

**30 May 2001**  
**15/01**

## **INQUIRY REPORT**

### **APPLICATION A277**

### **INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE**

An Application was submitted by Foodsense Pty Ltd, on behalf of Orafti Belgium Ltd to the then National Food Authority in July 1995 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- adopt energy factors for soluble and insoluble dietary fibre (later withdrawn).

Following a considerable ‘stop clock’ period<sup>4</sup>, receipt of reports from two consultants, an opinion survey, consideration by an Expert Working Group and public consultation on the Full Assessment report of A277, the following definition of dietary fibre for regulatory purposes is recommended:

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*Dietary fibre is that fraction of the edible part of plants or their extracts, or synthetic analogues, 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 (degree of polymerisation (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.*

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Suitable analytical methods for inulin, and inulin and FOS combined, have been accepted and thus these components have been accorded dietary fibre status. Recognition of polydextrose as dietary fibre was sought by a submitter at Full Assessment, and at Inquiry in accordance with the definition of dietary fibre proposed at Full Assessment, however that request could not be included in the recommended variation because it was not the subject of the application.

Nutrition labelling requirements have been modified from specific reference to fructans (as the subject under consideration until Full Assessment) to generic provision for approved dietary fibre fractions that are the subject of nutrition claims to trigger the concomitant declaration of dietary fibre in the Nutrition Information Panel.

The applicant's original application for dietary fibre to be deducted from 100 in the calculation of carbohydrate by difference was dealt with in P167 – Nutrition Labelling, which was completed in 2000.

## INTRODUCTION

### Previous Authority consideration

ANZFA considered the Full Assessment Report in November 2000 and advertised the report for public comment on 29 November 2000.

#### **Executive Summary from the Full Assessment Report, November 2000**

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 synthetic analogues, 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 — from plant sources, but not microbiological, fungal or animal;
4. Macro components — naturally occurring, extracts or synthetic analogues;
5. Chemical constituents — including non-starch polysaccharides, resistant oligosaccharides, lignin plus associated plant substances; and
6. Suitable analytical methods — AOAC 985.29; 991.43 and 997.08.

Under the proposed definition, inulin and FOS would qualify as dietary fibre for food labelling purposes because they:

1. are plant extracts, comprised of poly- and oligo-saccharides;
2. are not digested by the enzymes of the human small intestine;
3. are completely fermented in the large intestine;
4. mildly increase stool mass, and can ease constipation; and
5. can be reliably determined by an AOAC method of analysis.

Evidence for physiological effects on glucose and lipid metabolism is variable, but there is promising evidence for a stimulatory effect of calcium absorption along the whole intestine.

The decision to permit declaration of fructans as dietary fibre will require the following labelling requirements to ensure consumers are informed about the relation of fructans to dietary fibre. When fructans are either the subject of a nutrition claim (including a nutrient content claim) or referred to as dietary fibre in a nutrition claim, entries for both dietary fibre and fructans should be shown in the Nutrition Information Panel (NIP), with fructans indented under dietary fibre. Fructan content should be determined according to the method of analysis submitted in the original Application and adopted as first action (#997.08) by AOAC International.

This assessment concurs with the conclusions of Review P177 – Derivation of Energy Factors, that dietary fibre should be excluded from the result of carbohydrate calculated by difference for the purposes of calculation of energy content, and for declaration of carbohydrate as a claim and in the Nutrition Information Panel.

Submissions received in 1996 generally supported the Application, although reservations were held about the suitability of the submitted method for regulatory purposes because it had not, at that time, undergone collaborative testing.

The regulatory impact analysis concluded that the Authority's proposals would benefit the community as well as industry, at very little cost to industry, providing there was general support for the Authority's proposals by the nutrition and health communities.

WTO notification as a Technical Barrier to Trade was considered necessary as the proposals expand the definition of dietary fibre and the range of components that can be declared as dietary fibre.

It is proposed that the date of effect of the draft variation to both the Australian *Food Standards Code* and the joint *Australia New Zealand Food Standards Code* be on gazettal.

## **SUMMARY OF NEW SUBMISSIONS RECEIVED AT INQUIRY**

Nineteen submissions were received from three jurisdictions, several manufacturers and some health research and professional groups. Submissions were generally supportive of ANZFA's proposed definition of dietary fibre as well as recognition of inulin and FOS as dietary fibre. Several industry submissions were opposed to the declaration of fructans (interpreted to mean inulin and FOS) in the Nutrition Information Panel in the absence of a nutrition claim. Some submissions queried the suitability of the AOAC 999.03 method, which measures only the inulin fraction of fructans.

### **Other relevant factors**

Following the adoption of Volume 2 of the *Food Standards Code* (previously known as the *Australia New Zealand Food Standards Code*), ANZFA now considers the need for drafting in Volume 1 (formerly the *Food Standards Code*) on a case-by-case basis. Comments from some submissions addressed perceived inconsistencies between the two sets of drafting, particularly in relation to calculation of carbohydrate by difference and the text prescribing analytical methods. ANZFA proposes to cease consideration of drafting for Volume 1 for this matter and to make recommendation to the Ministerial Council on amendments to Volume 2 only.

## ASSESSMENT OF ISSUES RAISED IN PUBLIC SUBMISSIONS AT INQUIRY

### 1 General Definition of Dietary Fibre

Most submissions that made reference to this issue were in support of the proposed definition; indeed the applicant suggested it would make a mockery of the consultation process if such a definition were not adopted.

Penford Australia suggested there was no indication that the listed physiological effects were achievable from materials with very high levels of low Degrees of Polymerisation (DP). One way to address this concern was to raise the lower limit to an average DP of 10, although any arbitrary cut-off (including that proposed for  $DP \geq 2$ ) was also a problem for compliance since the proposed analytical methods did not discriminate on the basis of DP.

Nestle requested that DP be spelled out. National Foods sought clarification on the term *analogous carbohydrates* and suggested *analogous substances* or similar as a more suitable term.

#### *Range of physiological effects*

Several submissions suggested that, by limiting the definition to one or more of three listed physiological effects, fibres with other known effects such as favourable short chain fatty acid profiles or newly determined effects might be excluded. DAA and Penfords suggested that the three currently listed effects should be given as examples of beneficial effects through the use of the term 'such as'.

#### *Criteria for determination of physiological effect*

Queensland Health suggested that demonstration of specific physiological action or benefit under defined conditions and appropriate control needs to be attained. National Foods sought clarification on whether the beneficial effects must be evaluated for the fibre within a food matrix, or for the fibre alone; also that the term 'promote' was unclear as to the extent required.

### Assessment

The nexus between definition and analytical method of dietary fibre has never been a perfect fit. ANZFA recognises that these two elements are still not a perfect fit but that by defining dietary fibre in regulation, more precise methods will be developed in future. Enforcement action would proceed on the basis of non-compliance with prescribed methods. In response to Penford Australia's concern about the ability of low DP components to exert physiological effects, reference is made to the scientific paper given at Appendix 3 of Attachment 3 of the Full Assessment report which refers to a 1.5-2 gram faecal bulking effect per gram of non-digestible oligosaccharide ( $DP \leq 10$ ) ingested and evidence of normalisation of stool frequency of constipated individuals.

The DP is given in brackets to explain the term 'oligosaccharides'. It is recognised that the prescribed AOAC method 997.08 does not discriminate on the basis of degree of polymerisation (other than single fructose units), and thus the potential exists for the amount of dietary fibre that could be declared for some foods to be overestimated, depending on other

concurrent sources of fibre in the food. Given that inulin and FOS contain a range of DPs, the amount of overestimation due to counting DP= 2 in general is likely to be small.

*Analogous carbohydrates* are those carbohydrates that are not parts of plants or their extracts but which nevertheless are resistant to digestion and absorption in the human small intestine, usually with complete or partial fermentation in the large intestine.

The term could refer to those carbohydrates derived naturally from microbiological, fungal or animal sources, or synthesised to simulate carbohydrates from plants or these other sources. It is reasonable therefore to interpret carbohydrates as pure or mixtures of carbohydrate-predominant compounds. National Foods' suggested term *analogous substances* accounts for compounds other than carbohydrates such as proteins or fats. The Expert Working Group believed that proteins and fats resistant to digestion did not constitute dietary fibre.

ANZFA accepts Nestlé's suggestion that DP (degree of polymerisation) should be spelled out in the Standard.

#### *Range of physiological effects*

The three physiological effects were deliberately selected because they were the three most demonstrated and understood effects. The current description does not preclude other effects from being attributed to dietary fibre in future; however, ANZFA does not believe there would be sufficient consensus on a carbohydrate being considered a dietary fibre if *none* of the three listed effects could be demonstrated from human studies.

#### *Criteria for determination of physiological effect*

ANZFA's recognition of dietary fibre components centres on the ultimate application of eligibility criteria to each of the physiological effects to determine dietary fibre status. The Full Assessment report stated that, in the case of inulin and FOS, [they] increase the bacterial biomass that leads to a mild increase in faecal output comparable to soluble dietary fibre and resistant starch (1-2 g faecal weight increase/g FOS ingested at intakes 15-40g/day) and potential normalisation of stool frequency at doses of 10-15 g/day. Laxation was the only one of the three effects defined at that stage ( $\geq 1$ g faecal wet weight increase/gram ingested in either food matrix or supplementary form) and it is proposed that other criteria will be developed for the two other effects as the need arises. These outcome criteria will be added to ANZFA's user guides and guidance for prospective applicants as they are developed.

## **2 Inulin and Fructooligosaccharides as Dietary Fibre**

Most submissions that made reference to this issue were in support. The Victorian Food Safety Council however, was opposed and referred to the lack of evidence for these components to support health and prevent disease.

*Would increased use of these ingredients lead to need for laxative warning/advisory statement?*

Penford Australia suggested that the tolerance to low DP carbohydrates was likely to be substantially less than the amount of 20-30g/day suggested in the Full Assessment report which stated "it appears that up to 20-30g/day of inulin and FOS can be tolerated by most

adults (Briet et al, 1995)”. Queensland Health also expressed concern at the potential flow-on effects from approval of this Application, in which the community could be exposed to greater amounts of these components and which could lead to a need for a laxative warning statement. The Victorian Food Safety Council referred to isolated reports of anaphylaxis and allergic reaction to inulin and FOS.

### Assessment

The Expert Working Group considered appropriate end points for determination of dietary fibre status and concluded that endpoints based on physiological effects rather than health maintenance or reduction in disease risk was the only practical approach if ANZFA were prepared to consider novel sources of non-digestible food fractions as dietary fibre.

The issue of intestinal tolerance or otherwise of low DP fructooligosaccharides is tangential to the definition of dietary fibre. If the amounts of inulin and FOS increase in the diet as a result of this regulatory change, then mechanisms are available through Standard 1.2.3 to impose labelling that warns consumers of adverse gastrointestinal consequences.

The question of allergy and anaphylaxis was referred to the applicant for response. The sponsoring company, Orafit had issued a general circular addressing the issue and this is given at Appendix 1.

### **3 Polydextrose**

Danisco Cultor, manufacturers of polydextrose submitted that polydextrose conformed to the definition for dietary fibre proposed at Full Assessment on the basis that polydextrose:

- is a carbohydrate with mean DP of 12 that is resistant to digestion and absorption in the human small intestine and undergoes partial fermentation in the large intestine; and
- promotes the beneficial physiological effects of laxation and modulation of blood glucose as well as other effects commonly associated with dietary fibre.

Several published papers of studies conducted in animals and humans were supplied in support of Danisco Cultor’s claims as well as details of a method of analysis recently adopted by AOAC and published in revisions to the 17<sup>th</sup> edition (2000) of *Official Methods of Analysis*.

### Assessment

Recognition of polydextrose as dietary fibre was sought by a submitter at Full Assessment and Inquiry, in accordance with the definition of dietary fibre proposed at Full Assessment, however it could not be included in the recommended variation because it was not the subject of the application. The ANZFA Act requires that variations to a standard be made through a proposal or an application, and that the Act mandates consultation processes for applications and proposals. This allows for open and transparent notification of a proposed variation and affords the opportunity for people to make submissions on the proposal or variation.

## **LABELLING**

### **4 Calculation of Carbohydrate by Difference**

Several submissions queried why two alternate formulas were given for the calculation of carbohydrate by difference in Volume 1 of the Food Standards Code especially, as AFGC pointed out, if dietary fibre is zero then the first of the alternate formulas is redundant (*note no further work is proposed on drafting for Volume 1*).

BRI Australia commended the continuance of ‘difference carbohydrate’ for labelling purposes stating that it was the only practical measurement until such time as sufficient and suitably validated methods for analysis of all possible carbohydrate compounds are developed to enable summing of carbohydrate components. BRI suggested however that the mandatory deduction of dietary fibre from 100 may cause unnecessary hardship for producers of low fibre foods, and that this could be alleviated by exempting foods with dietary fibre contents of 1% or less from the need to quantify dietary fibre for calculation of carbohydrate by difference.

#### Assessment

BRI’s comment possibly assumes that all nutrient values required for calculation of carbohydrate by difference need be consistently derived, i.e. as all analyses or as all generally available values. This is a misconception; there is no requirement for dietary fibre to be analysed for calculation of carbohydrate by difference. Under the BRI suggestion, manufacturers of foods with low dietary fibre contents would need to ascribe a value to the fibre content to determine whether their food would exceed or not the 1% dietary fibre threshold. Because this same value could be ascribed to dietary fibre in the calculation of carbohydrate by difference, there is no need to amend the originally proposed approach.

### **5 Requirement for Fructans (meaning inulin and FOS) to be Declared in the Nutrition Information Panel (NIP)**

All submissions agreed that fructans should be declared in the NIP when they are the subject of a nutrition claim; but industry submissions unanimously disagreed with the proposed requirement for fructans to be declared in the NIP when only a dietary fibre claim is made. A consequence of the drafting proposed at Full Assessment was that any mention of dietary fibre in a label as a claim or just listed in the NIP would necessarily require the quantification of fructan content, whether in the form of added fructans or intrinsic to other types of dietary fibre. Queensland Health commented that very few Australian laboratories are set up to conduct fructan analysis.

Nestle suggested that in anticipation of a more generic approach, the drafting need not refer specifically to fructans; instead Standard 1.2.8(5)(5) could be expanded to include reference to ‘type of fibre’. Queensland Health saw merit in the separate declaration of fructans under dietary fibre in the NIP when a claim made reference to ‘fibre’/‘dietary fibre’ but only for significant sources of fructans.

## Assessment

Provisions already exist to require the quantification of fructans in the NIP when they are the subject of a claim. The consequence of the drafting proposed at Full Assessment to necessarily require the quantification of fructan content when it was intrinsic to other types of dietary fibre was unintentional.

The intent of Standard 1.2.8(5)(5) is to trigger the concomitant declaration of dietary fibre in the NIP when certain related claims are made. However, because the drafting did not reflect the intent of the subclause and was causing confusion, ANZFA independently proposed to clarify the wording by deleting ‘type of carbohydrate’ from the first part of subclause 5.

This Inquiry report can be used for this purpose. Also, since the definition of dietary fibre includes components other than carbohydrates, eg lignin, Nestlé’s suggestion is proposed to be adopted, that is, to include another paragraph referring to ‘type of fibre’. Making this type of change in Standard 1.2.8(5)(5) provides generically for dietary fibre fractions to trigger the declaration of dietary fibre in the NIP, and negates the need for subclause 5(9) proposed at Full Assessment.

## **6 Use of the Term ‘Fructan’ in Nutrition Labelling**

All industry submissions queried the apparent requirement to use the term fructans in the NIP when a claim could refer to other terms such as inulin or fructooligosaccharide. Many of these submissions pointed out that consumers were not familiar with the term fructans. AFGC pointed to the inconsistency between use of terms in the ingredient list and ‘fructan’ in the NIP. The applicant also pointed out that the term fructans is a general term for any carbohydrates in which one or more fructosyl-fructose links constitutes the majority of osidic bonds. Fructans not only include  $\beta(2-1)$  bonds but also levans, found in wheat and grasses, which have  $\beta(1-6)$  bonds.

### *Education*

Several submissions observed that consumers had a general understanding of the concept of dietary fibre, but that if fructans were required to be specified on the label, then consumer education in relation to the new term would be required. DAA believed that ANZFA should be responsible for the development of some educational materials.

## Assessment

By not proceeding with subclause 5(9) but instead making generic reference to any specifically named fibre in subclause 5(5) eliminates the issue about use of the term fructans in the NIP. Manufacturers are at liberty to refer to specific types of fibre using appropriate terminology, and it behoves them to provide appropriate information on what may be unfamiliar terms to consumers.

## **7 Methods of Analysis**

### *Prescriptive approach to types of fibre*

The Victorian Food Safety Council, Nestle and some other submissions drew attention to the need for other possible types of fibre such as resistant starch and vegetable gums to be considered in the future, with the consequent expansion of prescription of analytical methods. National Foods questioned the need for analytical methods to be prescribed at all.

### *Specific methods*

Most submissions that referred to methods of analysis supported the inclusion of alternate dietary fibre method AOAC 991.43 and the specific method for inulin and FOS - AOAC 997.08. BRI suggested that the rationale given for AOAC 991.43 was out of date and that the advantages now relate to efficiency and reduced usage of alcohol.

The applicant pointed out that method AOAC 999.03 determines only the inulin fraction and cannot be used for the quantitative analysis of fructooligosaccharides. AFGC compared the form of drafting for Volume 1 - substituted paragraph of Standard A1(13)(j); and Volume 2 - Standard 1.2.8(18) and preferred the form for Volume 1 as it was much clearer. Attention was also drawn to the need to potentially revise Standard 1.2.8(5)(8) and that the term 'fructan' was erroneously used in clause 18(3) of that Standard.

### Assessment

The reliance on methods of analysis to define dietary fibre is well established in regulations of other countries. It is inevitable that such reliance would lead to an increasing range of analytical methods as more components are accepted as dietary fibre. The way is open via applications to ANZFA for consideration to be given to more components being regarded as dietary fibre, providing they comply with the definition. In anticipation of future applications, Clause 18 has been redrafted in tabular form.

Information from the applicant states that the AOAC methods 997.08 and 999.03 respectively measure inulin and FOS combined, and inulin only. AOAC method 999.03 will be retained, as it may be appropriate for the analysis of some foods. Manufacturers should not be disadvantaged by not being able to use the simpler 999.03 if inulin only is added to a previously fibre-free food such as some dairy products. The terms inulin and fructooligosaccharide will replace the term fructan for reasons given above.

## **8 Links to COPONC**

National Foods pointed to the connection with the conditions for dietary fibre claims given in the Australian Code of Practice on Nutrient Claims (COPONC), especially that high fat foods should not bear dietary fibre claims. This will apply to foods like table spreads that can incorporate inulin as a fat replacer.

### Assessment

This is a good point and worthy of bearing in mind. The proposal (P234) reviewing criteria for nutrient claims is now in train and this point has been referred to that project team.

## **CHANGES TO FULL ASSESSMENT/RIS RESULTING FROM INQUIRY**

Several changes to the drafting at Full Assessment are proposed.

- 1 Cease consideration of drafting for Volume 1 of the Food Standards Code because Volume 1 is time limited and the outcome of this application is forward looking and provides only new permissions.
- 2 Spell out DP (degree of polymerisation) in the definition for dietary fibre given in Clause 1 to improve clarity.
- 3 Insert a new paragraph in Standard 1.2.8(5)(5) to refer to ‘any specifically named fibre’ and delete proposed subclause 5(9). This has the effect of linking a claim referring to a dietary fibre fraction with the mandatory declaration of dietary fibre in the Nutrition Information Panel. (Existing provisions already require the quantification of the dietary fibre fraction in the NIP when such a fraction is the subject of a nutrition claim.)
- 4 Reformat clause 18 into tabular form in anticipation of future components being regarded as dietary fibre. In doing so, delete reference to fructan and substitute inulin and fructooligosaccharide in relation to AOAC method 997.08 and inulin in relation to AOAC 999.03.

## **CONCLUSIONS**

Given the changes made to the assessment of this matter since Full Assessment, it is concluded that:

The proposed definition of dietary fibre is appropriate and that components that comply with that definition and have a method of analysis prescribed in Standard 1.2.8, in this case – inulin and fructooligosaccharide are regarded as dietary fibre for nutrition labelling and associated purposes. It is appropriate for dietary fibre fractions such as those mentioned above to trigger the concomitant quantification of dietary fibre in the Nutrition Information Panel.

### **Attachments:**

1. Proposed Variations
2. Statement of Reasons
3. Summary of Submissions

## **FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND**

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the *New Zealand Fair Trading Act 1986* and all food sold in Australia must comply with the *Australian Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the *Australian Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

## **FURTHER INFORMATION**

**Submissions:** No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia New Zealand Food Standards Council for consideration.

**Further information** on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

PO Box 7186  
Canberra Mail Centre ACT 2610  
AUSTRALIA  
Tel (02) 6271 2258  
Email: [slo@anzfa.gov.au](mailto:slo@anzfa.gov.au)

PO Box 10559  
The Terrace WELLINGTON 6036  
NEW ZEALAND  
Tel (04) 4739942  
Email: [anzfa.nz@anzfa.gov.au](mailto:anzfa.nz@anzfa.gov.au)

Requests for copies of the full Inquiry Report or other information papers should be addressed to the Authority's Information Officer at the above address, or Email [info@anzfa.gov.au](mailto:info@anzfa.gov.au)



To Whom It May Concern:

### **Regarding: Allergic Potential of Inulin and Oligofructose**

Recently, in a letter to the editor (therefore non- peer reviewed) Gay-Crosier et al (2000) reported one single male subject showing anaphylactic reactions to foods, which happened to also contain inulin and oligofructose. As far as Orafti can ascertain the reactions were specific but, however not life threatening to him.

This is the only case of allergic reaction to foods containing our ingredients that we have encountered or heard about. Because of the unexpected nature of this allergic reaction, we are concerned to understand it fully and we are studying all aspects of it in more detail.

Similar to starch, inulin and oligofructoses have been present in significant amounts in the daily diet of the whole population of the planet since homosapiens developed. Certainly it is now well documented that there are natural chemicals such as salicylates and amines, found in vegetables to which certain individuals have particular sensitivities to. Only very exceptional cases of allergic reactions to vegetables containing inulin have been reported before, and the possibility of it being the other chemicals has never been clearly tested. Consequently, our experts have concluded that the risk of allergic reactions to inulin seems exceedingly small (Internal report, 1999).

Thousands of tons of RAFTILINE® (inulin) and RAFTILOSE® (oligofructose) are used by the food industry every year. Inulin is used in several hundreds of consumer products worldwide, mainly for its beneficial health effects in the human metabolism (such as dietary fibre and prebiotic effects, stimulation of calcium uptake). Every year, millions of people consume them. In more than 10 year of this activity, we have never heard of any other case of allergic reaction to our ingredients.

Inulin is being used as a diagnostic agent for renal clearance tests since the early 1900's. Nobody has ever reported an allergic or other adverse reaction to such intravenous injections of inulin.

Consequently, compared to other allergenic food ingredients like peanuts, strawberry, sea fruit, wheat, milk, soy etc. our ingredients have an allergenic potential that could be considered negligible.

At the moment therefore, we are confident that our ingredients RAFTILINE® (inulin) and RAFTILOSE® (oligofructose) are safe for use as food ingredients and there is NO COUNTRY IN THE WORLD which requires any specific labelling or warning statement on label

**Since the publication of the Gay-Crosier letter almost a year ago, nobody has reported any comparable allergic reaction with other patients up to now.**

Tienen, March 30, 2001

Reference : Gay-Crosier F., Schreiber G. and Hauser D. (2000) "Anaphylaxis from Inulin in Vegetables and Processed Food" The New England Journal of Medicine, May 4, 2000, p. 1372.

Annex : Taylor S.L. (1999) "Assessment of the allergenicity of inulin" ORAFTI internal report.

VARIATIONS TO THE *FOOD STANDARDS CODE*

## APPLICATION A277

## INULIN AND FRUCTOOLIGOSACCHARIDE AS DIETARY FIBRE

To commence: On gazettal

[1] *Standard 1.2.8 of Volume 2 of the Food Standards Code is varied by –*

[1.1] *inserting in clause 1, immediately following the definition of carbohydrate -*

**dietary fibre** 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;

[1.2] *deleting subclause 5(5), substituting -*

(5) The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with subclause (7), where a nutrition claim is made in respect of -

- (a) fibre; or
- (b) any specifically named fibre; or
- (c) sugars; or
- (d) any other type of carbohydrate.

<p><b>Editorial note:</b></p> <p>Absence of dietary fibre must be declared as zero (0).</p>
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[1.3] *deleting clause 18, substituting -*

**18 Methods of analysis to determine total dietary fibre and specifically named fibre content of food**

(1) Subject to subclause (2) the methods set out in the Table to this 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)**

<b>Column 1 Food Component</b>	<b>Column 2 Method of analysis</b>
Total dietary fibre	Section 985.29 of the A.O.A.C, 17th Edition (2000), or Section 991.43 of the A.O.A.C, 17th Edition (2000).
Inulin and fructooligosaccharide	Section 997.08 of the A.O.A.C, 17th Edition (2000)
Inulin	Section 999.03 of the A.O.A.C, 17th Edition (2000)

(2) The results obtained using the analytical methods outlined in column 2 must be summed together after ensuring that there is no double counting of any specifically named fibre.

## STATEMENT OF REASONS

### APPLICATION A277

#### INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

The Australia New Zealand Food Authority (ANZFA) had before it an application received in July 1995 from Foodsense Pty Ltd on behalf of Orafit Belgium Ltd to the then National Food Authority seeking the following changes to Volume 1 of the *Food Standards Code* (formerly the Australian *Food Standards Code*) to:

1. Permit the declaration of inulin and fructooligosaccharides (FOS) as dietary fibre on food labels;
2. Adopt officially the submitted analytical method for the determination of inulin and FOS;
3. Amend the calculation of carbohydrate by difference by including dietary fibre in the range of macronutrients deducted from 100; and
4. Adopt energy factors for soluble and insoluble dietary fibre (later withdrawn).

However, since then, Volume 2 of the *Food Standards Code* (formerly the *Australia New Zealand Food Standards Code*) has come into effect including the adoption of bullet point 3 above.

ANZFA recommended the adoption of the draft variation to Volume 2 only, as amended, for the following reasons:

- 1 A definitional framework for dietary fibre has been established in regulation in addition to prescribed analytical methods, to provide a benchmark for the assessment of components as dietary fibre and to guide future development of appropriate methods of analysis. The framework elements comprise origin, chemistry and physiological effects.
- 2 Internationally, there is increasing recognition of inulin and FOS as dietary fibre. Assessment of evidence of the dietary fibre performance of these components against the drafted definitional framework for dietary fibre resulted in their recognition as dietary fibre for nutrition labelling purposes.
- 3 Specific methods of analysis for inulin and FOS combined, and inulin have been prescribed to add to the existing methods, in order to prevent consumer deception, ensure fair trade as well as facilitate enforcement of the regulations.
- 4 Nutrition labelling requirements have been modified to ensure that when a type of dietary fibre is the subject of a nutrition claim, total dietary fibre is declared in the Nutrition Information Panel in addition to the type of dietary fibre.

The drafting was prepared after Full Assessment is amended for the following reasons:

- 1 Confine the draft recommendations to Volume 2 of the Food Standards Code because Volume 1 is now severely time limited, and the outcome of this application provides only new permissions.
- 2 Spell out DP (degree of polymerisation) in the definition for dietary fibre to improve clarity.
- 3 Expand the nutrition labelling requirements to cater for all (future) approved types of dietary fibre, in addition to fructans (inulin and FOS).
- 4 Delete the inadvertent requirement for the quantification of fructans in the Nutrition Information Panel when dietary fibre containing fructans is the subject of a nutrition claim.
- 5 Reformat Clause 18 into tabular form in anticipation of future components being regarded as dietary fibre. In doing so, delete reference to fructan, and substitute inulin and FOS in relation to AOAC method 997.08 and inulin in relation to AOAC 999.03.

## **REGULATION IMPACT**

ANZFA has undertaken a regulation impact analysis, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That analysis concluded, that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.

## **WORLD TRADE ORGANIZATION (WTO) NOTIFICATION**

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter was notified to the WTO because the proposals establish a definitional framework for dietary fibre and expand the range of components considered as dietary fibre, prescribe additional methods of analysis, and modify nutrition labelling requirements to ensure consumers are adequately informed.

## SUMMARY OF SUBMISSIONS

## A277 – INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

	Submitter	Submission
1	Queensland Health	Supports inulin and FOS as dietary fibre. Supports separate declaration of fructans in the NIP only when they constitute the majority of the declared dietary fibre. Recommends that consideration be given to developing an Information Circular on dietary fibre for consumers and health professionals. Supports the methods AOAC 991.43 for analysis of total dietary fibre (Volume 1), 997.08 but not 999.03 for analysis of inulin and FOS. Supports the amendment of the definition of carbohydrate by difference in Volume 1. Additional comments referred to a requirement to acknowledge in the report, the impact of newly prescribed methods on analytical laboratories. The potential increase in use of inulin and FOS in foods and the likely increase in consumption may warrant a statement, advising consumers of a potential laxative effect.
2	Victorian Food Safety Council, food standards sub-committee	Does not support the draft variation because: Debate continues whether inulin and FOS satisfy any of the 3 physiological effects listed in the definition Dietary fibre is defined analytically by CODEX according to methods that yield 'total dietary fibre' [INCORRECT, no method has ever been prescribed – Project Manager] Codex is still undecided as to whether a revised definition of fibre should be adopted which includes animal material and other chemically characterized substances. [INCORRECT, the Full Assessment report quoted the Codex definition, which includes animal sources – Project Manager]. The current approach could lead to a range of separate methods being prescribed, which is prescriptive The proposed methods do not meet performance criteria for regulatory methods i.e. practical, validated, and reliable. The generic definition means that consideration would need to be given other novel sources of fibre, even chewing gum! There are isolated reports of inulin causing anaphylaxis and allergic reactions.
3	New Zealand Ministry of Health	Supports inulin and FOS being declared as dietary fibre, the proposed analytical methods, the proposed labelling requirements, but recommends that the term 'analogous carbohydrates' in the generic definition, be defined.
4	Dietitians Association of Australia	Supports the redefinition of dietary fibre to include inulin and FOS. Does not support the alternative definitions of carbohydrate proposed for Volume 1, rather that only one definition apply, which deducts dietary fibre from 100. Believes that the 3 mentioned physiological effects are too limiting, and prefers these to be examples only. Sought clarification of <i>words of similar import</i> when linked to fructans.
5	CSIRO Health Sciences & Nutrition	Supports the proposed variations, particularly the generic definition of dietary fibre.
6	Australian Food and Grocery Council	Supports the definition of dietary fibre as proposed, recognition of inulin and FOS as dietary fibre, and the methods of analysis for dietary fibre and for fructans. Believes it not necessary for the fructan proportion of dietary fibre to be always identified when a dietary fibre claim is made. The term fructan should not be mandated as consumers won't be familiar with it, and will be inconsistent with terms used in the ingredient list. Supports the definition of carbohydrate for Volume 1. Suggested changes to the drafting to improve clarity.

	<b>Submitter</b>	<b>Submission</b>
7	Weston Technologies	Supports the definition of dietary fibre as proposed, and the methods of analysis for dietary fibre and 997.08. Believes it not necessary for the fructan proportion of dietary fibre to be always identified when a dietary fibre claim is made. The term fructan should not be mandated as consumers won't be familiar with it, and will be inconsistent with terms used in the ingredient list. Does not support the alternative definitions of carbohydrate proposed for Volume 1, rather that only one definition apply, which deducts dietary fibre from 100.
8	BRI Australia Limited	Disagrees with the FAO/WHO proposal regarding use of the term 'non-glycaemic carbohydrate' without a comprehensive consumer education program. Contends that the lack of available, validated methods must be solved before the sum of total carbohydrate components could replace carbohydrate by difference. Points out that difference carbohydrate remains one of the most precise and reproducible measurements on food labels. Congratulates ANZFA on accepting the challenge of finding a robust generic definition of dietary fibre, but suggests that dependence on only 3 physiological effects may prove to be a severe limitation. Suggests that foods with eg 1% dietary fibre or less should be exempt from quantifying dietary fibre in the calculation of carbohydrate by difference. Believes it not necessary for the fructan proportion of dietary fibre to be always identified when a dietary fibre claim is made. The term fructan should not be mandated as consumers won't be familiar with it.
9	Goodman Fielder	Supports the generic definition of dietary fibre and the recognition of inulin and FOS as dietary fibre. Appreciates that by recognition of inulin and FOS as dietary fibre reduces their energy content [from 17kJ/g to 8kJ/g]. Supports AOAC 997.08 but is sceptical about 999.03. Supports carbohydrates by difference. Believes it not necessary for the fructan proportion of dietary fibre to be always identified when a dietary fibre claim is made. The term fructan should not be mandated as consumers won't be familiar with it.
10	National Foods Limited	Disagrees with elements of the generic definition of dietary fibre: 'analogous carbohydrates' is too limiting and should be amended to 'analogous substances'; there are no performance criteria specified eg how much effect, and should evaluation be limited to performance within a specified food matrix, or for the fibre alone; how does this variation relate to the criteria for dietary fibre claims specified in the Code of Practice on Nutrient Claims; explain DP. Supports the recognition of inulin and FOS as dietary fibre. Appreciates that by such recognition the energy content of these constituents is reduced. Opposes prescribed methods of analysis. Seeks clarification on when to use the alternate definitions of carbohydrate by difference in Volume 1. Believes it not necessary for the fructan proportion of dietary fibre to be always identified when a dietary fibre claim is made. The term fructan should not be mandated as consumers won't be familiar with it, and will be inconsistent with terms used in the ingredient list.
11	Food Technology Association of Victoria	Accepts the proposed variations without further comment.

	<b>Submitter</b>	<b>Submission</b>
12	Nestle Australia Ltd	Supports the recognition of inulin and FOS as dietary fibre. Suggests that DP in the generic definition of dietary fibre should be spelled out. Believes it not necessary for the fructan proportion of dietary fibre to be always identified when a dietary fibre claim is made. The term fructan should not be mandated since its appearance only within a Nutrition Information Panel (NIP) may mislead consumers. Suggests that drafting for Volume 1 will need to explicitly require indentation of fructan under dietary fibre. Suggests that in Volume 2, clause 5(5) of Standard 1.2.8 would be a simple way to ensure that any type of fibre triggers declaration of dietary fibre in the NIP. Company experience suggests that consumers do not have a good understanding of what dietary fibre <i>is</i> , although they recognise particular foods, especially unrefined foods, as sources of dietary fibre.
13	Unilever Australasia	Fully supports the generic definition of dietary fibre and the proposed variation.
14	Penford Australia Limited	Disagrees with elements of the generic definition of dietary fibre, especially the recognition of components that have high levels of low DP oligosaccharides because of doubts about their ability to act as dietary fibre, and their laxative potential. Suggest raising the minimum DP to greater than 10. The method of analysis cannot differentiate by DP (other than for free fructose), hence DP=2 FOS would necessarily inflate any analytical result. Believes that the 3 mentioned physiological effects are too limiting, and prefers these to be examples only. If dietary fibre components are to be listed in NIPs or ingredient lists, then consumers need to be educated about the physiological relevance and importance of the dietary fibre material.
15	InforMed Systems Ltd	Supports the proposed variations, particularly the recognition of inulin and FOS as dietary fibre.
16	New Zealand Dairy Board	Seeks clarification on the scope of the proposed amendments to apply to other oligosaccharides, the rationale for limiting the physiological effects in the generic definition to only 3 [incorrect interpretation of the definition – PM], mandating use of the term fructan, and potential resulting consumer confusion.
17	Foodsense (Applicant)	Points out that AOAC 997.08 measures inulin and FOS, whereas 999.03 measures inulin only. Orafit has communicated these points to AOAC to incorporate into the appropriate procedures. Suggests that the requirement to declare fructans when only a dietary fibre claim is made is inconsistent with ANZFA’s objective of promoting consistency between domestic and international food standards; furthermore, such a requirement is discriminatory against fructans. The term fructan should not be mandated as consumers won’t be familiar with it, and will be inconsistent with terms used in the ingredient list. Also, strictly speaking, fructan is a general name for any carbohydrate in which one or more fructosyl-fructose links constitute the majority osidic bonds i.e. it includes $\beta(2-6)$ levans as well as $\beta(2-1)$ inulins. Applicant provided information on evidence of inulin and FOS causing allergic or anaphylactic reactions.
18	Danisco Cultor USA Inc	Supports the generic definition of dietary fibre. Seeks the inclusion of polydextrose as dietary fibre as it conforms to the proposed definition of dietary fibre. The submission contained several scientific papers in support of the request. Believes it is not necessary for the specific dietary fibre fraction to be always identified when a dietary fibre claim is made, given it would be listed in the ingredient list and included within the dietary fibre entry in the NIP. Seeks clarification on the rationale for providing an alternate calculation of carbohydrate by difference.