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 Orafti 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- adopt energy factors for soluble and insoluble dietary fibre (later withdrawn).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;

5. Chemical constituents — including non-starch polysaccharides, resistant oligosaccharides, lignin plus associated plant substances; and
6. Suitable analytical methods — AOAC 985.29 or 991.43; and 997.08 or 999.03.

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 a component of 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 (AOAC #997.08) or its simpler alternative (AOAC #999.03).

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 analytical 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 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.

BACKGROUND

In July 1995, the then National Food Authority received an Application from Foodsense on behalf of Orafti, Belgium to vary 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 statutory timeframe for the Application was frozen (clock stopped) in March 1996 to await the outcome of the results of collaborative trials by the Association of Official Analytical Chemists (AOAC) on the submitted analytical variation to the prescribed method. The Authority was notified that AOAC had approved the method as first action in June 1997 and therefore the statutory timeframe was resumed once the final version of the documents were received from the applicant in October 1997.

Because the Authority had limited expertise in 1) the physiological determinants of dietary fibre; and 2) dietary fibre analytical methodology, the Authority contracted respectively:

1) Dr David Topping and Dr Lynne Cobiac, CSIRO Division of Human Nutrition; and

2) Mr David Mugford, BRI Australia Limited (formerly Bread Research Institute of Australia, Limited)

to provide expert advice on these two matters. Their reports, completed in March and January 1998 respectively, are given at Appendixes 1 and 2 of Attachment 3.

Further discussions on the outcome of the Application were held with the applicant in April 1998 that resulted once more in a 'clock stop' until more information was made available. During the period April to December 1998, the project manager met with Orafti staff in the Netherlands in May 1998, and in September 1998, the project manager accompanied by the CSIRO consultant met with the applicant, Orafti staff, and Orafti's scientific adviser, Professor M Roberfroid in Adelaide. The statutory timeframe was resumed in December 1998 after the requested information had been received.

At ANZFA53, it was agreed that this Application should be considered in the light of the 1997 report and recommendations of the Joint FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition* (FAO/WHO, 1998). These recommendations are discussed in the body of the assessment report. The Board considered the Full Assessment report at ANZFA56 (April 1999), but was not inclined to accept the report's recommendation to recognize inulin and FOS as dietary fibre. Further work was requested which comprised: an interactive website opinion survey, and the formation of an Expert Working Group to develop a general definition of dietary fibre.

The results of the opinion survey are given at Appendix 5, Attachment 3, and the outcome of the Expert Working Group, the draft definition of dietary fibre and related matters, is given at Appendix 4 of the same Attachment.

ISSUE

The question of whether fructan carbohydrate such as inulin should be considered as dietary fibre is central to this Application. Fructans have been defined elsewhere as 'any compound where one or more fructosyl-fructose linkages constitute a majority of the linkages. That is, not restricted to molecules with a Degree of Polymerisation (DP) > 10 even including dimeric inulobiose' (Lewis, 1993).

Manufacturers of fructans are seeking to expand market opportunities for products containing these constituents by being permitted to refer to inulin and FOS as dietary fibre and for such products to potentially qualify to make dietary fibre content claims.

Currently, Standard A1(13) of the Australian *Food Standards Code* (the Code) stipulates that declaration of fibre in the Nutrition Information Panel (NIP) should be as dietary fibre (as opposed to crude fibre for example); and defines dietary fibre for labelling purposes as that measured by the prescribed AOAC enzymatic-gravimetric method of analysis 985.29. This method does not measure the majority of fructans because of their solubility in 80% v/v ethanol which is discarded during the analytical procedure. The New Zealand Food Regulations refer to this method by the original 1984 journal reference that reported the results of the collaborative trial of this method (see Relevant Provisions below).

Standard A1(13) also requires calculation of 'Carbohydrate - total' in the NIP by difference, that is, to include the contribution from all types of carbohydrates including dietary fibre and other non-digestible carbohydrates such as fructans. This panel entry, although representing a group of compounds that have chemical characteristics in common, does not differentiate carbohydrates on a physiological basis. Inulin and FOS are not digested in the small intestine but fermented completely in the large intestine thus providing a lower energy yield than available or 'glycaemic' carbohydrates (ie those that provide carbohydrate for metabolism).

The Code currently assigns 17 kJ/g (the energy factor normally assigned to *available* carbohydrate) to the calculated total carbohydrate content, which thus overestimates the energy content of fibre-containing foods. A similar situation exists in New Zealand (see Relevant Provisions section below).

This Full Assessment report considered calculation of carbohydrate for nutrition labelling purposes because of its original inclusion in Application A277. Two proposals relevant to the development of the draft joint Australia New Zealand *Food Standards Code* (the draft joint Code) are P177 - Derivation of Energy Factors, which reviewed the matter of calculation of carbohydrate content *for the purposes of calculating its contribution to energy content* and P167 – Nutrition Labelling which recommended that the same calculation of carbohydrate be adopted *for nutrition labelling purposes*. These recommendations have been adopted in the draft joint Code, and are proposed to be reflected in the Australian *Food Standards Co*de as an alternative to current provisions, by virtue of this Application.

OBJECTIVE

The objective of this report is to assess the possibility of permitting fructans to be declared in food labels as dietary fibre, and if so, to assess the regulatory suitability of the applicant's submitted analytical method (subsequently AOAC 997.08) for the measurement of the fructan content of food.

RELEVANT PROVISIONS

Australian Food Standards Code

- Standard A1(13)(c)(ia) requires that the declaration of fibre in a Nutrition Information Panel must refer to dietary fibre; and

- Standard A1(13)(j) defines dietary fibre as that measured by the prescribed method of analysis ie Section 985.29 of the publication *Official Methods of Analysis of the Association of Official Analytical Chemists* (AOAC) 15th edition (1990).

New Zealand Food Regulations, (1984)

- Regulation 2(1) defines dietary fibre such that:

> 'Dietary fibre' means edible plant material not hydrolysed by the endogenous enzymes of the human digestive tract and as determined by the AOAC method (Prosky method - JAOAC 67, No. 6, 1044-1052, (1984))

Draft Joint Australian New Zealand Food Standards Code

- Standard 1.2.8(5) requires that the declaration of fibre in a Nutrition Information Panel must refer to dietary fibre; and

- Standard 1.2.8(18) defines dietary fibre as that measured by the prescribed method of analysis ie Section 985.29 of the 4th supplement (1998) to the publication *Official Methods of Analysis of the Association of Official Analytical Chemists* (AOAC) 16th edition (1995) or in the alternate to Section 991.43 of the AOAC, 16th edition, (1995) insofar as these methods measure as the endpoint, the total dietary fibre and not the soluble and insoluble fractions of dietary fibre.

Codex Alimentarius

The Codex Guidelines on Nutrition Labelling (FAO/WHO, 1995) define dietary fibre as "edible plant or animal material not hydrolysed by the endogenous enzymes of the human digestive tract as determined by the agreed upon method". Codex also has approved analytical methods AOAC 985.29 and AOAC 991.43 for measurement of dietary fibre in special foods; and infant and follow up formulas respectively.

Other countries

According to the applicant, inulin and FOS are recognised as dietary fibre in 15 European countries; it is acceptable to the European Commission in the absence of a specific directive on that matter. Since the fructan method was adopted by AOAC, fructans are recognised as dietary fibre in the United States but no FDA authorisation is necessary. The United Kingdom notified interested parties on 22 September 2000 that the recommended reference procedure for analysis of dietary fibre was an AOAC International method eg 991.43, 997.08. This was a departure from previous advice that the Englyst method be used for the analysis of non-starch polysaccharides for labelling purposes. An application is in progress in Canada.

PUBLIC CONSULTATION

Following Preliminary Assessment in August 1995, 9 submissions were received. A summary of the submissions is given at Attachment 4 and discussed below.

OPTIONS (INCLUDING ALTERNATIVES TO REGULATION)

Alternatives could include:

Option 1 (Maintain existing regulation)
– maintain prescribed analytical method only; or

Option 2 (Modify existing regulation)
– modify Code provisions to permit the inclusion of fructans such as inulin and FOS content in a declaration of dietary fibre content; or

Option 3 (Develop an alternative to regulation ie provide a non-regulatory mechanism to guide declaration of dietary fibre content)
– provide non-regulatory mechanisms to guide declaration of dietary fibre content.

This third option could take the form of preferred methods of analysis, or a performance standard appropriate to food labelling. Given the current provisions in the *Food Standards Code* for regulation of identity of conventional dietary fibre, this alternative would need to apply not only to any new components approved to be identified as dietary fibre but also to conventional dietary fibre.

ASSESSMENT

Joint FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition*

The Report of the FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition* (1998) (the FAO/WHO Report) reviewed the developments in the scientific understanding of carbohydrates in human nutrition and made the following recommendations relevant to this Application:

1 That the terminology used to describe dietary carbohydrate be standardized 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+). Further division can be made on the basis of monosaccharide composition. Nutritional groupings can then be made on the basis of physiological properties.

2 That the concept of glycemic carbohydrate, meaning "providing carbohydrate for metabolism" be adopted.

3 Recommends against the use of the terms extrinsic and intrinsic sugars, complex carbohydrate and available and unavailable carbohydrates.

4 That food laboratories measure total carbohydrate in the diet as the sum of the individual carbohydrates and not "by difference".

5 That the use of the term dietary fibre should always be qualified by a statement itemizing those carbohydrates and other substance intended for inclusion. Dietary fibre is a nutritional concept, not an exact description of a component of the diet.

6 That the use of the terms soluble and insoluble dietary fibre be gradually phased out. The Consultation recognized that these terms are presently used but does not consider them a useful division either analytically or physiologically.

7 That the analysis and labelling of dietary carbohydrate, for whatever purpose, be based on the chemical divisions recommended. Additional groupings such polyols, resistant starch, non-digestible oligosaccharides and dietary fibre can be used, provided the included components are clearly defined.

Recommendations (1, 4) to more precisely measure and define carbohydrate components are endorsed. Recommendation (2) to use the term 'glycaemic' instead of such terms as 'available'; and conversely, 'non-glycaemic' instead of 'unavailable', is problematic and has not been adopted for the draft joint Code because it is not yet a widely understood descriptor for carbohydrates.

That dietary fibre be defined in terms of component composition, recommendation (5) is endorsed, as is recommendation (6) to phase out the terms 'soluble' and 'insoluble' in relation to dietary fibre. The FAO/WHO Report also discusses various compositional definitions suggested for dietary fibre, but states that no consensus currently exists as to whether components other than non-starch polysaccharides should be included.

Recommendation (7) urges labelling of carbohydrates to be based on the proposed chemical divisions. Depending on the definition of dietary fibre, this may be a simple or more complicated undertaking. The layout of terms in systematic formats such as NIPs enables the terminology hierarchy to be displayed. For example, resistant starch could be indented under dietary fibre to indicate its contribution to dietary fibre content. Clustering of like terms has been adopted in the draft joint Code.

Issues Raised By Public Submissions

Submissions were received in 1995 mainly from industry groups; only one was received from health professionals (Dietitians Association of Australia), and no consumer opinion was received. At that time, submissions were generally in favour of adopting fructans as dietary fibre, although Goodman Fielder advised caution until there was broad scientific consensus on the matter. CAFTA Victoria preferred a thorough review of the subject before a decision was made. The few responding State health departments did not venture an opinion or were opposed. There was general opposition to adopting the proposed method of analysis before collaborative testing had been carried out. (This was subsequently undertaken and the method adopted by AOAC in 1997). Most submissions favoured changing the definition of carbohydrates in nutrition labelling. There was mixed support for the applicant's submitted energy factors (later withdrawn from Application).

Several comments were received about the alignment of 'dietary fibre' in NIPs. Many NIPs currently align the voluntary dietary fibre entry to the left-hand margin, consistent with entry of any other voluntarily declared nutrient. Because dietary fibre is currently calculated as a component of the 'Carbohydrate - total' value, however, it could equally be indented under the carbohydrate heading, in alignment with 'sugars - total'. Of course, the present left-hand alignment would be appropriate if 'carbohydrate - total' is amended to exclude dietary fibre.

Axiome Pty Ltd suggested that the scope of the Application should be expanded to include polydextrose. However, it was considered more appropriate for that matter to be the subject of a separate application.

A summary of submissions is given at Attachment 4.

Scientific Evaluation

The scientific assessment of whether fructans constitute dietary fibre is made at Attachment 3. The conclusions of that assessment are that:

1. A definition of dietary fibre encompassing elements of origin, chemistry and physiological effect should be developed, specifically, that:

> 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.

2. Sufficient chemical and physiological evidence is available to demonstrate that the fructans, inulin and FOS, conform to the proposed definition of dietary fibre, and thus should be permitted to be declared on food labels as dietary fibre.

3. The analytical method of Lee AOAC 991.43 be adopted in the Australian Food Standards Code (as has been in the draft joint Code) as an alternative to the currently prescribed method AOAC 985.29 for the determination of 'total' dietary fibre as recommended in the second consultant's report (Appendix 3 to Attachment 2). This alternate method is also approved by Codex and gives manufacturers more flexibility in choosing an official method.

4. Fructan content of foods should be determined according to the prescribed analytical method, AOAC 997.08 (method submitted by applicant) or its simpler alternate, AOAC 999.03. Because both dietary fibre procedures AOAC 985.29 and AOAC 991.43 can incidentally measure up to 30% of fructan content, it is important to deduct such fructans from the dietary fibre result before it is combined with the result of AOAC 997.08 or 999.03, unless it is known that fructans are the only source of dietary fibre in the food. This ensures that any fructan content is not double counted.

These recommendations are consistent with the Codex guidelines and with the relevant recommendations of the FAO/WHO Report.

Calculation of carbohydrate for declaration in Nutrition Information Panels and for determining its contribution to declared energy content (consistent with approach adopted in draft joint Code)

Standard A1(13)(a) requires (total) carbohydrate content/100g to be calculated as the difference between 100 and the sum of the percentages of water, protein, fat and ash. The concept of carbohydrate by difference, which includes all forms of carbohydrate, is not used in nutrition

education and is not understood by consumers. It is not readily conveyed by NIPs unless dietary fibre is voluntarily declared and indented under total carbohydrate; it not conveyed when dietary fibre is aligned directly under total carbohydrate.

The calculated value for carbohydrate by difference includes completely-, partially- and non-digestible forms of carbohydrate and other minor constituents, plus any error from the estimated content of other macronutrients; it thus overestimates true carbohydrate content. The assignment of the *available* carbohydrate energy factor to the (total) carbohydrate content further compounds the overestimate of energy content. The discrepancy is greatest for high fibre foods. The applicant thus sought to amend the calculation of (total) carbohydrate for nutrition labelling and energy calculation purposes to include dietary fibre in the group of macronutrients whose content is subtracted from 100.

This assessment proposes that as an alternate in the Australian *Food Standards Code*, dietary fibre be subtracted from the result of carbohydrate by difference for energy calculation and carbohydrate declaration purposes ie:

'carbohydrate' means carbohydrate by difference, calculated by subtracting from 100 the average quantity expressed as a percentage of water, protein, fat, dietary fibre and ash.

Adopting such an approach will align with Codex, which has adopted a 'carbohydrate (excluding dietary fibre)' definition for the purposes of nutrition labelling.

Review Proposal P177 - Derivation of Energy Factors, previously proposed that the present approach of calculating carbohydrate by difference be retained, but that the calculation be amended to subtract dietary fibre (but also other unavailable carbohydrates) from 100. It is proposed that a simpler form of this deduction (subtract dietary fibre only) be introduced as an alternate provision in the current but time-limited *Food Standards Code* for manufacturers who might want to change their labels in the short term before the end of transition.

The FAO/WHO Report recommends that laboratories no longer report carbohydrate by difference. Both the Australian and New Zealand food composition tables (DCS&H/ANZFA, 1989-) (NZ Crop and Food Research/ Ministry of Health, 1997) as generally available data, are permitted to be used as a data source for nutrition labelling. The tables do not define total carbohydrate as carbohydrate by difference, rather as the sum of sugars, starch and dextrins, polyols where measured, but not dietary fibre. Currently, oligosaccharides, resistant starch and polyols are not comprehensively reported in the tables.

Until such time as data for these components are generally available for Australian and New Zealand foods, the proposed variation to carbohydrate by difference for nutrition labelling should suffice. No advantage would be conferred by requiring carbohydrate to be directly analysed and totalled, as the resultant value would either equate to a value calculated by difference, or more likely be an underestimate due to the presence of unrecognised minor carbohydrate constituents.

Adoption of the proposed change to the definition of carbohydrates would mean that dietary fibre in a NIP should always be directly aligned under carbohydrate.

Nutrition labelling of dietary fibre and fructans

Nutrition labelling provisions currently state that the subject of a nutrition claim includes reference to several nutrient categories as well as to 'any other nutrient'. Fructans are interpreted as an 'other nutrient' because they are a type of carbohydrate. When fructans are declared in a NIP, there is no requirement for dietary fibre also to be declared.

It is now proposed for the current *Food Standards Code*, and recommended for consequential amendment to draft Standard 1.2.8 - Nutrition Information Requirements, that a general definition of dietary fibre be inserted; and that when:

- fructans are the subject of a nutrition claim; or
- fructans are declared as dietary fibre in a nutrition claim (including a content claim); or
- fructans are simply declared in the NIP;

the NIP should show entries for:

- dietary fibre (incorporating fructan content); **and**
- fructan content indented under the dietary fibre entry.

It is not proposed to prescribe specific terms for the purposes of fructan declaration, but such terms could include fructans, inulin, resistant or non-digestible oligosaccharides etc as appropriate. This approach is consistent with recommendations (5) and (7) of the FAO/WHO Report to chemically define what is meant by dietary fibre. The approach could be further implemented by permitting reference to other components once analytical methods are collaboratively trialed and adopted or data for these components are generally available.

Conclusion

The scientific assessment concluded that sufficient evidence has accrued to extend the definition of dietary fibre beyond that which is analysed by the currently prescribed method (AOAC 985.29). It was further concluded that assessment of constituents as dietary fibre should be made according to a definition comprising elements of chemistry, physiology, origin. Such a definition has been proposed and incorporated into the drafting. According to this definition, fructans such as inulin and FOS would be considered to be dietary fibre. This assessment is in accord with the recommendations of the recent Report of the Joint FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition* (1998).

Consistent with its adoption in the draft joint Code, it is proposed to permit the use of method of analysis AOAC 991.43 as an alternative to the method currently prescribed in the Australian *Food Standards Code* for dietary fibre. It is further proposed to permit the use of AOAC 997.08 or its simpler alternate, AOAC 999.03 in both Codes to determine fructan content of foods, and as appropriate, to sum this result with the result of the prescribed method of analysis for dietary fibre or its proposed alternative, after fructans incidentally measured by AOAC 985.29 or 991.43 have been deducted.

It is concluded that the calculation of 'carbohydrate by difference' for the purposes of energy calculation and nutrition labelling in the Australian *Food Standards Code* should be retained but that the calculation should be amended so to subtract the percentages of water, protein, fat, dietary fibre and ash, from 100. Moreover, for both Codes, when fructans are the subject of a nutrition claim; or when fructans are declared as dietary fibre in a nutrition claim; or when

fructans are simply declared in the NIP; the NIP should show entries for dietary fibre (incorporating fructan content), **and** fructan content indented under the dietary fibre entry.

Proposed variation to the Australian Food Standards Code

Given that the Australian Food Standards Code is time-limited, Standard A1(13) is proposed to be varied to:

- include a general definition of dietary fibre;
- include as an alternate to the present method of carbohydrate by difference, an amended method of calculation for carbohydrate by difference in which dietary fibre (and fructans as appropriate) are included in the range of macronutrient contents subtracted from 100; and
- require declaration in the NIP of dietary fibre and fructans as a component of dietary fibre when fructans are the subject of a nutrition claim or when fructans are declared as dietary fibre in a nutrition claim or when fructans are simply declared in the NIP.

Standard A1(13)(j) is also proposed to be varied to:
- permit the alternate use of method of analysis AOAC 991.43 to determine dietary fibre;
- permit the use of AOAC 997.08 or its simpler alternate, AOAC 999.03 to determine fructan content of foods, and as appropriate, to sum this result with the result of the prescribed method of analysis for dietary fibre or its proposed alternative, after deducting fructans measured by AOAC 985.29 or 991.43;
- update the reference manual *Official Methods of Analysis of the AOAC International* to the 17th edition, (AOAC Int, 2000).

Proposed variation to the draft joint Australia New Zealand Food Standards Code

Draft Standard 1.2.8 is proposed to be varied to:

- include a general definition of dietary fibre;
- require declaration in the NIP of dietary fibre and fructans as a component of dietary fibre when fructans are the subject of a nutrition claim or when fructans are declared as dietary fibre in a nutrition claim or when fructans are simply declared in the NIP.
- delete the restriction on the use of AOAC 991.43 to determine total dietary fibre only;
- permit the use of AOAC 997.08 or its simpler alternate AOAC 999.03 to determine fructan content of foods, and as appropriate, to sum this result with the result of the prescribed method of analysis for dietary fibre or its proposed alternative, after deducting fructans measured by AOAC 985.29 or 991.43;
- update the reference manual *Official Methods of Analysis of the AOAC International* to the 17th edition, (AOAC Int, 2000).

REGULATORY IMPACT ANALYSIS

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community, which includes the consumers, food industry and governments in both countries. The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

In the course of assessing the regulatory impact, the Authority is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice.*

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the regulatory impact statement (RIS). Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

Option 1 - Status quo: maintain prescribed analytical method for dietary fibre; retain dietary fibre in the value for carbohydrate by difference; no control over nutrition labelling of dietary fibre constituents.

- *Advantages/benefits*

For industry, prescription of an analytical method provides an analytical definition for a very diverse group of compounds, and therefore a level of consistency in measurement of dietary fibre content that could otherwise provide some manufacturers with an unfair advantage. No other nutrient has a prescribed method of analysis for nutrition labelling, however this approach has substituted to some extent for a physiological definition of dietary fibre. The prescribed method is one of the less complicated methods available and as such is comparatively rapid and inexpensive. The facility to calculate dietary fibre content from food tables that have employed the same method of analysis provides a ready alternative to direct analysis. Within the context of nutrition labelling regulations, industry has the most flexibility as to the form and placement of declared unavailable carbohydrate components in the NIP.

For consumers, prescription of an analytical method provides a level of consistency that could otherwise be open to abuse and thus potentially confuse consumers. The prescribed method provides a reasonable approximation of the dietary fibre content of a wide range of foods. Consistency of the prescribed method with that used in food composition tables and also used to set population consumption targets for dietary fibre enables health professionals and consumers easy comparison against a dietary target. There are no advantages for consumers in retaining dietary fibre in the calculation for carbohydrate by difference as this does not relate to current nutrition education concepts.

For government, prescription of an analytical method provides for straightforward enforcement of labelling regulation. Consistency of the prescribed method with that used in food composition tables and used to set population consumption targets for dietary fibre facilitates monitoring against dietary targets. There are no advantages for government in retaining dietary fibre in the calculation for carbohydrate by difference, or for permitting the current ambiguous NIP labelling situation with respect to total carbohydrate and dietary fibre to continue.

- *Disadvantages/costs*

For industry, prescription of an analytical method may incur additional costs of analysis, although the option exists to use 'generally available data' from analyses by the same method as that prescribed in the Code in calculations of dietary fibre content. The method is only an approximation of the unavailable carbohydrate content. As well as not measuring fructans, it also does not completely measure components already approved to be identified as dietary fibre such as resistant starch.

There is no flexibility in the prescribed method to use well-accepted alternate enzymes in the methodology. The disadvantage for industry in retaining dietary fibre in the calculation for carbohydrate by difference is that it is required to declare a value that has no meaning to consumers, and the NIP regulations with respect to total carbohydrate and dietary fibre are ambiguous.

For consumers, the cost of analysis may be passed to consumers. Because of the limitations on the presently prescribed methodology, the dietary fibre content of some foods may not be accurately portrayed. There are no advantages for consumers in retaining dietary fibre in the calculation for carbohydrate by difference as this outmoded concept is not included in current nutrition education. Because the current regulation does not direct industry to indent an entry for dietary fibre under the total carbohydrate heading, the consumer could be misled to believe that the value for total carbohydrate excludes dietary fibre.

For government, consumers may not be receiving accurate information about the fibre content of their diets which may have consequences in terms of unnecessary or insufficient dietary modification or reliance on goods with laxative effects.

Option 2 - modify Code provisions to permit the declaration of fructans such as inulin and FOS as dietary fibre; introduce new prescribed analytical methods for dietary fibre and fructans; omit dietary fibre from the value for carbohydrate by difference; introduce control over nutrition labelling of dietary fibre constituents.

- *Advantages/benefits*

For industry, the modifications introduce more flexibility in choosing a method of analysis, and the option for those products containing fructans to declare that content as dietary fibre and to potentially make dietary fibre content claims. This may support product innovation through the use of more fructans such as inulin and FOS in products that would benefit manufacturers. The current inconsistency with consumer understanding of total carbohydrate and the ambiguity in the NIP regulation would be resolved.

For consumers, if adopted by manufacturers of foods containing added fructans, consumers would be provided with a greater range of identifiable sources of dietary fibre especially from foods that are not traditionally considered as being a source of dietary fibre such as dairy foods. This in turn would potentially increase consumers' intake of dietary fibre without significant sustained dietary change which may result in improved health outcomes. The NIP labelling would more clearly relate to consumer understanding of total carbohydrate, and facilitate understanding by indenting fructans where declared, under dietary fibre in the NIP.

For government, it may increase awareness among consumers of dietary fibre and result in improved health outcomes from an increased intake of dietary fibres. Labelling would more closely align with current nutrition education concepts.

- *Disadvantages/costs*

For industry, the modifications only introduce costs for those manufacturers who choose to declare fructan content itself or as dietary fibre. All other manufacturers would remain unaffected. Changes to labelling requirements would introduce costs for manufacturers who chose to use nutrition labelling.

For consumers, if adopted by manufacturers of foods containing added fructans, consumers may be confused as to sources of dietary fibre because some foods not traditionally considered as sources of dietary fibre such as dairy foods and meat products, could be so promoted. Consumers may be confused by seeing different values given for total carbohydrate in the NIP of foods with which they are familiar.
For government, if adopted by manufacturers of foods containing added fructans, nutrition education messages and programs would need to account for the changing market place which may result in increasing complexity of the messages and consumer confusion and cynicism.

Option 3 - Provide a non-regulatory mechanism that guides use of dietary fibre values. For nutrition labelling aspects, refer to either Option 1 or Option 2.

This option could take the form of preferred methods of analysis, or simply a performance standard such as to be appropriate for food labelling purposes. However, there are many methods of analysis for dietary fibre which measure different forms and amounts of dietary fibre components that could result in widely different values for the same food. Given the current provisions in the Code for regulation of identity of conventional dietary fibre, this alternative would need to apply not only to any new components approved to be identified as dietary fibre, but to conventional dietary fibre itself.

- *Advantages/benefits*

For industry, this option could potentially provide a wider choice of a suitable [and potentially unsuitable] methods of analysis, through guidelines of preferred methods or a performance standard such as appropriate methods.
For consumers, there would be no advantages for consumers.
For government, enforcement of this aspect of labelling would no longer be a government responsibility.

- *Disadvantages/costs*

For industry, having guidelines on preferred methods or simply a performance standard would potentially give some manufacturers an unfair advantage depending on which of the many methods of analysis was selected. Industry compliance would be very difficult to independently verify by analysis without additional funds for enforcement.
For consumers, consumers could no longer have the same level of assurance about the comparability of dietary fibre content declarations among food products or with food tables or dietary targets.
For government, government would no longer have a definition of dietary fibre in food regulation, albeit a chemical definition, and it could no longer rely on consistency of dietary fibre content declarations on food products with food tables or dietary targets. Modifying regulation to guidelines would transfer the responsibility for enforcement from State authorities to either co-regulation or industry self regulation. Analytical verification of labelled nutrient content is a complex and potentially costly exercise that is undertaken from time to time by State authorities, but without additional funding, it is unlikely that industry would be prepared to assume such a role.

Conclusion

Consideration of the regulatory impact of this application concludes that Option 2 would enable some manufacturers to more accurately declare the dietary fibre content of foods, and would potentially increase the number of products eligible to carry dietary fibre claims. This in turn could benefit consumers who wish to increase or maintain their dietary fibre intake from a broader range of foods without having to make and sustain significant dietary change. Consumers generally might also increase their awareness of dietary fibre and its importance for health by being exposed to promotion of dietary fibre content and its nutritional benefits of a greater range of products. The risk of consumer confusion would be minimised if nutrition education policies supported the approach recommended from this assessment. The current ambiguity for industry and consumers of the relative placement of total carbohydrate and dietary fibre in NIPs would be resolved once the quantity given for total carbohydrate aligns with current consumer understanding and nutrition education concepts for available carbohydrate.

ANZFA'S SECTION 10 OBJECTIVES

Protection of public health and safety

The safety of fructans such as inulin and FOS has not been assessed as part of this application. Inulin, and FOS are already permitted food ingredients. Fructans are also consumed in the diet in small quantities from natural food sources. Any novel sources of fructans would be regulated in the future by the novel foods standard.

Adequate information to enable informed choice and to prevent fraud and deception

It is considered that, as unavailable carbohydrates, fructans are forms of dietary fibre and that manufacturers should be permitted to include the fructan content of their products in a declared dietary fibre value, but if they do, that the dietary fibre content and its fructan component should both be declared in a NIP.

It is assumed that manufacturers of foods containing at least noteworthy amounts of fructans would wish to analyse the fructan content or calculate it from recipe ingredients. The option to calculate the fructan content from 'generally available data' such as food composition databases is not currently available. Such a proposal would not disadvantage consumers as the declaration of dietary fibre content itself either as the subject of a nutrition claim (including a content claim) or in a NIP is currently voluntary. However, once a fructan claim or a dietary fibre claim that includes a fructan contribution is made, both the fructan content and the dietary fibre content should be declared. Prescribing such a requirement shows the relation of fructans to dietary fibre to consumers who may be unfamiliar with the fructan terminology.

Manufacturers are not prohibited from using terms such as inulin, resistant or non-digestible oligosaccharides etc on labels, however, such terms are currently unfamiliar to consumers or are confused with other health terms such as insulin. Given the general consumer understanding of dietary fibre as a beneficial dietary component, and the evidence for potential health benefits of fructans, adoption of this Application would not constitute fraud or deception of consumers.

Consumers are generally not well informed about the physiological properties of different types of dietary fibre, although most can generally associate dietary fibre with laxative properties. Nutrition education programs have traditionally promoted cereals, fruit and vegetables as sources of dietary fibre. Adoption of the conclusions of this assessment could result in expansion of the range of fibre-containing foods including dairy and meat products. Consumer understanding of physiological benefits of dietary fibre other than laxation is currently not well developed, however this situation and the possible new food sources of dietary fibre could be addressed through educative efforts by health authorities and professionals, and has the potential to be supported by the food industry.

Fair trade

Maintaining a prescribed method of analysis for voluntary declaration of dietary fibre and prescribing a method for the voluntary inclusion of fructans in a dietary fibre claim as well as requiring declaration of dietary fibre and the fructan component in the NIP would ensure fair trade.

Promotion of Trade and Commerce

Adoption of the conclusion of this assessment supports industry innovation by providing manufacturers with an additional incentive to develop new products or modify formulations of existing products to have a positive nutritional profile.

International Consistency

Codex has formulated a physiological definition of dietary fibre, and approved two AOAC methods of analysis for labelling of dietary fibre content. The proposed approach is fundamentally consistent with Codex but provides more flexibility than Codex.

OTHER RELEVANT MATTERS

If adopted, it is proposed that the date of effect of the draft variation to the Australian *Food Standards Code* be on gazettal and in tandem with the date of effect of the draft variation to the joint *Australia New Zealand Food Standards Code*.

CONCLUSIONS

It is concluded that:

- sufficient evidence has accrued to extend the definition of dietary fibre beyond that which is analysed by the currently prescribed analytical method (AOAC 985.29);
- assessment of constituents as dietary fibre should be made according to a definition comprising elements of chemistry, physiology, origin and according to this definition, fructans such as inulin and FOS would be considered to be dietary fibre;

In the Australian *Food Standards Code:*

- the method of analysis AOAC 991.43 should be permitted as an alternative to the current method for dietary fibre analysis; and
- the calculation of 'carbohydrate by difference' should be retained but that an alternate calculation should be inserted so to subtract the percentages of water, protein, fat, dietary fibre and ash, from 100.

In the draft joint *Australia New Zealand Food Standards Code:*

- delete the restriction on the use of AOAC 991.43 to determine total dietary fibre only.

In both the Australian *Food Standards Code* and the draft joint *Australia New Zealand Food Standards Code:*

- insert a general definition of dietary fibre;
- AOAC 997.08 or its simpler alternate, AOAC 999.03 are proposed to be permitted to determine fructan content of foods;
- when fructans are the subject of a nutrition claim; or when fructans are declared as dietary fibre in a nutrition claim; or when fructans are simply declared in the NIP; the NIP should show entries for dietary fibre (incorporating fructan content), **and** fructan content indented under the dietary fibre entry; and
- references to AOAC are to be updated to the 17th edition, 2000.

Consideration of the Regulatory Impact of this Application concludes that Option 2 provides the most advantages and benefits to industry, consumers and government. The outcome of the full assessment fulfils the Authority's section 10 objectives. 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.

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 should be advised to the WTO as a TBT Notification because the proposed change to the regulation expands the definition of dietary fibre and the components that can be claimed to be dietary fibre.

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ATTACHMENTS TO THE REPORT:

1. Draft Variation to the Australian *Food Standards Code;*
   Draft Variation to the *Australia New Zealand Food Standards Code*

2. Draft Explanatory Notes

3. Scientific Evaluation

Appendix 1	Consultancy Report 1, CSIRO Division of Human Nutrition
Appendix 2	Consultancy Report 2, BRI, Australia Limited
Appendix 3	Van Loo J et al (1999) Functional food properties of non-digestib oligosaccharides: a consensus report for the ENDO project (DGXI AIRII-CT94-1095) *Brit J Nutr* 81:121-32.
Appendix 4	Expert Working Group, outcomes
Appendix 5	Results of ANZFA's dietary fibre opinion survey

4. Public Comment Received

DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE AND THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

APPLICATION A277 - INULIN AND FRUCTOOLIGOSACCHARIDE AS DIETARY FIBRE

To commence: On gazettal

The Food Standards Code and the Australia New Zealand Food Standards Code are varied by the following -

(1) Paragraph (13)(a) of Standard A1 of the Food Standards Code, is varied by deleting-

'carbohydrate' means carbohydrate by difference, calculated by subtracting the percentages of water, protein, fat and ash, from, 100;

substituting

'carbohydrate' means carbohydrate by difference, calculated by subtracting -
(i) the percentages of water, protein, fat and ash, from 100; or
(ii) the percentages of water, protein, fat, dietary fibre and ash from 100;

'dietary fibre' means that fraction of the edible part of plants or their extracts, or analogous carbohydrates that -
- (a) are resistant to digestion and absorption in the human small intestine, usually with complete or partial fermentation in the large intestine; and
- (b) promote one or more of the following beneficial physiological effects;
  - (A) laxation;
  - (B) reduction in blood cholesterol; or
  - (C) modulation of blood glucose;

and includes polysaccharides, oligosaccharides (DP > 2) and lignins;

(2) inserting immediately after subparagraph (13)(c)(iii) of Standard A1 of the Food Standards Code -

(iv) Where on the label on or attached to a package containing food -

- (A) a reference is made in a nutrition claim to fructans or words of similar import;
- (B) fructans are referred to in a nutrition information panel; or
- (C) the fructan content of the food is declared as dietary fibre;

entries in the nutrition information panel for both dietary fibre and fructans should be shown in the left hand column of the panel, with the fructans being indented under the total of dietary fibre.

Editorial note:

When fructans and dietary fibre are declared in the left hand column of a nutrition information panel, it should be done in the form shown below-

Dietary Fibre	- total
	- fructans

(3) deleting paragraph (13)(j) of Standard A1 of the Food Standards Code, substituting-

(j) **Method of analysis**. The methods set out in this paragraph are the prescribed methods of analysis for the determination of the total dietary fibre and fructan content of food for the purposes of nutrition labelling as specified in this clause.

(i) Prescribed method of analysis for the determination of total dietary fibre in Food Total dietary fibre is determined according to Section 985.29 of the A.O.A.C, 17th Edition (2000), or in the alternate, to Section 991.43 of the A.O.A.C, 17th Edition (2000).

(ii) Prescribed method of analysis for the determination of fructans in food The fructan content of food is determined according to Section 997.08 of the A.O.A.C, 17th Edition (2000), or in the alternate, to Section 999.03 of the A.O.A.C, 17th Edition (2000).

(iii) Determination of the dietary fibre, including the fructan content of food The results obtained using the analytical methods prescribed in subparagraphs (13)(j)(i) and (13)(j)(ii) of this Standard should be summed together after ensuring that there is no double counting of fructans.

(4) *inserting immediately following the definition of carbohydrate in clause 1 of Standard 1.2.8 of the Australia New Zealand Food Standards Code -*

'dietary fibre' means that fraction of the edible part of plants or their extracts, or analogous carbohydrates that -

(a) are resistant to digestion and absorption in the human 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; or

(ii) reduction in blood cholesterol; or

(iii) modulation of blood glucose;

and includes polysaccharides, oligosaccharides (DP > 2) and lignins;

(5) inserting immediately after subclause 5(8) of Standard 1.2.8 of the Australia New Zealand Food Standards Code -

(9) Where on the label on a package containing food -

(a) a reference is made in a nutrition claim to fructans or words of similar import; or
(b) fructans are referred to in a nutrition information panel; or
(c) the fructan content of the food is declared as dietary fibre;

entries in the nutrition information panel for both dietary fibre and fructans should be shown in the left hand column of the panel, with the fructans being indented under the total of dietary fibre.

(6) deleting clause 18 of Standard 1.2.8 of the Australia New Zealand Food Standards Code, substituting

18 Methods of analysis to determine total dietary fibre and fructan content of food

(1) The methods set out in this clause are the prescribed methods of analysis for the determination of total dietary fibre and fructan content of food for the purposes of nutrition labelling as specified in this standard.

(2) Total dietary fibre is determined according to Section 985.29 of the A.O.A.C, 17th Edition (2000), or in the alternate, to Section 991.43 of the A.O.A.C, 17th Edition (2000).

(3) The fructan content of food is determined according to Section 997.08 of the A.O.A.C, 17th Edition (2000), or in the alternate, to Section 999.03 of the A.O.A.C, 17th Edition (2000).

(4) The results obtained using the analytical methods prescribed in subclauses (2) and (3) should be summed together after ensuring that there is no double counting of fructans.

Editorial note:

Subclause 18(2) sets out the prescribed method of analysis for the determination of total dietary fibre in food.

Subclause 18(3) sets out the prescribed method of analysis for the determination of the fructan content of food.

Subclause 18(4) prescribes how to determine the combined dietary fibre and fructan content of food.

EXPLANATORY NOTES - DRAFT

APPLICATION A277

INULIN AND FRUCTOOLIGOSACCHARIDE AS DIETARY FIBRE

The Australia New Zealand Food Authority has before it an application received in July 1995 from Foodsense Pty Ltd on behalf of Orafti Belgium Ltd to amend 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 statutory timeframe was suspended on two occasions to permit further information to be provided.

The Full Assessment of this Application was conducted in the light of the recommendations from the 1997 Joint FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition* (FAO/WHO Report) (FAO/WHO, 1998) which reviewed the developments in the scientific understanding of carbohydrates in human nutrition and made the following recommendations relevant to this Application:

1 That the terminology used to describe dietary carbohydrate be standardized 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+). Further division can be made on the basis of monosaccharide composition. Nutritional groupings can then be made on the basis of physiological properties.

2 That the concept of glycemic carbohydrate, meaning "providing carbohydrate for metabolism" be adopted.

3 Against the use of the terms extrinsic and intrinsic sugars, complex carbohydrate and available and unavailable carbohydrates.

4 That food laboratories measure total carbohydrate in the diet as the sum of the individual carbohydrates and not "by difference".

5 That the use of the term dietary fibre should always be qualified by a statement itemizing those carbohydrates and other substance intended for inclusion. Dietary fibre is a nutritional concept, not an exact description of a component of the diet.

6 That the use of the terms soluble and insoluble dietary fibre be gradually phased out. The Consultation recognized that these terms are presently used but does not consider them a useful division either analytically or physiologically.

7 That the analysis and labelling of dietary carbohydrate, for whatever purpose, be based on the chemical divisions recommended. Additional groupings such polyols, resistant starch, non-digestible oligosaccharides and dietary fibre can be used, provided the included components are clearly defined.

The Authority concluded that the present situation of relying on a prescribed method of analysis as the sole means of defining dietary fibre for regulatory purposes is unsatisfactory. It does not permit due consideration of the physiological impact of new forms of food ingredients that either are not part of, or a small part of the traditional diet. On the other hand, reliance in Australia on an imprecise analytical method as the only definition of dietary fibre has meant that any constituent incidentally measured by the prescribed method could be classified and declared as dietary fibre irrespective of its physiological effect. In practice, however, such constituents would comprise only a minor portion of the overall determined value.

Adoption of a physiological definition in food regulation, as is the case in New Zealand, would not necessarily modify a dietary fibre value on the label as determined by analysis, but would signal the extent to which origin, chemistry and physiological effects should be established before approval of a new method of analysis was sought. It would also provide a clearer direction for future development of analytical methods that would more precisely reflect the definition.

It is considered appropriate to adopt a definition of dietary fibre comprising elements of origin, chemistry and physiology, similar to those given in the Codex Guidelines on Nutrition Labelling (FAO/WHO, 1995) and the New Zealand Food Regulations (1984).

<u>New Zealand Food Regulations, (1984), Regulation 2(1)</u>

> "Dietary fibre" means edible plant material not hydrolysed by the endogenous enzymes of the human digestive tract and as determined by the AOAC method (Prosky method - JAOAC 67, No. 6, 1044-1052, (1984))

<u>Codex Guidelines on Nutrition Labelling</u>

Dietary fibre is defined as "edible plant or animal material not hydrolysed by the endogenous enzymes of the human digestive tract as determined by the agreed upon method".

Codex also has approved analytical methods AOAC 985.29 and AOAC 991.43 for measurement of dietary fibre in special foods; and infant and follow up formulas respectively.

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;
5. Chemical constituents — including non-starch polysaccharides, resistant oligosaccharides, lignin plus associated plant substances; and
6. Suitable analytical methods — AOAC 985.29 or 991.43; and 997.08 or 999.03.

Comment is particularly sought on the proposed definition of dietary fibre for regulatory purposes, but also for broader adoption among the nutrition science and nutrition education communities. The ramifications of permitting such a broad definition clearly expands the range of fibre sources in the diet from plant foods containing intrinsic fibre, to a potentially wider range of foods, including those not considered or promoted as traditional sources of dietary fibre such as dairy foods and meat. The range does not extend however to therapeutic goods or dietary supplements regulated as therapeutic goods because declaration of fibre is not controlled by a prescribed method of analysis under the regulatory system for therapeutics.

Fructans

Fructans have been defined elsewhere as "any compound where one or more fructosyl-fructose linkages constitute a majority of the linkages. That is, not restricted to molecules with a Degree of Polymerisation (DP) > 10 even including dimeric inulobiose" (Lewis, 1993). Inulin is not a single entity, rather a polydisperse saccharide comprised essentially of linear 2-1 ß fructose units with a DP distribution of 3-70. Dietary fructans occur naturally in plant foods such as wheat, bananas, Jerusalem artichokes, artichoke, onions and leeks. In nature their DP ranges from 2 - 70; native chicory inulin has an average DP of 10-20, whereas Jerusalem artichoke averages a DP of 6. Average daily consumption of fructans has been estimated as 1-4 g in the United States and 3-11 g in Europe (Roberfroid and Delzenne, 1998).

Several fructan products are available to the food industry. Fructan ingredients can be extracted from naturally-occurring fructans in chicory root. The oligosaccharide fraction of fructans of native chicory inulin is about 30%. Such extracts may undergo hydrolysis and fractionation to produce a variety of ingredients that vary in their proportion of glucose, fructose, FOS and fructo-polysaccharides so as to perform a range of different technological functions. FOS can also be synthesised using fungal enzymes to produce compounds with a DP of 2-4 (Roberfroid and Delzenne, 1998). Rather than needing to deal with definitions which arbitrarily exclude some individual components such as inulobiose, it has been suggested that novel oligo/polysaccharide constituents such as synthesised fructan species should be classified according to their average DP (Cummings et al, 1997).

Fructans

Fructans such as inulin and FOS are not digested in the small intestine as demonstrated from *in vitro* studies and studies using ileostomists (Roberfroid and Delzenne, 1998). They do not contribute to postprandial glycaemia.

However, they exhibit some features attributed to some forms of dietary fibre. A consensus paper from European Community scientists (Van Loo et al, 1999) reviewed the analytical aspects and physiological properties of fructans relating to:

- bowel habit and gut flora;
- mineral absorption;
- lipid metabolism; and
- experimental effects in relation to colon cancer.

According to the consensus paper (Van Loo et al, 1999), inulin and FOS are highly fermentable by the colonic bacteria in the large intestine and exhibit the following effects:

- selective stimulation of enteric bifidogenic and lactobacillus bacterial growth;
- colonic production of short chain fatty acids particularly acetate and some butyrate; and
- increase in bacterial biomass that leads to a mild increase in faecal output comparable to soluble dietary fibres and resistant starch (1-2g faecal weight increase/g FOS ingested at intakes 15-40g/day), and potential normalisation of stool frequency at doses of 10-15 g/day (Alles et al, 1996; Kleessen et al, 1997).

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

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

Research into systemic effects on lipid and glucose metabolism are yielding ambiguous results at present. There is promising evidence in adolescents for stimulation of apparent calcium absorption along the entire intestine (similar results with sugar beet fibre and possibly other fibres (Coudray et al, 1997; Van Loo et al, 1999), and animal models are being used to assess the potential for inulin and FOS to protect against bowel cancer (Van Loo et al, 1999).

Prescribed methods of analysis

The Application submitted an analytical procedure for measurement of fructans as dietary fibre. This method is based on high performance anionic exchange liquid chromatographic measurement with electrochemical detection. It involves a 3-stage extraction/hydrolysis procedure and measurement of resultant sugars. The method could be used as an extension to the AOAC method of analysis for dietary fibre (AOAC 985.29) currently prescribed in the Australian and New Zealand food regulations. The fructan method has been subject to international collaborative testing and was adopted as first action by AOAC in 1997 and given the reference number 997.08. Final action status was granted in 1999.

The Authority accepts that method of analysis AOAC 997.08 is suitable in a regulatory context for determination of total fructan content. However, when the method is used in conjunction with the prescribed method for dietary fibre, fructans incidentally measured by the latter method should be deducted from the combined result to ensure that fructan content is not double counted. This adjustment would not be necessary in cases where it is known that fructans are the only source of dietary fibre in the food.

The Authority also recognises AOAC 999.03, a simpler spectrophotometric method using a purified fructanase enzyme, as an alternate method for determination of fructan content.

The Authority also proposes to adopt the equivalent analytical method of Lee, AOAC 991.43, in the Australian *Food Standards Code*, consistent with its adoption in the draft *Australia New Zealand Food Standards Code*, for the determination of dietary fibre as an alternative to the currently prescribed method AOAC 985.29 so as to allow the use of alternative enzymes. This method yields equivalent results to the Prosky method (AOAC 985.29) and is recognised by Codex as suitable for measurement of dietary fibre.

Nutrition labelling of fructans and dietary fibre

The proposed permission to declare fructans as dietary fibre would 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 (which also covers a nutrient content claim), or referred to as dietary fibre in a nutrition claim, or it is intended that fructans simply are declared in the NIP, entries for both dietary fibre and fructans should be shown in the Nutrition Information Panel (NIP), with fructans indented under dietary fibre. This is consistent with recommendations 5 and 7 from the FAO/WHO Report.

Carbohydrate by difference for adoption in the Australian *Food Standards Code*

This assessment proposes that an alternate calculation of carbohydrate by difference in which dietary fibre is also deducted, for the purposes of calculation of energy content and carbohydrate declaration in claims and in the NIP should be introduced, that is:

> *'carbohydrate' means carbohydrate by difference, calculated by subtracting the percentages of water, protein, fat, dietary fibre and ash, from 100'.*

Adoption of the proposed change to the definition of carbohydrate means that dietary fibre should always be left aligned under carbohydrate in a NIP. This approach is consistent with Codex, which adopted a 'carbohydrate by difference (excluding dietary fibre)' definition for the purposes of nutrition labelling.

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.

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REGULATORY IMPACT ANALYSIS

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community which includes the consumers, food industry and governments in both countries. The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice.*

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the RIS. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

Consideration of the Regulatory Impact of this Application concludes that modification of the Code provisions to permit the voluntary declaration of fructans such as inulin and FOS as dietary fibre but to require quantification of total dietary fibre content and the fructan contribution, would enable some manufacturers to more accurately declare the dietary fibre content of foods, and would potentially increase the number of products eligible to carry dietary fibre claims. This in turn could benefit consumers who wish to increase or maintain their dietary fibre intake from a broader range of foods without having to make and sustain significant dietary change. Consumers generally might also increase their awareness of dietary fibre and its importance for health by being exposed to promotion of dietary fibre content and its nutritional benefits, of a greater range of products. The risk of consumer confusion would be minimised if nutrition education policies supported the approach recommended from this assessment.

The current ambiguity for industry and consumers of the relative placement of total carbohydrate and dietary fibre in NIPs would be resolved once the quantity given for total carbohydrate aligns with current consumer understanding and nutrition education concepts for available carbohydrate.

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).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter does need to be notified to the WTO as a Technical Barriers to Trade (TBT) notification because the proposed change to the regulation expands the definition for dietary fibre and the opportunity for fibre claims.

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. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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 the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia other than from New Zealand** must comply solely with the Australian *Food Standards Code.*

- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination of both.

- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. 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 for most products comply solely with the Australian *Food Standards Code.*

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*.

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has completed a full assessment of the application, prepared draft variations to the Australian *Food Standards Code* and will now conduct an inquiry to consider the draft variations and its regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A277** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

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PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by **10 January 2001.**

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt.
Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.

SCIENTIFIC EVALUATION

A277 - INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

Over recent decades, dietary fibre has emerged as an important dietary component because of its many health attributes. Its status as an essential nutrient however is not as apparent as for some other nutrients. This is because dietary fibre is not digested and absorbed like other nutrients, and therefore cannot be subject to the same type of deficiency and repletion studies that demonstrate dietary essentiality for nutrients such as vitamins. Although most nutritionists would consider dietary fibre to be a nutrient and thus important for health, its identity in terms of structure and function have been vigorously debated for many years.

Codex Guidelines for Nutrition Labelling (FAO/WHO, 1995) defines a nutrient as:
"any substance normally consumed as a constituent of food:
(a) which provides energy; or
(b) which is needed for growth, development and maintenance of life; or
(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur."

The question of whether isolated substances when added to food products confer the same effects as in their native food is important to resolve. For fortificant micronutrients, the biological activity or otherwise of specific chemical forms can be demonstrated, regardless of the fortification vehicle. However, because of its heterogeneity and inability to directly affect metabolic processes, assessment of what constitutes dietary fibre required an epidemiological perspective confirmed by clinical trials. The difficulty in chemically identifying all forms of natural dietary fibre has been the basis for the ongoing debate about the dietary fibre. Regulators and nutrition scientists need to decide the basis for the identity of dietary fibre as many sources of extrinsically derived unavailable carbohydrates are now added to foods.

DEFINITIONS OF DIETARY FIBRE

The generic term 'dietary fibre' encompasses a heterogeneous collection of substances, mainly carbohydrates, that exhibit different physical properties and various physiological effects. Since the early 1970s, up to some 50 definitions have been put forward to cover the botanical and chemical nature, and physiological effects of dietary fibre but a single definition that satisfies everyone remains elusive. Recently, the report of the Joint FAO/WHO Expert Consultation on *Carbohydrates in Human Nutrition* (the FAO/WHO Report) (FAO/WHO, 1998) suggests that the term 'dietary fibre' has caused many difficulties within the scientific community because of controversies regarding definition. It does not venture to put forward another definition of dietary fibre, instead it proposes that dietary fibre should be considered as a nutritional concept rather than as an exact description of a dietary component.

The original definition proposed by Trowell (1972) was "that portion of food which is derived from cellular walls of plants which is digested very poorly by human beings" (Trowell et al, 1972). By 1976 Trowell and others had expanded their original definition to "remnants of plant cells resistant to hydrolysis by the alimentary enzymes of man. It is composed of cellulose, hemicelluloses, oligosaccharides, pectins, gums, waxes and lignin" (Trowell and Burkitt, 1986) because of their previous lack of awareness "that any part of the plant cell other

than the cell wall was not hydrolysed by the alimentary enzymes of man" (Trowell et al, 1976). A 1994 definition more than 20 years later put forward by an European Community food industry working group referred to fibre as "... the part of oligo- and polysaccharides and their (hydrophilic) derivatives which by human digestive enzymes cannot be decomposed to absorbable components in the upper alimentary tract. It includes lignin" (Anon, 1994).

In 1996, Baghurst and others (Baghurst et al, 1996) proposed an Australian working chemical definition which included all non-starch polysaccharides (NSP) and lignin from plants, and resistant starch:

Dietary Fibre = Non-Starch Polysaccharides + Resistant Starch + Lignin

Chemical definitions attempt to identify the components in foods that are responsible for the physiological effects of dietary fibre. However, as fibre-containing foods are generally complex matrices, and the physical structure of fibre contributes to its physiological effects, a chemical definition is necessarily over simplistic because it does not account for the food context in which the fibre component is found. Chemical definitions imply that the dietary fibre entity, in whatever context, would exert the same physiological effect. It is nevertheless important to understand the relation between the chemistry and physiological effects of dietary fibre and for the fibre contents of foods to be quantified.

To date, Australia has not adopted an official physiological definition of dietary fibre although an analytical definition is prescribed in food regulation. New Zealand includes a physiological definition in its food regulations in addition to a prescribed method of analysis.

The Consultancy Report from CSIRO Division of Human Nutrition at Appendix 1 calls for a more physiological definition of dietary fibre, with due acknowledgment of associated health benefits, to be adopted in Australia and New Zealand. Others have echoed the call for an official physiological definition of dietary fibre in Australia (Mugford, 1993).

Expert Working Group on Dietary Fibre

An Expert Working Group was established by ANZFA and met on 12 July 2000 to advise ANZFA on an appropriate definitional framework for dietary fibre. The Group's membership comprised the chair, Dr Alex Proudfoot, ANZFA's Medical Advisor, and eight nominees from invited Australian and New Zealand organisations and individual experts in the field of dietary. Ms Jane Barnes, representing the Applicant, Orafti, was invited to make a presentation to the Group. The Group's membership and terms of reference are given at Appendix 4.

Recommendation of the Expert Working Group

The Working Group adapted a recent American Association of Cereal Chemists (AACC) definition which was subsequently finetuned to the following:

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, lignins and oligosaccharides. Dietary fibre promotes one or more of these beneficial physiological effects: laxation, reduction in blood cholesterol and/or modulation of blood glucose.

The original AACC definition, which was recently adopted by the AACC Board after much international discussion via the internet as well as support at technical meetings in the United States during 1999, is given below.

Dietary fibre is the edible part of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fibre includes polysaccharides, oligosaccharides, lignins, and associated plant substances. Dietary fibres promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation.

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.

Analytical methods for dietary fibre were also generally discussed and it was recognised that for regulatory purposes, analytical methods needed to be rigorous, economical, and widely available. ANZFA's previous recommendations were supported i.e. that the current AOAC method 985.29 in the Australian and New Zealand food regulations be retained and that AOAC method 991.43 be considered as an alternative. The method of Champ[2] given in the FAO report *Carbohydrates in Human Nutrition*[8] was the best and simplest method for measurement of resistant starch.

The Expert Working Group acknowledged the future direction of the FAO report[3] and recommended that any change to regulations mirror community understanding of dietary fibre terms.

CHEMICAL FEATURES OF DIETARY FIBRE

Distinction between poly- and oligo- saccharides

Definitions of dietary fibre that include the term 'polysaccharide' imply a clear chemical definition of such constituents, yet in reality, polysaccharides and oligosaccharides are along a carbohydrate continuum that is distinguished in chemical terms somewhat arbitrarily.

The International Union of Pure and Applied Chemistry defines polysaccharides chemically as carbohydrates with >10 monomeric units, whereas the British Nutrition Foundation defines them as having a minimum of 20 residues (Asp, 1994). The FAO/WHO Report defined polysaccharides as having 10 or more monomeric units (ie Degree of Polymerisation (DP) >9). A polysaccharide is defined in this report as having a DP > 9, and an oligosaccharide, a DP of 3-9.

It has recently been suggested (Cummings et al, 1997) that the oligo/poly distinction should be made according to solubility in 80% v/v ethanol because some branched chain carbohydrates of DP 10-100 (chemically defined as a polysaccharide) remain in solution (not measured by the prescribed AOAC method of analysis) thus exhibiting the characteristic of an oligosaccharide. Inulin and polydextrose further confuse the situation by containing mixtures of polymers of different chain lengths that cross the oligo/poly saccharide divide.

Polysaccharides

Storage polysaccharides including starches and fructans, structural materials of plant cell walls, and the non-structural soluble components, ie gums and mucilages form the naturally occurring (intrinsic) polysaccharides in foods. Extrinsic polysaccharide ingredients and food additives can be added in the manufacture of foods. The main groups of polysaccharides range in size from a DP of less than 100 to more than 100 000. They can be divided into subgroups on the basis of (i) the monosaccharides that form the backbone of the polymer and (ii) the configuration of the glycosidic linkages in the backbone. Such configurations determine the tertiary structure and hence the physical properties of the polysaccharides and their capacity to associate with other polysaccharide chains.

The following table shows the general classification of polysaccharides.

Table 1: Classification of polysaccharides (Plaami, 1997)

Source in diet	Major types	Polysaccharide species	Monosaccharide backbone	Bonds in backbone
INTRINSIC				
Storage	starch*	amylose	glucose	linear 1-4α
		amylopectin	glucose	branched 1-4α
	resistant starch		glucose	1-4/1-6α
	fructans	inulin etc	fructose	linear 2-1β
	galactomannans	guar gum, locust bean gum etc	mannan	linear 1-4β
Plant cell wall	noncellulosic	pectin components	galacturonic acid	linear 1-4α
		arabinogalactans	galactose	linear 1-4α
	hemicelluosic	arabinoxylans	xylans	linear 1-4 β
		glucuronoxylans	xylans	linear 1-4β
		□-glucans	glucose	mixed 1-3, 1-4β
		xyloglucans	glucose	linear 1-4β
	cellulosic	cellulose	glucose	linear 1-4β

Non structural glucosidic soluble components	gums and mucilages	many hetero-polysaccharides	very diverse	non-α -bonds
EXTRINSIC				
Ingredients and food additives	starch	esters, ethers	glucose	1-4/1-6α
	modified cellulose	ethers	glucose	1-4β
	pectins	amidated	galacturonic acids	1-4α
	alginates		galacturonic/ mannuronic	
	gums, storage		mannan	
	gums, exudate		wide range	

* digested by human alimentary enzymes

Lignin

Lignin is not a polysaccharide, but a cross-linked complex polymer of approximately 40 oxygenated phenylpropane units. It is a structural component of plants that is specifically included within most definitions of dietary fibre that adopt a chemical perspective or that make reference to plant sources.

Fructans

Fructans have been defined elsewhere as "any compound where one or more fructosyl-fructose linkages constitute a majority of the linkages. That is, not restricted to molecules with a Degree of Polymerisation (DP) > 10 even including dimeric inulobiose" (Lewis, 1993). Inulin is not a single entity, rather a polydisperse saccharide comprised essentially of linear 2-1ß fructose units with a DP distribution of 3-70. Dietary fructans occur naturally in plant foods such as wheat, bananas, Jerusalem artichokes, artichoke, onions and leeks. In nature their DP ranges from 2 - 70; native chicory inulin has an average DP of 10-20, whereas Jerusalem artichoke averages a DP of 6. Average daily consumption of fructans has been estimated as 1-4 g in the United States and 3-11 g in Europe (Roberfroid and Delzenne, 1998).

Several fructan products are available to the food industry. Fructan ingredients can be extracted from naturally-occurring fructans in chicory root. The oligosaccharide fraction of fructans of native chicory inulin is about 30%. Such extracts may undergo hydrolysis and fractionation to produce a variety of ingredients that vary in their proportion of glucose, fructose, FOS and fructo-polysaccharides so as to perform a range of different technological functions. FOS can also be synthesised using fungal enzymes to produce compounds with a DP of 2-4 (Roberfroid and Delzenne, 1998). Rather than needing to deal with definitions which arbitrarily exclude some individual components such as inulobiose, it has been suggested that novel oligo/polysaccharide constituents such as synthesised fructan species should be classified according to their average DP (Cummings et al, 1997).

PHYSICAL PROPERTIES OF DIETARY FIBRE

The physiological effects of dietary fibre are dependent not only on chemical but largely on physical properties (Oakenfull, 1993). Some fibre components, particularly those that do not form energetically stable crystalline structures, are soluble in water although the time taken to dissolve in water is extremely variable. Almost all water-soluble polysaccharides produce viscous solutions which result from the physical interaction of the polysaccharide molecules in solution. Viscosity depends on the amount of 'space occupancy' of the molecules and the concentration at which they become entangled. The viscosity of dietary fibre in the gut has the greatest effect on gastric and small intestinal function, although not all soluble fibres form viscous solutions in the lumen, and such viscosity may differ from the viscosity measured before ingestion. Because of their small molecular size, fructans exhibit little viscosity.

Water holding or water binding capacity (terms often used interchangeably) are both measures of the ability of a fibre component to swell through absorption of water. Both soluble and insoluble fibre components have the ability to hold water particularly those components with sugar residues with free polar groups, however it is not possible to generalise about the correlation of water binding capacity with chemical structure of dietary fibre fractions. Oligofructose has no water binding capacity.

Cation exchange, organic compound absorptive properties for such constituents as lipids and bile acids are also features of certain types of dietary fibre, but it is not clear that *in vitro* demonstration or otherwise of these properties are translated to directly related *in vivo* effects, particularly as some types of fibre are degraded to some extent during passage along the digestive tract.

PHYSIOLOGICAL EFFECTS OF DIETARY FIBRE

Dietary fibre

The gastrointestinal and physiological effects of dietary fibre can be described at several levels of detail. The most obvious and agreed upon characteristic, is dietary fibre's indigestibility by the alimentary enzymes of the human gastrointestinal tract. The major effects from an intra-gastrointestinal perspective are summarised below. These effects are not produced by any one type of dietary fibre, but together they:

- retard gastric emptying;
- modulate (hasten or delay) total intestinal transit;
- slow starch hydrolysis and moderate glucose absorption;
- slow fat absorption;
- increase bile acid excretion;
- increase faecal bulk and thus decrease gastrointestinal pressure;
- adsorb mutagens;
- contribute to the lowering of intracolonic pH; and
- increase intracolonic concentrations of short chain fatty acids (SCFA) as a result of anaerobic microbial fermentation.

The extent to which these effects are mediated by the different types of dietary fibre is related to the chemical and thus physical properties of the dietary fibre constituents. The major physiological action of 'insoluble' dietary fibre is to increase faecal bulk. 'Soluble' fibre on the other hand, exerts a greater variety of effects; in general they:

- delay small intestinal transit;
- modulate glucose absorption; and
- promote anaerobic fermentation in the large intestine resulting in production of short chain fatty acids and lactate, gases such as hydrogen, methane and carbon dioxide, and a decrease in intracolonic pH, which in turn, affects the bacterial populations such that some increase in size and others decline.

Taken at a systemic level, these effects translate to:

- maintenance of the integrity of the bowel wall;
- facilitation of laxation, protection against and efficacy in treating constipation;
- modification of cholesterol and triglyceride metabolism; and
- improvement of glycaemic control in diabetic individuals.

Fructans

Fructans such as inulin and FOS are not digested in the small intestine as demonstrated from *in vitro* studies and studies using ileostomists (Roberfroid and Delzenne, 1998). They do not contribute to postprandial glycaemia. However, they exhibit some features attributed to some forms of dietary fibre. A consensus paper from European Community scientists (Van Loo et al, 1999) which is reproduced at Appendix 3, reviewed the analytical aspects and physiological properties of fructans relating to:

- bowel habit and gut flora;
- mineral absorption;
- lipid metabolism; and
- experimental effects in relation to colon cancer.

According to the consensus paper (Van Loo et al, 1999), inulin and FOS are highly fermentable by the colonic bacteria in the large intestine and exhibit the following effects:

- selective stimulation of enteric bifidogenic and lactobacillus bacterial growth;
- colonic production of short chain fatty acids particularly acetate and some butyrate; and
- increase in bacterial biomass that leads to a mild increase in faecal output comparable to soluble dietary fibres and resistant starch (up to 2g faecal weight increase/g FOS ingested at intakes 15-40g/day), and potential normalisation of stool frequency at doses of 10-15 g/day (Alles et al, 1996; Kleessen et al, 1997).

Research into systemic effects on lipid and glucose metabolism are yielding ambiguous results at present. There is promising evidence in adolescents for stimulation of apparent calcium absorption along the entire intestine (similar results with sugar beet fibre and possibly other fibres (Coudray et al, 1997; Van Loo et al, 1999). In summary, inulin and FOS exhibit characteristics in common with those produced by all types of dietary fibre in the small intestine (not digested in the small intestine; do not contribute to postprandial glycaemia) and by some types of dietary fibre in the large intestine (highly fermentable by the colonic bacteria; increase in biomass and faecal output; production of SCFA).

Potential adverse gastrointestinal effects

FOS intake has been studied to ascertain its potential for adverse gastrointestinal effects such as diarrhoea. It appears that up to 20-30g/day of inulin and FOS can be tolerated by most adults (Briet et al, 1995). The applicant stated that added fructan content of products is likely to be 1-3 g/serve, thus at least 7 serves of inulin containing foods would most likely be tolerated by adults. Note that inulin and FOS are currently permitted as food ingredients without the need for a laxative warning statement. If the dietary intake significantly increased, then the need for such a statement may be warranted.

HEALTH BENEFITS OF DIETARY FIBRE

Consumption of high fibre diets has been associated with maintenance of health status and reduction in risk of some diseases. Support for a protective effect of dietary fibre is most often associated with a reduction in risk of coronary heart disease, diverticular disease, and colo-rectal cancer, although the range and strength of evidence varies among the diseases. Dietary fibre intake appears also to be associated with improved glycaemic control in individuals with diabetes.

Evidence for these roles of dietary fibre is provided from epidemiological observations and clinical animal, and to a lesser extent, human studies. The evidence for the physiological action of dietary fibre as the active constituent however, is often difficult to separate from the consumption of foods in which dietary fibre is present. Recent large scale epidemiological studies have cast doubt on the popular notion that dietary fibre in the form of wheat bran fibre, or a low fat, high fibre diet can protect high risk groups from colo-rectal cancer (Schatkin et al, 2000), (Alberts et al, 2000)

The US Food and Drug Administration considered that health claims on food labels that linked dietary fibre *per se* with reduction in risk of heart disease or cancer was not warranted, however some claims have recently been permitted for foods containing specific fibre sources such as oats and psyllium husk.

Very little data is available on the longer term health effects of inulin and FOS.

CRITERIA TO DETERMINE THE REGULATORY STATUS OF A COMPONENT AS DIETARY FIBRE

Possible approaches

1 The first and in theory, simplest approach is to devise a suitable definition for dietary fibre containing elements of origin, chemistry and physiological effect, that from scientific observation and research, best characterise the dietary constituents; and to prescribe appropriate methods of analysis that measure such defined constituents in food.

The drawback to this approach is that the simplest analytical methods, which are usually preferred for regulatory purposes, only approximately measure the range of defined constituents. For example, the currently prescribed AOAC enzymatic-gravimetric method measures, in addition to a wide range of non-starch polysaccharides and lignin, only some resistant starch fractions, some higher fructans, gums and waxes, tannins, maillard products, but not FOS. Conversely, use of the Englyst method provides a more precise measurement of some defined components, but it is more a complex procedure.

To date, reliance in Australia on an imprecise analytical method as the only definition of dietary fibre has meant that any constituent incidentally measured by the prescribed method could be classified and declared as dietary fibre irrespective of its physiological effect. In practice, however, such constituents would comprise only a minor portion of the overall determined value. Adoption of a physiological definition in food regulation, as is the case in New Zealand, would not necessarily modify a dietary fibre value on the label as determined by analysis, but would signal the extent to which origin, chemistry and physiological effects should be established before approval of a new method of analysis was sought. It would also provide a clearer direction for future development of analytical methods that would more precisely reflect the definition.

The simplest physiological effect is indigestibility in the small intestine, which is a current feature of definitions of dietary fibre. The issue then becomes to what extent should physiological effects be described?

2 The second approach is to restrict the term 'dietary fibre' to represent those compounds in end-products consumed in typical amounts, that could be scientifically demonstrated to exert a range of one or more pre-defined physiological effects consistent with that shown for

conventional dietary fibre. Such an approach would require the development of a range of protocols for clinical trials to study the impact of the selected compound's known physiological effects compared with pre-defined endpoints. Clearly this approach could not be used for all conventional or native food sources of dietary fibre, but could be confined to novel fibre sources. This would introduce a dual system for acceptance of constituents as dietary fibre.

This second approach was taken by Health Canada to assess the **safety and efficacy** of novel fibres ie those that are not: traditionally consumed; chemically or physically processed; or extracted and highly concentrated from its plant source. Health Canada issued a *Guideline concerning the safety and physiological efficacy of novel fibre sources and foods containing them* (Health Canada, revised 1997) to examine the physiological efficacy of novel dietary fibres (presumably would include inulin and FOS extracted and concentrated from plant sources).

The Guideline selected four physiological effects for human clinical study related to one or more of: lipid metabolism, glucose tolerance, weight control, and laxation. The Canadians considered that the "physiological efficacy of the food must be demonstrated by scientific evidence" because the "physico-chemical nature of the dietary fibre in a food cannot reliably predict the potential benefit of that food". For example, for the Canadian laxation studies, the null hypothesis to be tested was that "the average daily fecal output with the diet including the test fibre is not greater than that of the diet without the test fibre, the negative control". The alternative hypothesis was that "the test fibre fecal output is greater than that of the negative control". It was considered that biological significance could be shown if "the observed change in average daily fecal output with the addition of the test fibre to the basic diet is at least 50% of that seen with the addition of the standard wheat bran (AACC course hard red wheat bran), the 'positive control'".

The underlying premise of the Canadian approach is that the meaning of 'dietary fibre' itself, as a nutrient, and as distinct from any nutrition- or health-related claim referring to dietary fibre, must convey a sense of specific physiological benefit. Of course, not all nutrients convey that same sense of benefit, for example, fat or sodium. The Canadian approach can also be used to substantiate claims of laxation benefit.

3 The third approach extends the Canadian approach from examination of physiological effects of novel fibres to investigation of reduction of disease risk. This approach however is impractical because of the time, cost and effort required in reaching a scientific conclusion, which is often multivariate in nature.

Consideration of appropriate approach

For the first approach, the extent of the origin and chemical divisions would need to be decided. Specifically, should the extent be confined to plant polysaccharides, or should animal sources be included within origin; and should oligosaccharides be included within the chemical division? Given that commercial inulin can sometimes span the divide between oligo- and poly-saccharide, and that the analytical methods for fructans and dietary fibre do not clearly delineate between the chemically appropriate but physiologically arbitrary division between oligo- and poly-saccharides, the ultimate decision would need to be practical and account for these realities.

For either the first or second approach, it is necessary to decide the scope of the physiological effects and the extent to which they should be demonstrated. Is it reasonable for such effects to be confined to indigestibility in the human small intestine, or should evidence exist in humans for conventional dietary fibre-like properties such as stool bulking and laxation, colonic fermentation, effects on glucose or lipid metabolism? and at what level of evidence?

Given the FAO/WHO Report has suggested that dietary fibre is a concept rather than an exact description of a dietary component, the selection of fibre-like properties for potential study would need to be broad. The questions then become:

1. How many properties need to be demonstrated and in what combination?
2. Should there be consistency of approach between naturally occurring, extracted or synthetic forms of potential fibres?
3. Would some naturally occurring indigestible carbohydrates already considered to be dietary fibre by virtue of being measured as such, need to be thoroughly examined in their native state as well as in non-native foods?

There is no easy or obvious answer to these questions. In considering the implementation of option 2, the balance between the amount of effort required to establish a system to answer these questions, compared with the potential for consumer deception, needs also to be borne in mind.

Two Consultants were engaged to assist the Authority in consideration of these issues.

CONSULTANTS' REPORTS

1 Physiological and consumer aspects

The Authority engaged CSIRO to review of the evidence for the performance of fructo-oligo/poly saccharides as dietary fibre. The Consultant's Report is given at Appendix 1. The Consultant was requested to define dietary fibre, noting that the food regulations currently define dietary fibre as that which is measured by AOAC procedure 985.29; to advise the Authority, after review of relevant scientific evidence, whether inulin and FOS should be classified for food labelling purposes as dietary fibre; also, to report on the consumer understanding of dietary fibre.

The Report first reviewed the physiological effects of dietary fibre and the current status of knowledge of its health effects. The health related physiological effects of inulin and FOS were then examined, but because very little data from human studies was available at the time of writing, the Report referred mostly to evidence from rat studies. Since that time, more evidence of physiological effects from human studies has been published, and a summary is given in Van Loo et al (1999) at Appendix 3. Very little data is available on the longer term health effects of inulin and FOS.

Dietary fibre

The Report concludes that on the basis of the evidence reviewed:

"Dietary fibre is the structural and exudative polysaccharides [DP > 10] of plants and lignin which are not digested in the human small intestine but pass into the large bowel. Other carbohydrates from any source which have equivalent physiological actions should be

classified as fibre equivalents. These actions include lowering of plasma cholesterol, lowering of glycaemic response or greater faecal bulking accompanied with fermentation by the large bowel microflora with production of SCFA [short chain fatty acids]. Any such change in description would need to be accompanied by appropriate analytical procedures to measure fibre and fibre equivalents.

[It is concluded] that inulin and fructooligosaccharide not be considered as contributor to dietary fibre. They might be considered as fibre equivalents if the case were to be supported by strong evidence of physiological actions in humans".

The Report did not put forward criteria against which to measure the strength of acceptable evidence, nor did it support as a criterion for the physiological action of dietary fibre, evidence of colonic fermentation alone, without other attendant physiological effects.

Dietary fibre equivalents

The consultant explained 'dietary fibre equivalents' as extracted or manufactured non-digestible carbohydrate components that are added to foods that may not necessarily be natural sources of such components. These new components are not covered by traditional botanico-physiological definitions of dietary fibre and may not be consumed as part of traditional plant sources of dietary fibre.

According to the consultant's definition and providing there was strong evidence of physiological action in humans, extracted inulin or FOS added to foods would be classified as dietary fibre equivalents. On the other hand, that part of naturally-occurring inulin (DP >10) measured by the AOAC method 985.29, would be classified as dietary fibre.

Consumer expectations of dietary fibre

The consultants were asked to assess Australian and New Zealand consumers' understanding of the term 'dietary fibre'. They report that from the limited range of relevant information available, consumers attribute a significant dietary fibre intake to assisting in the prevention or treatment of bowel problems and constipation, but more surprisingly, to playing a protective role in the development of bowel cancer. Such consumer expectations for the latter effect extend beyond the careful conclusions of many researchers in the field (Cassidy et al, 1994; Fuchs et al, 1999).

A technical function of some fructans is that they act as an effective fat replacer in table fat spreads as well as a prebiotic in cultured milk products and yoghurt. If fructans are classified as dietary fibre, fibre content claims in accordance the Authority's Code of Practice on Nutrient Claims could appear in labels and advertising of foods that are not natural sources of dietary fibre. The Consultant referred to the perception among consumers that 'the experts are always changing their minds'. Any regulatory change resulting in fructans being classified as dietary fibre, should be broadly supported by the wider nutrition community so as to:

- counter consumer misunderstanding;
- not further confuse or mislead consumers; and
- integrate the new information into general nutrition education.

2 Method of analysis for fructans separately or as dietary fibre

The Application submitted an analytical procedure for measurement of fructans as dietary fibre. This method is based on high performance anionic exchange liquid chromatographic measurement with electrochemical detection. It involves a 3-stage extraction/hydrolysis and measurement of resultant sugars. The method can be used as an extension to the AOAC method of analysis for dietary fibre in the currently prescribed in the Australian and New Zealand food regulations. The fructan method has been subject to international collaborative testing and was adopted as first action by AOAC in 1997 and given the reference number 997.08. Final action status was granted in 1999. BRI Australia Ltd was engaged as a consultant to assess the suitability of the submitted method of analysis for regulatory purposes. The consultant's Report is provided at Appendix 2.

Table 2 of the BRI consultancy Report lists several official methods of analysis for the measurement of dietary fibre. According to this Report, the currently prescribed method in the Food Standards Code: AOAC 985.29, measures the content of non-starch polysaccharides (NSP) + lignin + some resistant starch (RS3) (+ some highly polymeric fructans). The Report suggests that current methods should not be regarded as immutable, but rather serve as an interim compromise to provide an index of 'dietary fibre' content, until a more superior, nutritionally relevant and analytically validated methodology becomes available.

Some of the methods listed in Table 2 of the Report can be used to determine soluble and insoluble fibre fractions. However, the Report casts doubt on the relative unreliability of estimation of the soluble fraction. In addition, the strong relation of solubility in water to the physiological effects of 'insoluble' and 'soluble' dietary fibre has become less straightforward with evidence that certain fibres manifest some, but not all, of the classic effects such as fermentability and viscosity; or unfermentability and good water holding capacity. This is the reason that the FAO/WHO Report recommended that the terms ‘soluble’ and ‘insoluble’ were phased out.

The consultant's Report assessed the suitability for regulatory purposes of the applicant’s submitted method of analysis (AOAC 997.08), and concluded that the method fulfils requirements for accuracy and precision. It warns however, of the need to avoid double counting that fraction of the fructan component that is measured by both fructan and dietary fibre methods.

The Authority accepts the consultant’s advice that method of analysis AOAC 997.08 is suitable in a regulatory context for determination of total fructan content. However, when the method is used in conjunction with the prescribed method for dietary fibre, fructans incidentally measured by the latter method should be deducted from the combined result to ensure that fructan content is not double counted. This adjustment would not be necessary in cases where it is known that fructans are the only source of dietary fibre in the food. The Authority also recognizes AOAC 999.03, a simpler spectrophotometric method using a purified fructanase enzyme, as an alternate method for determination of fructan content.

The consultant also urged the Authority to adopt the method of Lee, AOAC 991.43 for the measurement of dietary fibre as an alternative to the existing prescribed method so as to allow the use of alternative enzymes and buffer. This method yields equivalent results to the prescribed method. The Lee method, however, also includes steps for the measurement of insoluble fibre and soluble fibre fractions that are summed to yield the dietary fibre result.

Although these methods measure soluble and insoluble dietary fibre fractions, the consultant advised that the results for these fractions were not reliable.

It should be noted that therapeutic goods such as fibre supplements are not subject to determination by the methods prescribed for foods. An example was seen recently where a powdered fibre supplement previously regulated as a therapeutic good and originally labelled as containing 76% fibre, was re-labelled as containing about 38% dietary fibre, when the decision was made to regulate the product as a food.

SURVEYS OF SCIENTIFIC OPINION

From a small, informal set of opinions obtained from nutrition scientists and dietitians by the applicant, and independently by the Authority, there appears to be an increasing acceptance in Australia of fructans as dietary fibre on the basis of chemistry and non-digestion in the small intestine. The requirement for demonstrated physiological effects or health benefits do not feature greatly in the reasons for such acceptance.

An international multiple-choice survey of some 150 professionals in the dietary fibre field from 30 countries, plus a followup survey was conducted between 1992 and 1994 to solicit opinions on the definition and analysis of dietary fibre (Lee and Prosky, 1995). A total of 70% respondents endorsed a physiological-chemical basis for the definition of dietary fibre; 43% of respondents supported a definition founded on polysaccharides and lignin escaping digestion in the small intestine. Six percent believed dietary fibre was non-starch polysaccharides only and 3% supported the definition as plant cell wall components. With respect to oligosaccharides, 57% of respondents supported inclusion of resistant oligosaccharides within a dietary fibre definition, whereas 32% were opposed. Also a majority of respondents (77%) did not favour making the term dietary fibre redundant in the scientific literature.

ANZFA Opinion Survey

ANZFA conducted an Opinion Survey between January – March 2000 via its website. Notice of the website Survey was placed in several stakeholder newsletters including ANZFA News. Fifty-one responses were received, the majority of which were from various industrial sectors, government, and the health/nutrition education profression. The results of the Survey are given at Appendix 5. Overall, the majority of responses outlined dietary fibre as:

- having beneficial physiological effects;
- being derived from plants;
- having a chemical composition of non-starch polysaccharides, lignin, resistant starch and non-digestible oligosaccharides;
- at least three degrees of polymerisation if a non-digestible oligosaccharide; and
- having a physiological effect of normalisation of stool frequency, colonic fermentation, faecal bulking, production of short chain fatty acids, moderation of blood absorption, and reduction in plasma cholesterol;.

AUTHORITY CONSIDERATION OF CONSULTANTS' REPORTS

The CSIRO Report must be considered in the light of the current regulatory context, Codex Standards and recent Authority decisions. At present, any constituent that is measured by the

AOAC prescribed method can be declared as dietary fibre. By default then, fibres such as isolated cellulose, pectin etc. currently added to foods for technological purposes would be measured as dietary fibre. Although the results of studies investigating these constituents or similar were available in the general scientific literature, no physiological criteria were established to assess such studies, nor was scientific documentation as to physiological effect required before regulatory permission was granted.

In its 1995 consideration of Application 244 - deletion of reference to crude fibre as a definition for fibre-increased bread, the Authority agreed that resistant starch was a form of dietary fibre. The Authority's assessment was based on consistency of performance of physiological effect with conventional dietary fibre and on that basis, the potential for health benefit as reported in the general scientific literature. Evidence was examined of physiological effects beyond small intestinal indigestibility such as fermentability in large intestine, production of short chain fatty acids, laxative effects, however no consideration was given to differentiating the different forms or origins of the resistant starch. The prescribed analytical method for label declaration of dietary fibre content, which only partially measures resistant starch, was not amended however because no methods of analysis were available at the time that had undergone collaborative testing.

Dietary fibre equivalents

The Authority accepts that the concept of dietary fibre equivalents may meet the needs of research nutritionists, however, it is unlikely that consumers reading food labels could differentiate between the subtlety of dietary fibre and dietary fibre equivalents. Using the consultant's example of retinol equivalents, this term is used in the scientific literature and food composition tables, but an alternate term – vitamin A is used in food labelling.

For regulatory purposes, the concept of dietary fibre equivalents would need to be either integrated into the concept of dietary fibre, or excluded from it altogether. The proposed definition for dietary fibre below would include dietary fibre equivalents because it does not differentiate between native or added sources of fibre; rather it relies on evidence for physiological effects.

AUTHORITY PROPOSAL

The Authority proposes to adopt the first approach described above, founded on definition and analytical method, because of its overall simplicity and previous success. It also has the advantage of consistency of approach with both the New Zealand food regulations and the Codex nutrition labelling guidelines.

It is proposed that the scope of physiological effect in the definition should rely on nondigestibility by endogenous enzymes in the human digestive tract as well as evidence for dietary fibre-like effects in the large intestine. This approach means that use of 'dietary fibre' on a food label for a candidate food constituent need not be based on prior evidence for a reduction in disease risk for that particular constituent. However, it is expected that reference to 'dietary fibre' in the context of a nutrition message or potential future health claim would be based on scientifically substantiated demonstrated physiological benefit.

The second approach was not favoured because it has only been applied to novel fibres, and relies on a small number of physiological effects that can be measured by clinical human study.

The study protocols need to be established in each case, including setting endpoints of physiological rather than just statistical significance. It would be very difficult to firmly and unequivocally establish such endpoints. In the Canadian example, results at least 50% of the positive control in a laxation test would need to be achieved for the test fibre to be considered dietary fibre. No explanation is given as to the choice of 50% as the cut off point.

The third approach as explained above was not seriously considered.

Proposed definition of dietary fibre for regulatory purposes

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 — 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
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:

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

Proposed acceptance of methods of analysis

The Authority accepts the consultant's Report and recommendations with respect to the applicant's submitted method to measure total fructans, now adopted as first action by AOAC (AOAC 997.08) and agrees that the method is suitable for regulatory purposes. When used in conjunction with the prescribed method for dietary fibre, some higher level fructans may be analysed by both methods. Adjustments would need to be made to ensure that those fructans are not double counted, before the results of the two methods could be summed to yield a final dietary fibre value.

The Authority also accepts that an AOAC alternate method of analysis for dietary fibre (AOAC 991.43) should be prescribed in the Australian *Food Standards Code* as already prescribed in the draft joint Code. Although reference was made in the joint Code to restricting these methods to determination of total dietary fibre, this has been deleted because more reliable methods are not available.

CONCLUSIONS

It is concluded that:

1 A definition of dietary fibre encompassing elements of origin, chemistry, and physiological effect should be developed, specifically that:

> 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.

2. Sufficient chemical and physiological evidence is available to demonstrate that the fructans inulin and FOS conform to the proposed definition of dietary fibre, and thus should be permitted to be declared on food labels as dietary fibre.

3. The analytical method of Lee AOAC 991.43 be adopted in the Australian *Food Standards Code* (as has been in the draft joint Code) as an alternative to the currently prescribed method AOAC 985.29 for the determination of 'total' dietary fibre as recommended in the second consultant's report (Appendix 3 to Attachment 2). This alternate method is also approved by Codex and gives manufacturers more flexibility in choosing an official method.

4. Fructan content of foods should be determined according to the prescribed analytical method, AOAC 997.08 (method submitted by applicant). Because both dietary fibre procedures AOAC 985.29 and AOAC 991.43 can incidentally measure up to 30% of fructan content, it is important to deduct such fructans from the dietary fibre result before it is combined with the result of AOAC 997.08, unless it is known that fructans are the only source of dietary fibre in the food. This ensures that any fructan content is not double counted.

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Appendix 1
Attachment 3

A277 - INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

CONSULTANCY REPORT 1

CSIRO DIVISION OF HUMAN NUTRITION

PHYSIOLOGICAL AND CONSUMER ASPECTS OF DIETARY FIBRE, AND OF FRUCTANS

MARCH, 1998

Appendix 2
Attachment 3

A277 - INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

CONSULTANCY REPORT 2

BRI AUSTRALIA LTD

SUITABILITY OF FRUCTAN METHOD OF ANALYSIS FOR REGULATORY PURPOSES

JANUARY, 1998

A277 - INULIN AND FRUCTOOLIGOSACCHARIDES AS DIETARY FIBRE

Van Loo J et al (1999) Functional food properties of non-digestible oligosaccharides: a consensus report for the ENDO project (DGXII AIRII-CT94-1095) ***Brit J Nutr*** **81:121 – 32**

Appendix 4
Attachment 3

Expert Working Group

1 Terms of Reference

To develop a definitional framework for dietary fibre to inform regulatory decisions about potential dietary fibre constituents

In developing such a framework, expert advice supported by appropriate evidence is sought on the following points:

1. Selection of an appropriate end point to decide the status of constituents as dietary fibre eg health benefit/reduction in disease risk, or demonstrated similar/equivalent physiological effects.

2. Selection and characterisation of the following elements in a definitional framework: origin, structure, chemical composition, health/disease/physiological effects appropriate to the selected end point.

3. The need for and selection of analytical methods suitable for regulatory purposes that measure constituents in accord with advice given under points 1 and 2.

2 Outcomes of Working Group deliberations

An Expert Working Group met on 12 July 2000 in Sydney to consider an appropriate definitional framework for dietary fibre. The Group's membership comprised the chair, Dr Alex Proudfoot, ANZFA's Medical Advisor, and eight nominees from invited Australian and New Zealand organisations and individual experts in the field of dietary fibre (see Attachment 3). Ms Jane Barnes, representing the Applicant, Orafti, was invited to make a presentation to the Group.

Members were asked to consider several elements in the definition of dietary fibre including its:

a) relation to health;
b) physiological actions;
c) dietary sources;
d) macro components;
e) chemical constituents; and
f) suitable analytical methods.

The agreed elements are shown on the work plan.

The Working Group summarised its deliberations by adapting a recent AACC definition as given in Prosky to the following:

Dietary fibre is that fraction of the edible part of plants and analogous carbohydrates and carbohydrate-based food ingredients that are resistant to digestion and absorption in the human small intestine, usually with complete or partial fermentation in the human large intestine. It includes polysaccharides, lignins, oligosaccharides, and associated substances such as the wax compounds, suberin and cutin. Dietary fibre exhibits one or more of the physiological actions: laxation, (faecal bulking and softening, increased frequency; and/or regularity), reduction in blood cholesterol and/or blood glucose.

The original AACC definition, which had been recently proposed after much international discussion via the internet as well as support at technical meetings in the United States during 1999, is given below.

Dietary fibre is the remnants of the edible part of the plant and analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the human large intestine. It includes polysaccharides, oligosaccharides, lignins, and associated substances. Dietary fibre exhibits one or more of either laxation, (faecal bulking and softening, increased frequency; and/or regularity), blood cholesterol attenuation, and/or blood glucose attenuation.

Analogous carbohydrates is defined as those carbohydrate-based food ingredients that are non-digestible and non-absorbable and which are similar to plant dietary fibre which most of the dietary fibre research has encompassed.
Associated substances include the wax compounds, suberin and cutin.

Analytical methods for dietary fibre were also generally discussed and it was recognised that for regulatory purposes, analytical methods needed to be rigorous, economical, and widely available. ANZFA's previous recommendations were supported i.e. that the current AOAC method 985.29 in the Australian and New Zealand food regulations be retained and that AOAC method 991.43 be considered as an alternative insofar as it measured total dietary fibre. The method of Champ[2] given in the FAO report *Carbohydrates in Human Nutrition*[8] was the best and simplest method for measurement of resistant starch.

The Expert Working Group recognised that such as definition would mostly be used to determine the regulatory status as dietary fibre of novel constituents similar to inulin, rather than constituents of whole plant foods. To make consistent determinations on the regulatory status of constituents as dietary fibre, the Expert Working Group recommended that criteria be developed in relation to each of the 3 listed physiological actions in the above definition.

The Expert Working Group acknowledged the future direction of the FAO report[3] and recommended that any change to regulations mirror community understanding of dietary fibre terms.

3 Membership of Expert Working Group

Dr Alex Proudfoot, Chairman
Ms Janine Lewis, Secretariat

Name	Organisation
Dr Geoffrey Annison	Australian Food and Grocery Council
Dr Ian Brown	Starch Australasia Ltd
Associate Professor Lynnette Ferguson	Auckland Cancer Society Research Centre
Associate Professor Gwyn P Jones, PhD	Faculty of Health and Behavioural Sciences, Deakin University
Dr John Monro	NZ Institute for Crop and Food Research
Dr Rosemary Stanton	Nutritionist
Dr David Topping	CSIRO Health Sciences and Nutrition
Emeritus Professor Stewart Truswell	University of Sydney

Appendix 5
Attachment 3

Summary of results of ANZFA Dietary Fibre Survey									
Total number of respondents = 51									
Respondent profile	**No.**	**%**	**Notes**						
Q1- Type of Work									
Academic/industrial research	14	27%	15 respondents nominated more than one type of work						
Cereal food industry	6	12%							
Dairy food industry	2	4%							
Food ingredients industry	3	6%							
Other food industry	4	8%							
Government	7	14%							
Health/nutrition educator	13	25%							
Consumer	0	0%							
Other	2	4%	Pharmaceutical industry						
Q2- Country of residence									
Australia	46	90%							
New Zealand	4	8%							
USA	1	2%							
Survey questions	**No.**	**%**	**Notes**						

Q1- Endpoint for definition			More than one answer acceptable						
Risk reduction	9	18%							
Physiological effects	34	67%							
Other	12	24%	Comments ranged from analytical definition only; indigestibility in small intestine only; to presently described and future physiological effects; to querying physiological effects as a basis for definition of DF						
Q2- Dietary source			More than one answer acceptable						
Plant cell walls	46	90%							
Plant cells	43	84%							
Microbiological	21	41%							
Animal	12	24%							
Extracellular components	22	43%							
Other	7	14%	Other intracellular carbohydrate material; analogous cho-based food ingredients; anything else not digested by human alimentary enzymes that adds to faecal bulking; absurd to include plant cells - this would mean that DF would include all food plants						
Q3A- Chemical composition			More than one answer acceptable						
Non-starch polysaccharides only	2	4%							
NSP + Lignin	34	67%							
NSP + Resistant starch	36	71%							
NSP + Waxes and associated plant material	25	49%							
NSP + Non-digestible oligosaccharides	36	71%							
NSP + Protein and/or lipid that escapes SI digestion	9	18%							

Other	5	10%	All components of plant cell walls; Lactose (for some people); all cho not digested in SI; restrict definition to plant cell walls and exclude isolates of cellular substances						
Q3B- Degree of polymerisation if selected non-digestible oligosaccharides, n=36									
DP = 2	5	14%							
DP = 3	13	36%							
DP = 4	0	0%							
DP = 5	0	0%							
DP = 6	1	3%							
DP = 7	0	0%							
DP = 8	1	3%							
DP = 9	0	0%							
DP = 10	2	6%							
No response from eligible respondents	14	39%							
Q4- Reason for response given in Q3			General support for restriction to cho and lignin species. Some disagreement with need to specify DP. FAO/WHO cutoff DP cited in support of some responses.						
Q5- Physiological effects	*Some*		*None*		*Not Sure*		*No answer*		
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	
Weight control	31	61%	9	18%	6	12%	5	10%	
Faecal bulking	45	88%	0	0%	1	2%	5	10%	
Normalisation of stool frequency	46	90%	1	2%	0	0%	4	8%	
Complete colonic fermentation	24	47%	7	14%	12	24%	8	16%	
Partial colonic fermentation	42	82%	1	2%	3	6%	5	10%	
No colonic fermentation	16	31%	15	29%	8	16%	12	24%	
Production of short chain fatty acids	39	76%	1	2%	6	12%	5	10%	
Moderation of glucose absorption	39	76%	1	2%	5	10%	6	12%	

Reduction of plasma cholesterol	37	73%	1	2%	5	10%	8	16%	
Reduction in fasting triglycerides	17	33%	4	8%	20	39%	10	20%	
Interference/assistance mineral absorption	35	69%	2	4%	7	14%	7	14%	
Other: comments suggested energy source; effect on gut structure and barrier function; stimulate immune response; altered gut transit and activation of ileo-colonic break; modified steroid excretion; moderation blood insulin; modulation colonic microflora	6	12%	0	0%	4	8%	41	80%	
Q6- Reduction of risk of which diet related diseases	**No.**	**%**	**Notes**						
Colo-rectal cancer	41	80%	More than one answer acceptable						
Coronary heart disease	37	73%							
Constipation	44	86%							
Diverticular disease	34	67%							
Irritable bowel syndrome	23	45%							
Inflammatory bowel disease eg Crohn's	15	29%							
Diabetes	32	63%							
Other	7	14%	Obesity, dental decay; gallbladder disease; haemorrhoids; evidence for disease risk not available in most cases						
Q7- Phase out terms soluble and insoluble DF?									
Yes	21	41%							
No	7	14%							
Not sure	10	20%							
Maybe	9	18%							
No response	4	8%	Refer to 'cold water' solubility; not discrete categories of solubility and fermentability; useful term for consumers; trend to partitioning into DF components that need public education to be useful						
Q8- Submitted definitions of DF									
1. Any food or food component being either plant, animal or combination of both which is not digested (hydrolysed) by the alimentary enzymes of man and adds to faecal bulking									

2. Any undigested CHO
3. As an educator in the nutrition field I find students and the public confused on definitions of fibre but relate best to the concept of soluble and insoluble fibre (not the chemical structures which we as scientists relate to). They relate the term dietary fibre to insoluble fibre that is not fermented in the colon. I suggest we go with this as it is easily understood. Oligosaccharides and other fermentable fibres should be referred to as soluble fibre.
4. Carbohydrate from plant, animal or bacterial sources, and other plant derived materials (e.g. lignin), that resist digestion and absorption in the small intestine, but reach the colon where they are fermented to a greater or lesser extent
5. Components of food which resist hydrolysis by human digestive enzymes and perform a physiological function in the bowel, which contributes to improved health status.
6. Dietary fibre is a combination of non-starch polysaccharides, resistant starch and lignins which have a physiological or functional role in the human body - see diagram on survey form
7. Dietary fibre is composed of plant cell walls and components obtained from these walls. It also includes non-starch polysaccharides from sources other than plant cell walls" (Harris and Ferguson, 1993, Mutat. Res 290, 97-110
8. Dietary fibre is that portion of any carbohydrate material that exits the small intestine of normal healthy individuals
9. Dietary fibre is the structural, exudative and storage polysaccharides of plants + lignin which are not digested in the human small intestine but pass into the large bowel. Other carbohydrates from any source which have equivalent physiological actions should be classified as fibre equivalents. These actions include laxation, lowering of plasma cholesterol, lowering of glycaemic response or fermentation by the large bowel microflora. Any such change in description would need to be accompanied by appropriate analytical procedures to measure fibre and fibre equivalents.
10.Dietary fibre refers to edible plant parts and analogous carbohydrate based food ingredients which
11.Edible carbohydrates and associated substances that are resistant to hydrolysis by human alimentary enzymes
12.I agree with the definition of Trowell. However, it would be necessary to include analytical methods for enforcement and compliance.
13. I couldn't put it better than Trowell on page 1
14. I would like to see the term dietary fibre removed from legislation and replaced with more descriptive terms such as "non starch polysaccharides" and "resistant starch" and "indigestible protein"
15, Indigestible substances in foods which include saccharides in their structure, and which usually have at least one of a variety of effects on the functioning of the digestive system (pretty loose!)
16. Indigestible components of plant foods - structural components and resistant carbohydrates
17. Material from plant cells that is incompletely digested by enzymes of the human digestive system
18. My feeling is that it should be physiological/functional rather than chemical/analytical. Something along the lines of: edible plant* material resistant to hydrolysis by the alimentary enzymes of humans. *Ideally I'd also like to include analogous animal materials (such as keratin or collagen) but I think this would be departing too far from the current understanding of dietary fibre
19. Non-digestible carbohydrate includes NSP; Resistant Starch; Fructo-oligosaccharides, e.g. inulin; Other resistant oligosaccharides, e.g. raffinose etc. But where does that leave lignin? I.e., not a carbohydrate
20. Our definition is restricted to carbohydrate materials and is: "Dietary Fibre is that that portion of any carbohydrate material that exits the small

intestine of normal healthy individuals".
21. Physiological definition: Plant material that resists digestion by human alimentary enzymes. It includes substances of unique chemical structure, characteristic physical properties and individual physiological effects. Except for lignin, all are carbohydrates in nature. They are broken down by enzymes of gastrointestinal bacteria to give, by fermentation, H2, Ch4, CO2 and short chain fatty acids" (Kritchevsky, 1988. (I think it is importaot to avoid definitions of dietary fibre that generalise about effects, particularly in relation to the diet-related diseases.) Chemical analysis: The sum of oligosaccharides, nonstarch polysaccharides, starch and lignin derived from edible plant material not hydrolysed by the endogenous enzynes of the human digestive tract. (For labelling purposes a chemical definition is required. Researchers in this area must be more specific about the exact nature of the 'dietary fibre' under study.)
22. Plant cell material that is not broken down by digestive enzymes in the small intestine and passes to the colon.
23. Plant cell walls
24. plant sourced fibrous material, either soluble or insoluble, which helps in the bulking of faecal matter and facilitates intrabowel micro-organisms necessary for effective digestion
25. Please see my min-essay on the subject and 4 attachments, (A),(B), (C) and (D)
26. Remnants of edible parts of plants and or equivaltent/analogous carbohydrate based ingredients which resist digestion and absorption in the large intestine. There must be complete or partial fermentation in the large bowel. DF includes polysaccharides, oligosaccharides, lignin and other similar plant substances.
27. Roughage and gums
28. See also recent discussion promoted on the www by the American Assoc. Cereal Chemists. Ultimately there will be no single definition that is acceptable to all but I believe there needs to be (1) analytical definition e.g. fibre as measured by an agreed protocol - for food labelling purposes; (2) a definition derived from Trowell's description used in public information for consumers; (3) redundancy of the term dietary fibre in the professional and scientific literature
29. Similar to the Trowell definition
30. Substances from a plant origin which are not digestible in the human GI tract. These substances must be present in the plant in significant quantities
31. That portion of any dietary carbohydrate material that exits the small intestine and arrives in he large bowel of normal healthy individuals
32. Vegetable product not digested in the human digestive tract. Possibly should have some impact on Physiology of Humans

A277 - INULIN AND FRUCTOOLIGOSACCHARIDE AS DIETARY FIBRE

SUMMARY OF PUBLIC COMMENT

Submission	Position	Comments
South Australian Health Commission	Require more information Support	i) Require more information on the nutritional significance of inulin and oligofructose before could support declaration of these as dietary fibre in Nutrition Information Panel (NIP); ii) The definition of carbohydrate in NIP should be changed to exclude dietary fibre. Also supports the assignment of specific energy factors for soluble and insoluble dietary fibre.
Victorian Food Standards Committee of Department of Health and Community Services	Require more time	
Health Department of WA	Oppose	i) No evidence presented of collaborative testing of the method of analysis for inulin and oligofructose. Will also jeopardise the recommendation to replace a crude fibre method by the prescribed AOAC dietary fibre method for the assessment of the fibre content of fibre-increased bread; ii) Disagrees with applicant that the term 'total carbohydrate' is not meaningful; if dietary fibre were analysed and quoted separately, then a 'by difference' calculation would still need to be done; iii) Mandatory declaration of dietary fibre would impose enormous cost on industry; the extra information provided to the consumer is likely to be of little value; iv) It would be dishonest to label inulin and oligofructose as dietary fibre as they are not composed of a glucose polymer such as cellulose.
CAFTA Victoria, Inc	Oppose	i) Does not support application in present format. Would prefer a total review of all types of dietary fibre with respect to definition and methods of analysis;

	Support	ii) The definition of carbohydrate should be revised for labelling purposes.

Bread Research Institute of Australia Inc	Qualified support Support	i) A definition for dietary fibre should be based on chemical composition and physiological effects and extended to account for soluble and insoluble dietary fibre; ii) Inulin and oligofructose should be defined as dietary fibre, more specifically, soluble dietary fibre for purposes of nutrition labelling. However, there are limitations on the availability and acceptance of a reliable quantitative analytical method for these substances in foods. The method appears to be acceptable for foods formulated with commercially available inulin or oligofructose, but it may not be adequate for determination in other foods such as those rich in pectins; iii) Provision should be made for inulin and oligofructose to be claimed as dietary fibre but this should be optional rather than mandatory. The presently prescribed AOAC method for total dietary fibre should be retained but provision should be made for the use of AOAC or other validated methods to support the declaration of dietary fibre fractions in a NIP. This is because the current definition of dietary fibre by a single prescribed method of analysis in the Code may be a constraint to product development and consumer information; iv) The current NIP format is particularly confusing in that the optional declaration of dietary fibre is not nested under 'Carbohydrate - total' and therefore it is not readily apparent that its content contributes to the total carbohydrate content; v) Need to decide upon an agreed definition of carbohydrate for labelling purposes - either total carbohydrate, or available carbohydrate. The NIP format should then reflect the agreed meaning. This decision should take into account: usefulness for the consumer, potential consistency with the Australian food composition tables, practicality of analytical methods for enforcement purposes, current approaches in place overseas, the wider review of NIP format, optional declaration of dietary fibre and flexibility in level of detail and use of appropriate analytical methods; vi) The allocation of energy factors for total dietary fibre when this is the only dietary fibre value stated (6 -7 kJ/g was nominated in this case), or separate factors for soluble and insoluble dietary fibre, or other specific factors where these are scientifically validated and the amounts in food are known. However, the applicant's suggested factors for insoluble and soluble fractions are questioned.

Goodman Fielder	Support Qualified support Suggest Dispute	i) Dietary fibre should be listed in NIP in the same way as sugars, that is, nested under 'Carbohydrate - total'; ii) Classification of substances that have the physiological effects attributed to dietary fibres being included in that classification, however there should be consensus throughout the scientific community. Once broad support is obtained for inulin and oligofructose to be regarded as dietary fibre, then the proposed extension to the analytical method would be supported after being collaboratively tested. However, acceptance of methodological variations that measure specific dietary fibre fractions should not be confined to inulin and oligofructose; iii) As neither a large list of specific energy factors for individual fractions or a single or dual energy factors for total or soluble and insoluble dietary fibre will meet all requirements, it is suggested that the Authority raise a proposal to develop an approach to the general determination of energy factors otherwise there could be a never ending list of applications for new fibre sources; iv) Dispute the factor of 4kJ/100g for inulin and oligofructose based on values provided by the agents for the commercial product, instead a factor of 6kJ /100 g is suggested.
Uncle Tobys	Support Oppose Suggest	i) The classification of inulin and oligofructose as dietary fibre however other substances with the dietary fibre action should also be included within that classification; ii) Support the revision of the definition of total carbohydrate to exclude dietary fibre; iii) Disagree with the proposed energy conversion factors for soluble dietary fibre, and questions the value nominated for insoluble dietary fibre; iv) That the Authority collaborate with recognised experts such as the CSIRO Division of Human Nutrition.
Axiome Pty Ltd on behalf of Pfizer Food Science Group	Suggest	i) The definition of dietary fibre should be based on nutritional and physiological effects and not analytical or physico-chemical properties. The Authority should consider adopting the supplied definition of dietary fibre for labelling purposes from the report of the European food industry ad hoc working group on dietary fibre; ii) The entry in the NIP for total carbohydrate should be changed to reflect available dietary fibre ie mono- and disaccharides, digestible oligosaccharides and starch, dietary fibre would then be a separate entry;

	Support Suggest Propose	iii) Support the inclusion of inulin and oligofructose within the definition of dietary fibre but the definition should be broadened to include 'resistant oligo- and polysaccharides' such as polydextrose; iv) In addition to AOAC method for total dietary fibre, other validated methods for dietary fibre components should be permitted to be used; v) In light of polydextrose being accepted within the definition of dietary fibre for labelling purposes in a small number of countries, and the availability of a specific analytical method for polydextrose, the redefinition of dietary fibre should include polydextrose.
Dietitians Association of Australia	Oppose	i) Should not adopt an analytical method that has yet to be verified by collaborative testing. AOAC methods should be retained.