearly describing the ingredient as “a food ingredient consisting of chicory inulin, from which the smaller molecules were removed.” The Compositional Specifications further indicate the Average DP to be ≥ 23 . The term “long-chain FOS” is contradictory in itself as an oligosaccharide cannot be “long chain” (see point 2). However, it is sometimes used instead of inulin, because of a less potential confusion with “insulin”.

2. Recommended Chemical Nomenclature

In their 1980 recommendations for terminology of oligosaccharide chains, the IUB-IUPAC (International Union of Biochemistry - International Union of Pure and Applied Chemistry) Joint Commission on Biochemical Nomenclature defined **oligosaccharide** as “**a molecule containing a small number (2 to about 10) of monosaccharide residues, connected by glycosidic linkages**” (published in 1982).



In 1997, the Joint FAO/WHO Expert Consultation recommended that “the terminology used to describe dietary carbohydrate be standardised with carbohydrates classified primarily by molecular size (degree of polymerisation or DP) into sugars (DP 1-2), **oligosaccharides (DP 3-9)** and polysaccharides (DP 10+).”

3. Summary

By following the chemical definition on carbohydrates according to their chain-lengths as laid down by world-renowned independent institutions the following terminology is applicable:

- Inulin = a fructan with chain lengths of 3 to 60 units; average chain length between 10-12
- Long chain Inulin = fructan with an average chain length of at least 23
- Oligofructose = a fructan with a chain length of up to 9 units; synonym: FOS (Fructo-oligosaccharide)
- “Long chain FOS” = is erroneously used as a synonym to “long chain inulin”.



References

FAO-WHO; 1998; "Carbohydrates in human nutrition: Report of a Joint FAO/WHO Expert Consultation; Rome, 14-18 April 1997; ISBN 92-5-104114-8.

IUB-IUPAC; 1982; "Abbreviated Terminology of Oligosaccharide Chains; Recommendations 19980"; J. Biological Chemistry; 257; 7; 3347-3351.

Norman B.; Hojer- Pedersen B.. 1989; "The Production of Fructooligosaccharides from Inulin or sucrose Using Inulinase or Fructosyltransferase from *Aspergillus ficuum*"; Denpun Kagaku, 36; 103-111.

Van den Ende W.; Van Laere A.; 1996; "Fructan synthesis and Degrading Activities in Chicory Roots (*Cichorium intybus* L.) during Field-growth, Storage and Forcing"; J. Plant Physiol.; 149; 43-50.

Van Laere A.; Van den Ende W.; 2002; "Inulin metabolism in dicots: chicory as a model system"; Plant, Cell and Environment; 25; 803-813.

Van Loo J.; Coussement P.; De Leenheer L.; Hoebregs H.; Smits G.; 1995; "On the Presence of Inulin and Oligofructose as Natural Ingredients in the Western Diet"; Food Science and Nutrition, 35, 6, 525-552.



Figures

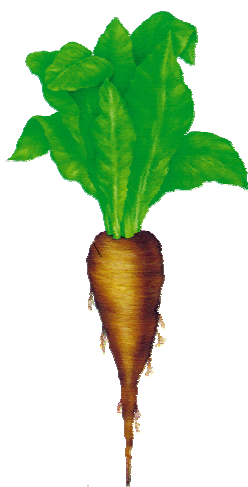


Figure 1: The chicory plant, with the root containing about 17% of inulin.

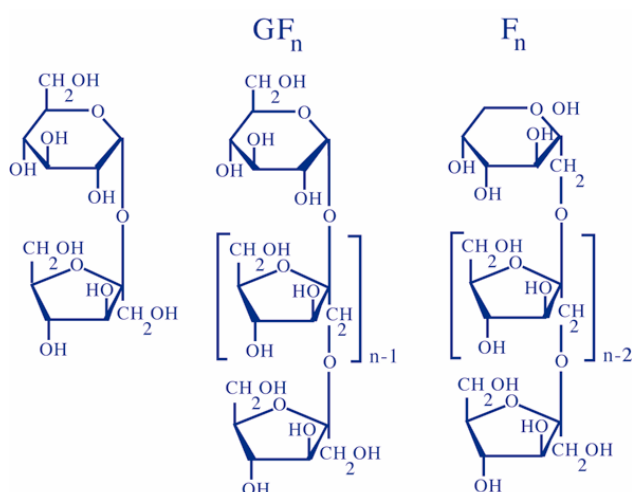


Figure 2: GF_n -type compounds and F_n -type compounds, as compared to normal sugar. Inulin exists mainly from GF_n -type compounds, with n ranging from 2 to 60+. Oligofructose from chicory is a mixture of GF_n - and F_n -type compounds, with n ranging from 2 to 9. Oligofructose from sugar exists mainly from GF_n -type compounds, with n ranging from 2 to 4.

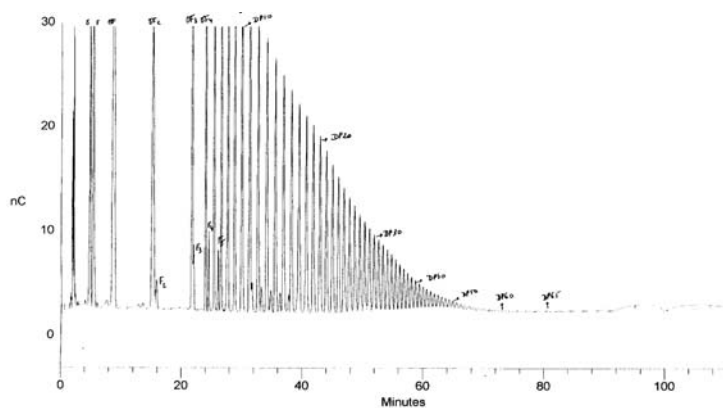


Figure 3.a: The composition of native inulin, as present in the chicory root and in standard inulin

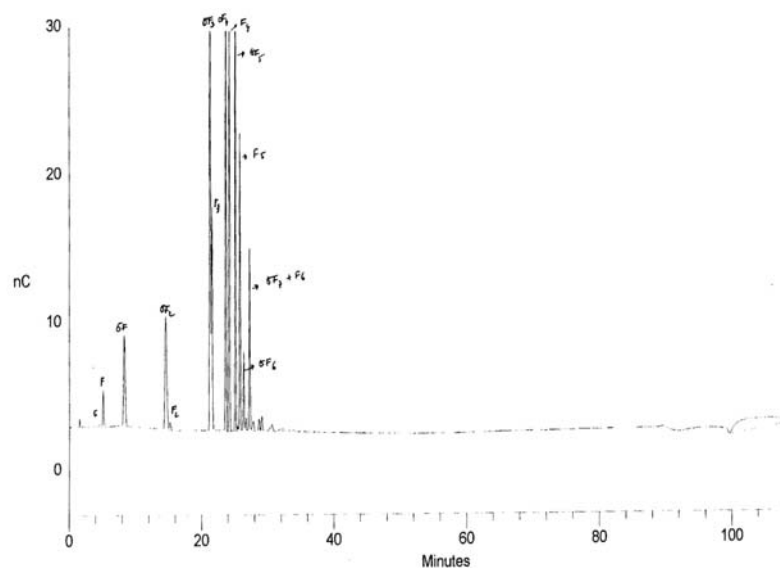


Figure 3.b: The composition of oligofructose (FOS) from inulin.

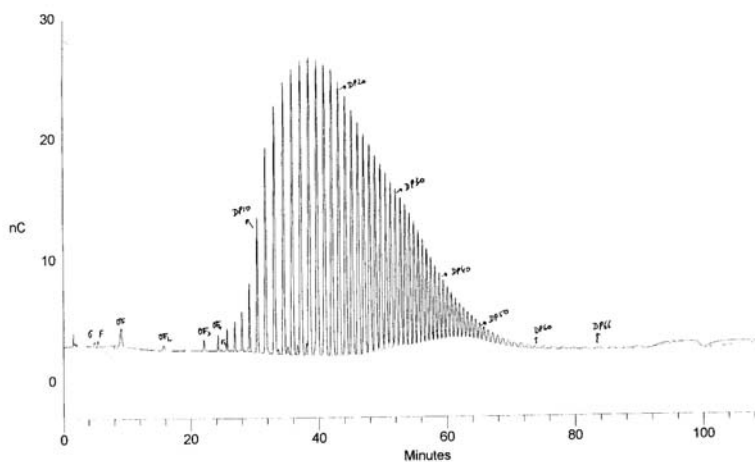


Figure 3.c: The composition of long-chain inulin.

Annex 7

**Statements from the authorities in Australia and New Zealand that confirm
the food status of inulin and oligofructose (FOS)**

Annex 7.1

**Letter of 1993 from the Australian National Food Authority
confirming the food status of inulin**



**National
Food
Authority**

Macquarie House
55 Blackall Street
Barton ACT 2600

PO Box 7186
Canberra MC ACT 2610

Ph: 06 271 2222
Fax: 06 271 2278

93/03889

Ms Jane A. Barnes
Foodsense
GPO BOX 51
NEUTRAL BAY NSW 2089

Dear Ms Barnes

Re: INULIN

I refer to the above matter. From the detailed information provided in your correspondence, it is considered that no amendment to the Code is required to regulate inulin as a food for the purposes of the Australian Food Standards Code.

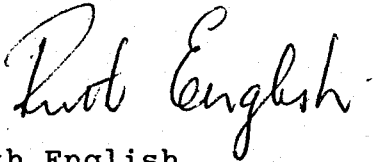
Inulin is one of those foods for which a standard has not been prescribed by the Code. It may be used in food manufacture in circumstances where the Code permits standardised foods to contain "other foods", or in "miscellaneous foods" regulated by Standard S1.

Should you wish to extend the use of inulin in foods beyond that currently permitted by the Code, you will need to make application to the Authority to have the Code amended. No therapeutic claim nor any other claim prohibited under the provisions of the Code, could be made about its use.

It is noted and confirmed that in December 1992, the State and Territory regulatory authorities considered inulin to be a food and the provisions of the Food Standards Code would apply.

It is the responsibility of any manufacturer to ensure that foods containing inulin comply with general provisions in State and Territory food legislation requiring food to be fit for human consumption and not adulterated.

I would also like to take the opportunity to thank you for bringing this matter to our attention. If I can be of any further assistance in this matter, please contact me on telephone (06) 271 2243.

A handwritten signature in cursive script that reads "Ruth English".

Ruth English
Project Manager
March 1993

cc State and Territory regulatory authorities

Annex 7.2

**Letter of 1993 from the Australian National Food Authority
confirming the food status of oligofructose**



**National
Food
Authority**

Jane A Barnes
Foodsense
GPO Box 51
Neutral Bay NSW 2089

Macquarie House
55 Blackall Street
Barton ACT 2600
PO Box 7186
Canberra MC ACT 2610
Ph: 06 271 2222
Fax: 06 271 2278

Dear Ms Barnes

RAFTILOSE

I refer to your letter of 13 August 1993 requesting confirmation of your opinion of the treatment of Raftilose.

When consulted about this product, State and Territory regulatory authorities agreed that raftilose is considered to be a food and hence its use is regulated by the provisions of the Food Standards Code (the Code). Raftilose is, however, one of those foods for which a standard has not been prescribed by the Code. Therefore, it may only be used in food manufacture in circumstances where the Code permits standardised foods to contain "other foods", or in "miscellaneous foods" regulated by Standard S1.

Should you wish to extend the use of raftilose in foods beyond that currently permitted by the Code, you will need to make application to the Authority to have the Code amended. No therapeutic claim nor any other claim prohibited under the provisions of the Code, can be made about its use. Furthermore, it is the responsibility of any manufacturer to ensure that foods containing raftilose comply with general provisions in State and Territory food legislation requiring food to be fit for human consumption and not adulterated.

Thank you for bringing this matter to the Authority's attention. If you have any further queries please contact Fiona Jolly on (06) 271 2251.

Yours sincerely

Fiona Jolly
Legal Section
4 November 1993

Annex 7.3

**Letter of 1994 from the New Zealand Ministry of Health
confirming the food status of inulin**

31 August, 1994

Ref. No _____

PH35-01

Jane Barnes
Consultant
Foodsense
GPO Box 51
Neutral Bay NSW 2089
AUSTRALIA

Dear Ms Barnes

Thank you for your letter of 25 May about Inulin. I apologise for the delay in responding to you.

I have examined the information that you provided and consider that under the New Zealand Food Regulations 1984 inulin would be classed as a foodstuff rather than a food additive. No amendment to the Food Regulations is required to regulate the use of inulin - it may be added to standardised foods wherever the Food Regulations specifically permit the addition of foodstuffs.

So for example, subclause 2(c) of regulation 121 for Ice cream provides for the addition of "other foodstuffs". Inulin could therefore be legitimately added to ice cream, so long as the other requirements of regulation 121 were still being complied with.

Conversely, regulation 119 for Yoghurt contains no provision for the addition of foodstuffs so inulin would not be permitted to be added to yoghurt. In such situations, where you may wish to extend the use of inulin in foods beyond those presently permitted by the Food Regulations, it would be necessary to make an application to the Food Standards Committee to consider amending the Food Regulations accordingly. The Food Standards Committee can be contacted as follows:

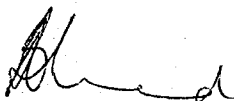
The Secretary
Food Standards Committee
PO Box 5013
WELLINGTON

I would also like to draw your attention to the use of therapeutic claims on foods. Therapeutic claims are regulated by the Medicines Act 1981. Only medicines and related products under the Medicines Act 1981 may make therapeutics claims.

Also, the Food Regulations regulation 4(8) prohibits the use of the word "health", or any variation of that word, when used as part of or in association with the name of the food.

I trust that I have clarified the status of inulin under the New Zealand Food Regulations 1984. Please contact me again if I can be of any further assistance on this matter.

Yours sincerely

A handwritten signature in dark ink, appearing to read 'Nicola Kenward', with a stylized, cursive script.

Nicola Kenward
Advisor (Food Technology)
for Manager
Food Administration

Annex 7.4

**Excerpt from the Australian Food Code of 1995,
Inulin included in the Standard G5 for Table Spreads**

G5 **TABLE SPREADS****Interpretation****1. In this Standard:**

'milk fat' means milk fat in the form of:

- (a) cream or butter; or
- (b) the clarified fatty portion of milk, cream or butter; or
- (c) the fractionated fatty portion of milk, cream or butter;

'table spread' means a mixture, in the form of a spreadable emulsion, of water and one or more of the following:

- (a) edible fat;
- (b) edible oil;
- (c) milk fat.

Compositional requirements**2. (1) Table spread must contain:**

- (a) vitamin A in proportion equivalent to not less than 8.5 mg/kg of retinol activity; and
- (b) vitamin D in proportion equivalent to not less than 55 µg/kg of cholecalciferol.

(2)⁽¹⁹⁾ Table spread must not contain more than:

- (a) in the case of table spread containing less than 800 g/kg total fat and oil - 2 g/kg of sorbic acid;
- (b) 40 g/kg of salt or potassium chloride or a mixture of them;
- (c) 10 g/kg of polyglycerol esters of fatty acids.

(3)^[27] Any one or more of the following may be added to table spread:

- (a) milk protein sources;
- (b) vegetable protein sources;
- (c) antioxidants in accordance with Standard A7;
- (d) modifying agents specified in Group I, II, III, IV or VI of Table 1 in Standard A10;
- (e) colouring substances specified in paragraph A5 (2)(a);
- (f) flavourings;
- (g) starter culture;
- (h) herbs and spices and extracts of herbs and spices;
- (i) gelatine;
- (j) vitamins A and D, in accordance with Standard A9;
- (k) sugars;
- (l) substances as specified in subclause (2);
- (m) inulin;
- (n) starch.

Use of 'reduced fat' and 'low fat'.

3. (1) Where the total fat and oil in a table spread is greater than 300 g/kg and not more than 600 g/kg the appropriate designation of the table spread and any description of the table spread in any advertisement must include the words: 'REDUCED FAT'.
- (2) Where the total fat and oil in a table spread is not greater than 300 g/kg the appropriate designation of the table spread and any description of the table spread in any advertisement must include the words: 'LOW FAT'.

Restrictions on appropriate designations of table spread

4. (1) 'Table spread' is not a prescribed name.
- (2) Notwithstanding Standards G2 and H6, the word 'butter' or 'margarine' if used in combination with the word 'spread' may:
- (a) where appropriate; and
 - (b) subject to this clause;
- be used as part of the appropriate designation and description of a table spread.
- (3) The word 'butter' must not be used as part of the appropriate designation or description of a table spread unless the total fat and oil content is comprised wholly of milk fat.

Annex 7.5

ANZFA, 2001

**FULL ASSESSMENT REPORT
AND REGULATORY IMPACT ASSESSMENT**

A277 - INULIN AND FRUCTOOLIGOSACCHARIDES

AS DIETARY FIBRE

FULL ASSESSMENT REPORT
AND REGULATORY IMPACT ASSESSMENT

A277 - INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

EXECUTIVE SUMMARY

An Application was submitted in July 1995 by Foodsense Pty Ltd on behalf of Orafit Belgium Ltd to the then National Food Authority seeking the following changes to the Australian Food Standards Code to:

- permit the declaration of inulin and fructooligosaccharides (FOS) as dietary fibre on food labels;
- adopt officially the submitted analytical method for the determination of inulin and FOS;
- amend the calculation of carbohydrate by difference by including dietary fibre in the range of macronutrients deducted from 100; and
- adopt energy factors for soluble and insoluble dietary fibre (later withdrawn).

The Full Assessment of this Application was conducted in the light of the recommendations from the Joint FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition* and concludes that the present situation of relying solely on a prescribed method of analysis as the means of defining dietary fibre is unsatisfactory. This Assessment has also drawn on the results of ANZFA's interactive website opinion survey conducted between January and March 2000, and the advice of the Expert Working Group on a generic definition for dietary fibre.

The Authority proposes the following definition of dietary fibre:

Dietary fibre is that fraction of the edible part of plants or their extracts, or analogous carbohydrates, that are resistant to digestion and absorption in the human small intestine, usually with complete or partial fermentation in the large intestine. The term includes polysaccharides, oligosaccharides (DP>2) and lignins. Dietary fibre promotes one or more of these beneficial physiological effects: laxation, reduction in blood cholesterol and/or modulation of blood glucose.

The definition of dietary fibre has been considered in relation to these aspects:

1. Relation to health — as physiological effect rather than reduction in disease risk;
2. Physiological effects — resistant to small intestinal digestion and absorption, and usually large intestinal fermentation laxation, reduction in blood cholesterol or modulation of blood glucose;
3. Dietary sources — mainly from plant sources, but not excluding microbiological, fungal or animal;
4. Macro components — naturally occurring, extracts or synthetic analogues;

Annex 7.6

Letter of 2002 from FSANZ regarding Application A277

Ms Jane Barnes
Foodsense
75 Parraween Street
Cremorne NSW 2090

Dear Ms Barnes

Re: Application A277 - Inulin and Fructooligosaccharides as Dietary Fibre

Please note that the Authority completed its assessment of the above application and made recommendations to the Ministerial Council which were subsequently agreed to. The amendments arising from this application are included in Amendment number 55 of the *Australia New Zealand Food Standards Code*, which was published on Thursday 30th August 2001. The Code is published on the Authority's website at www.foodstandards.gov.au

Amendment 55 varied clauses 1, 5(5) and 18 of Standard 1.2.8 resulting in permission for the ingredients inulin and fructooligosaccharide to be named as dietary fibre in food in Australia and New Zealand and thus labelled as such in manufactured food:

The relevant changes to the *Australia New Zealand Food Standards Code* were:

1 Definition of fibre:

dietary fibre [55] means that fraction of the edible part of plants or their extracts, or synthetic analogues that -

(a) are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and

(b) promote one or more of the following beneficial physiological effects;

- (i) laxation;
- (ii) reduction in blood cholesterol; and
- (iii) modulation of blood glucose;

and includes polysaccharides, oligosaccharides (degree of polymerisation > 2) and lignins;

2 Methods of analysis:

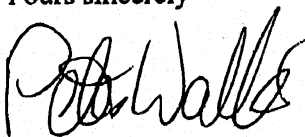
- (1) Subject to (2) the methods set out in the Table to the subclause are the prescribed methods of analysis for the determination of total dietary fibre and any specifically named fibre content of food for the purposes of nutrition labelling in this standard.

Table to subclause 18 (1)

| Column 1 | Column 2 |
|----------------------------------|---|
| Food Component | Method of analysis |
| Total dietary fibre | Section 985.29 of AOAC 17th edition (2000) or Section 991.43 of AOAC 17th edition (2000) |
| Inulin | Section 997.08 of AOAC 17th edition (2000) |
| Inulin and fructooligosaccharide | Section 999.03 of AOAC 17th edition (2000) |

I hope this information is of assistance.

Yours sincerely



Peter Wallner
Standards Liaison Officer
Food Standards Australia New Zealand

6 September 2002

Annex 8

**Media release on 13 June2007 of the
New South Wales Food Authority (NSWFA)**

Wednesday 13 June 2007

**FOOD AUTHORITY INVESTIGATES INFANT FORMULA
FOOD STANDARDS BREACH**

The food company Nutricia has been warned by food authorities in Australia and New Zealand that they may have breached the Australia New Zealand Food Standards Code by placing infant formulas on the market before receiving necessary approvals.

Nutricia has been informed that they should have sought express permission before adding any unapproved nutritive substance to infant formulas.

“There are obviously different standards for products for adults and products for infants – the rules are there for a reason – to protect the most vulnerable members of our society – and all companies must abide by the same rules,” NSW Food Authority Chief Scientist, Dr Lisa Szabo said.

“I am pleased to advise that NSW Health has said there is no cause for concern if infants are using the formulas but any breach of the approval process must be fully investigated.

“Nutritive substances are not permitted in infant formula under the current FSC. Therefore, the NSW Food Authority has requested the company to withdraw the product from the market and is also seeking legal advice.”

The products, Nutricia Karicare Gold Plus Infant Formula and Karicare Gold Plus Follow-On Formula, contain fructo-oligosaccharides (FOS) carbohydrates that are claimed to aid in digestion and occur naturally in a range of plants including wheat, bananas, onions and leeks and are also synthetically produced.

Dr Szabo, said that the Authority was not aware of any evidence that the products were unsafe.

“Similar products have been sold legally throughout Europe since 2000 with no known health issues among babies or infants,” Dr Szabo said.

The products have been on sale in Australia since January 2007 and NSW Health says they are not aware of any reports of problems.

Dr Szabo said, “However, all food manufacturers should be aware of the regulations and the need to strictly comply with them.”

“The requirement under the Food Standards Code to obtain express approval before adding any nutritive substance to food has been put in place for very good reasons. The system we have in place in Australia has proven to be a solid one that helps to keep our food safe.”

“We have reinforced this in our communications with Nutricia and informed them that we have the right to seize products as a result of non-compliance. We are also seeking further legal advice while we attempt to resolve this complex issue.”

If parents are concerned, they should consult their GP, Pharmacist, or early childhood health centre.

Anyone with questions can call the NSW Food Authority's Contact Centre on 1300 552 406.

MEDIA CONTACT – Michelle Parker 0412 044 471