FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

2-04
17 March 2004

FINAL ASSESSMENT REPORT

APPLICATION A495

POLYDEXTROSE AS DIETARY FIBRE

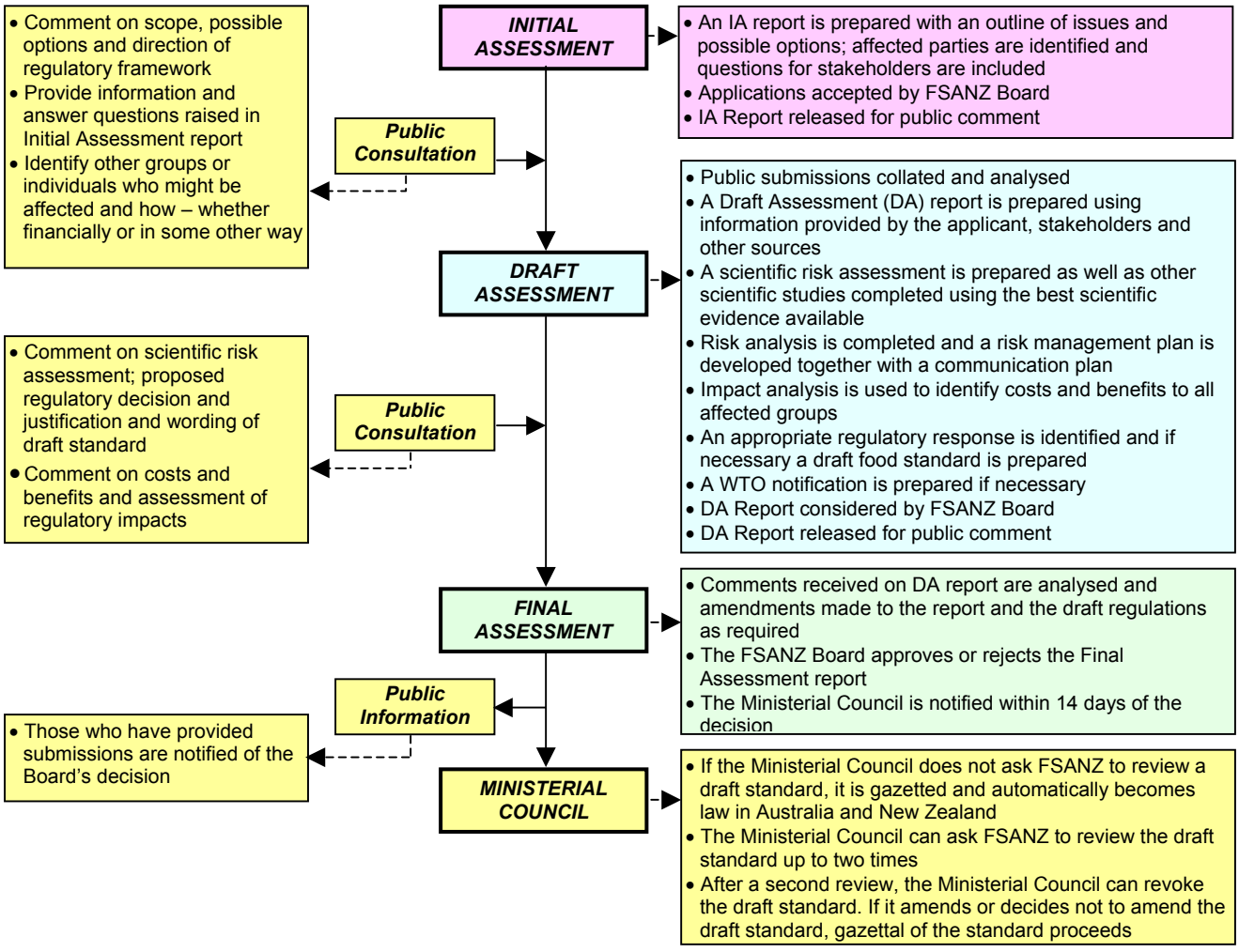
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of the Application and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application from Axiome Pty Ltd on behalf of Danisco A/S on 28 March 2003 seeking to amend Standard 1.2.8 – Nutrition Information Requirements of the *Australia New Zealand Food Standards Code* (the Code) to recognise Polydextrose polymer as a dietary fibre by including a specific method of analysis for dietary fibre in foods containing Polydextrose (AOAC method 2000.11 Polydextrose in Foods by Ion Chromatography).

Regulatory Problem

Standard 1.2.8 – Nutrition Information Requirements defines dietary fibre and prescribes methods of analysis to determine the total dietary fibre, and some specifically named fibre, content of food. This Standard currently does not permit a nutrition information statement to recognise Polydextrose polymer in the calculation of total dietary fibre content.

Objective

The specific objective of Application A495 is to ensure that the amendment to Standard 1.2.8 protects public health and safety to the appropriate level as included in section 10 of the FSANZ Act.

Issues

Several issues have been identified as important in meeting the objectives of this Application, and in assessing the regulatory status of Polydextrose polymer as dietary fibre:

- *Classification of Polydextrose as dietary fibre*
  Consideration of whether Polydextrose polymer should be considered as dietary fibre is fundamental to the assessment of this Application, as it will determine the most appropriate regulatory approach.

- *Dietary issues*
  Polydextrose can be used in a wide variety of foods at concentrations ranging from 2% –30% and 95% in the case of confectionery. If AOAC 2000.11 is accepted as a method of analysis in the Code, it is likely that the number of food products presenting as a source of dietary fibre will increase in Australia and New Zealand, and nutrition education may need to account for different sources of dietary fibre.

Options

There are two options for addressing this Application:

Option 1 *Maintain the status quo by not including a new method of analysis of Polydextrose polymer as dietary fibre in Standard 1.2.8.*

Option 2 *Include specific regulation in Standard 1.2.8 for a new method of analysis of dietary fibre specifically for foods containing Polydextrose.*

Impacts

The conclusion of the impact analysis is that **Option 2**, **to include specific regulation in Standard 1.2.8 for a new method of analysis of dietary fibre specifically for foods containing Polydextrose**, is the preferred option taking into account the definition of dietary fibre, matters raised by submitters and the Regulatory Impact Statement (RIS). Some of the specific considerations in reaching this conclusion were as follows:

- FSANZ is satisfied that Polydextrose meets all the requirements of the definition of dietary fibre. Foods containing Polydextrose are also required under Standard 1.2.3 – Mandatory Advisory Statements and Declarations Table 2 to clause 5, to carry a laxation statement where the concentration is more than 25 g/100g of food.

- Polydextrose is already regulated as food and permitted under Good Manufacturing Practice.

- After consideration by the Joint FAO/WHO Expert Committee on Food Additives, Polydextrose has been given no ADI status, that is, there is no upper tolerable limit of intake.

Consultation

A total of 14 submitters made comment to the Draft Assessment Report. Of these submitters, 10 unconditionally supported Option 2, two submitters supported Option 1, maintain the status quo. One submitter considered that there should be another round of public comment on the completion of a safety assessment report, one submitter considered it appropriate to hold a decision around the Application until the policy for health claims has been released. A summary of submissions is available at Attachment 2.

Conclusion and Statement of Reasons

FSANZ agrees to amend Standard 1.2.8 – Nutrition Information Requirements - to recognise Polydextrose polymer as a form of dietary fibre by including a specific method of analysis for dietary fibre in foods containing Polydextrose, (AOAC Official Method 2000.11) for the following reasons:

1. Polydextrose polymer meets the definition of dietary fibre given in Standard 1.2.8 because it:

    - is resistant to digestion in the small intestine and is partially fermented in the large intestine; and
    - promotes the physiological effect of laxation.

2. Polydextrose is listed as a permitted additive in Standard 1.3.1, Schedule 2 - Miscellaneous Additives in accordance with Good Manufacturing Practice (GMP) in processed foods specified in Schedule 1 of the Standard.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Axiome Pty Ltd on behalf of Danisco A/S on 28 March 2003 seeking to amend Standard 1.2.8 – Nutrition Information Requirements of the *Australia New Zealand Food Standards Code* (the Code) to recognise Polydextrose polymer as a dietary fibre by including a specific method of analysis for dietary fibre in foods containing Polydextrose (AOAC method 2000.11, Official Methods of Analysis of AOAC International' 17th edition 2000, Polydextrose in Foods by Ion Chromatography). The method can be used as an adjunct to the more traditional method of analysis of dietary fibre: AOAC 985.29. It involves enzyme treatment of a filtrate to remove any interfering oligosaccharides then high-pressure anion exchange chromatography to quantitate a molecular weight fraction of Polydextrose polymer.

Polydextrose has similar technological properties to sugar and functions in food as a humectant, bulking agent, stabiliser and texturiser. The Code permits Polydextrose in food by Standard 1.3.1, Schedule 2 - Miscellaneous Additives in accordance with GMP in Processed Foods specified in Schedule 1 of the Standard. FSANZ recognises that Polydextrose can be also used as a food ingredient when present in significant quantities (editorial note to clause 4, Standard 1.3.1) as a replacement for sugar and/or starch in food where lower energy content is desired. During the consideration to permit Polydextrose in Standard 1.3.1, a safety assessment was undertaken as detailed in section 5.3 of this Final Assessment report.

2. Regulatory Problem

2.1 Current Regulations – Standard 1.2.8

Standard 1.2.8 – Nutrition Information Requirements defines dietary fibre and prescribes methods of analysis to determine both the total dietary fibre and specifically named fibre content of food, such as inulin.

The methods of analysis for dietary fibre are prescribed in subclause 18(1) as follows:

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

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

Table to subclause 18(1)

Column 1	Column 2
Food Component	**Method of analysis**
Total dietary fibre	Section 985.29 of the AOAC, 17th Edition (2000), or Section 991.43 of the AOAC, 17th Edition (2000).
Inulin and fructo-oligosaccharide	Section 997.08 of the AOAC, 17th Edition (2000).
Inulin	Section 999.03 of the AOAC, 17th Edition (2000).

2.2 Requested Amendment to Standard 1.2.8

The Applicant has stated that current methods of analysis for dietary fibre prescribed in the Table to subclause 18(1) do not accurately measure the dietary fibre content of some substances in foods. Polydextrose polymer is one such substance. The Applicant has therefore applied to have the Polydextrose polymer recognised as a dietary fibre and to subsequently amend the Table to subclause 18(1) of Standard 1.2.8 to include a new method of analysis for Polydextrose polymer in foods.

In considering the regulatory problem, this paper will therefore assess the issues of whether Polydextrose polymer meets the definition of dietary fibre in Standard 1.2.8, and also whether it can be quantified using the existing methods of analysis listed in the Table to subclause 18(1) of Standard 1.2.8.

3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet the primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objective of Application A495 is to ensure that the amendment to Standard 1.2.8 protects public health and safety to the appropriate level as included in section 10 of the FSANZ Act.

4. Background

4.1 Historical Background

There is no universal consensus on a definition for dietary fibre, and often this term has referred only to the insoluble and indigestible parts of plants, or 'roughage'. Recently however, other substances that are soluble or can be partially digested have been shown to produce the physiological effects that are associated with traditionally accepted forms of dietary fibre.

Inulin and fructo-oligosaccharides (FOS) were considered by FSANZ, and subsequently approved as dietary fibre under Application A277. At that time, there was no existing definition of dietary fibre in the Code. As part of the consideration of Application A277, a general definition was developed and included in Standard 1.2.8.

4.2 International Background

The Applicant states that Polydextrose is permitted as a food additive in more than 50 countries.

4.2.1 Codex Alimentarius

The Codex Guidelines on Nutrition Labelling (FAO/WHO, 1995) define dietary fibre as the edible plant or animal material, that is not hydrolysed by the endogenous enzymes of the human digestive tract as determined by an agreed upon method. The Codex definition does not specify any analytical methods for the determination of dietary fibre for nutrition labelling.

The *Codex Committee on Nutrition and Foods for Special Dietary Uses* has not agreed on a definition of dietary fibre for the purposes of the *Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents* (CX/NFSDU 02/3). It was agreed at the 25th session of this Committee (2003) that the matter should be further considered by an electronic working group convened by France and Sweden, including proposals for a definition of dietary fibre, method of analysis and conditions for fibre content.

4.2.2 United States

The definition of dietary fibre for labelling purposes is based on methods of analysis. Polydextrose has obtained pre-market approval in the US as an additive in particular foods and as such, was subsequently self-determined by Danisco to have Generally-Recognised-As-Safe (GRAS) status in the United States. Polydextrose is permitted for use in food with no limitation other than current GMP (21 CFR – 170.36). Currently low level nutrition claims are permitted in the US without pre-market approval. Manufacturers are currently labelling foods containing Polydextrose as containing fibre without any comment from the US Food and Drug Administration.

The US Food and Nutrition Board, National Academy of Science, has recently developed a definition for total dietary fibre as part of the development of the Dietary Reference Intakes series.

It is not envisaged that this definition will impact on recommended levels of intake, however, it may help to delineate sources of dietary fibre and associated potential health benefits and have a positive impact on nutrition labelling. The proposed US definition of dietary fibre is:

> '*Dietary Fibre* consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants.
>
> *Functional Fibre* consists of isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.
>
> *Total Fibre* is the sum of Dietary Fibre and Functional Fibre.'

4.2.3 Japan

According to the Applicant, Polydextrose is considered to be a food, rather than a food ingredient/additive, and it is widely used in fibre-fortified health foods. It is also approved under the Japanese Food for Specified Health Use (FOSHU) regulations. FOSHU products can carry specific health claims. According to the Applicant, FOSHU products containing Polydextrose are permitted to use the claim 'provides improved intestinal function'.

4.2.4 Other countries

According to the Applicant, Polydextrose is permitted to be labelled as a dietary fibre in Argentina, Brazil, Benelux, Egypt, Indonesia, Japan, Korea, Poland, Spain, Singapore and Taiwan.

5. Relevant Issues

Several issues pertinent to the assessment of the regulation of Polydextrose have been identified:

- a determination of whether Polydextrose polymer should be considered as dietary fibre;
- the appropriateness of the method of analysis;
- the safety issues associated with Polydextrose use;
- the nutritional issues associated with dietary fibre; and
- the dietary consideration of Polydextrose in food.

5.1 Polydextrose and the Definition Of Fibre

The definition of dietary fibre is provided in Standard 1.2.8 as follows:

> **dietary fibre** means that fraction of the edible part of plants or their extracts, or synthetic analogues that -
>
> (a) are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and
>
> (b) promote one or more of the following beneficial physiological effects -

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

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

A determination of whether Polydextrose polymer should be considered as dietary fibre is fundamental to the assessment of this Application, as it will determine the most appropriate regulatory approach. For a food or ingredient to be considered as dietary fibre under the Code, it must meet each individual component of the definition outlined above.

The following sections assess Polydextrose against the definition of dietary listed above, incorporating information from the available scientific literature, and comments from submitters to the Draft Assessment report.

5.1.1 Physical attributes of Polydextrose

Commercially available Polydextrose is a randomly bonded glucose polymer produced by thermal polymerisation of glucose *in vacuo*. The random polymerisation results in highly branched structures in which the α-1,6 bond predominates, with small amounts of glucose and sorbitol. About 13% of the polymer is present as α-1,4 linkages, which are hydrolysed by mammalian enzymes in the small intestine. However, upon hydrolysis of these bonds, lower molecular weight Polydextrose polymers are produced that pass through to the large intestine where they are either fermented or excreted. Polydextrose has an average degree of polymerisation of 12 and an average molecular weight of 2000. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) compendium of specifications requires that Polydextrose contain a minimum of 90% polymer on an ash free and water free basis.

5.1.1.1 Submitter comments

Two submitters commented on the physical attributes of Polydextrose. The Australian Consumers' Association (ACA) interprets Polydextrose as being derived from starch with a structure radically different from starch, while the Dietitians Association of Australia (DAA) made reference to the descriptions of fibre (total, dietary and functional) proposed in the United States in relation to dietary requirements as described in section 4.2.2 of the Draft Assessment Report. DAA is of the opinion that considering the increase in number and availability of functional fibres permitted in the Code, that this system of labelling would be useful for health professionals and consumers. DAA requests that FSANZ considers the breakdown of fibres for use in the Nutrition Information Panel (NIP) in the future as they consider that this approach would be consistent with the requirement to break carbohydrates and fats into their respective components and list them in the NIP.

5.1.1.2 Assessment

FSANZ considers that Polydextrose meets the physical definition of fibre as it is a carbohydrate analogue derived from glucose with a degree of polymerisation greater than two. FSANZ recognises that more manufactured food ingredients with dietary fibre effects are becoming available, in addition to those extracted from plant sources.

The current regulations for declaration in the Nutrition Information Panel allows for subcategories of nutrients to be listed such as for dietary fibre, however this issue could be further considered in developing regulations on nutrient claims.

5.1.2 Polydextrose in the small intestine

The Polydextrose ingredient contains a small amount of glucose and sorbitol as by-products to the manufacturing process as shown in the certificate of analysis in Attachment 3. Studies of the digestive fate of Polydextrose are often unclear as to whether the Polydextrose investigated is the commercial ingredient (containing some glucose and sorbitol) or the polymer measured by the proposed method of analysis. This is important in deciding whether the substance as analysed strictly conforms to the definition of dietary fibre in the Code.

In support of the classification of Polydextrose polymer as dietary fibre, information has been cited indicating that the vast majority of commercial Polydextrose is indigestible with only 1.5% hydrolysed in the small intestine. Proposal P177 – Derivation of Energy Factors, completed in 1999, also concluded that 1.5% of Polydextrose Ingredient is digested in the small intestine[1]. There are no human studies that directly measure the small intestinal digestion of Polydextrose, however a report for Pfizer Inc[2] concluded that in two studies examining the effect of 50 g Polydextrose on blood glucose levels, the resulting insignificant rises in blood glucose were due to the small amount of free glucose present in the commercial Polydextrose product.

Because it can be assumed from the details given in these scientific papers that the commercial ingredient was the subject under investigation, there is some uncertainty about the origin of the absorbable fraction, particularly whether the absorbable fraction is comprised solely of the free glucose and sorbitol. However, another study measuring the resistance of Polydextrose to enzymes in the small intestine used radioactive labelled Polydextrose. Analysis of urinary radioactivity indicated that humans absorb a maximum of 0.03% of orally consumed Polydextrose polymer[3].

From this study it is clear that the amount of Polydextrose absorbed is extremely small. Furthermore, because the AOAC method 2000.11 has an extraction process as its first step, the absorbable fraction of the Polydextrose ingredient does not contribute to the analysed amount of Polydextrose polymer. Polydextrose is generally used in small amounts in foods, and that, given the method's average level of recovery of 94%[4], describing up to 1.5% of potentially digestible Polydextrose as fibre is within the limits of analytical and methodological error.

5.1.2.1 Submitter comments

A submission by the Applicant has made the following comments in reference to the small amounts of Polydextrose that can be absorbed in the small intestine:

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[1] Derivation of Energy Factors; Full Assessment Report; Proposal P177, ANZFA, 1999, p 35

[2] Bar A. Bioresco Bioresearch Management and Consulting Ltd. Polydextrose – Review on metabolism and energetic utilization prepared for: Pfizer Inc. July 1992

[3] Figdor S, Bianchine J. Caloric utilization and disposition of (^{14}C) Polydextrose in man. J. Agric. Food Chem. 1983, 31: 389-393

[4] Craig SAS, Holden JF, Khaled MY. Determination of Polydextrose in foods by ion chromatography: collaborative study. Journal of AOAC International. 2001, 84: 472-478

- ‘unless specifically stated otherwise, it can be assumed that the Polydextrose used in these studies was commercial Polydextrose. This is based on the situation that the results need to be able to be referenced to the commercially available form’; and

- ‘it would be clearly expected that any modified/purified form of Polydextrose used in a study would be clearly identified in the study abstract/report. This is in fact the case when specially prepared radio-labelled Polydextrose was used in several specific studies and this was clearly identified in the study abstracts/reports.’

5.1.2.2 Assessment

The literature suggests that 0.03% Polydextrose polymer and 1.5% of the Polydextrose ingredient is digestible in the small intestine however it is uncertain as to whether such amounts are due to the glucose and sorbitol by-products of the Polydextrose ingredient or to the digestion of the Polydextrose polymer itself. Due to the generally small amounts of Polydextrose currently used in foods and the limitations of the performance of any analytical method, FSANZ considers that for all practical purposes, Polydextrose polymer satisfies the criterion that requires dietary fibre to be indigestible in the human small intestine.

5.1.3 Polydextrose in the large intestine

In addition to being resistant to digestion and absorption in the small intestine, dietary fibre may also be either completely or partially fermented in the large intestine.

Fermentation of carbohydrates by colonic microflora is an anaerobic process producing gas (CO_2, H_2, CH_4) and organic acids, among which lactic acid and short chain fatty acids (SCFA) are found in colonic contents. Gases are utilised by bacteria, or absorbed then excreted in breath, or excreted in stools. Lactic acid either accumulates or is further metabolised into SCFA. The majority of SCFA are absorbed and only a small fraction is found in stools. Bacteria source energy from SCFA and the resultant biomass is subsequently excreted in stools.

The largest human study conducted to investigate the effects of Polydextrose on physiological function was by Jie *et al*[5] who studied a group of 120 Chinese people. The study comprised four groups, each with 30 participants. Members of the groups consumed either 0, 4, 8 or 12 g of Polydextrose from a powder dissolved in warm water. The results showed an effect on SCFA profile as a result of Polydextrose intake compared to baseline with statistical difference being observed in the amounts of acetate, butyrate and isobutyrate in those consuming either 8 or 12 g/day. Significant changes in faecal microflora were also noted, such that ingestion of 4, 8 or 12 g/day resulted in a decrease in the *Bacteroides* species and an increase in the *Lactobacillus* and *Bifidobacterium* species.

Wang and Gibson’s[6] smaller *in vitro* study of six faecal samples also showed an increase in colonic bacteria over a 24-hour period. Polydextrose was added to samples in order to give a final concentration of 0.7% (w/v).

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[5] Jie Z, Bang-Yao L, Ming-Jie X et al. Studies on the effects of Polydextrose intake on physiologic functions in Chinese people. Am J Clin Nutr. 2000, 72: 1503-9

[6] Wang X, Gibson G. Effects of the in vitro fermentation of oligofructose and inulin by bacteria growing in the human large intestine. J Appl Bacterial. 1993, 75: 373-80

5.1.3.1 Submitter Comments

None of the submissions made to the Draft Assessment commented on the indigestibility of Polydextrose in the large intestine.

5.1.3.2 Assessment

Polydextrose has been shown in both *in vitro* and *in vivo* studies to be at least partially fermented in the large intestine. Therefore, Polydextrose satisfies this part of the definition that is not obligatory, but is consistent with most types of recognised dietary fibre.

5.1.4 Determination of physiological effects

The definition of dietary fibre in clause 1 of Standard 1.2.8 currently has no quantified eligibility criteria that underpins the determination of beneficial physiological effect (laxation; reduction in blood cholesterol; or modulation of blood glucose) required to meet the definition of dietary fibre.

FSANZ has previously considered eligibility criteria for determining dietary fibre status, during Application A277. Laxation was the only effect with defined criteria developed at that time; other criteria were to be developed as the need arose. The laxation effect defined in Application A277 was: more than 1 g of faecal wet weight increase per gram of ingested FOS in either a food matrix or supplementary form. Inulin and FOS were shown not to be digested in the small intestine, to be partially or totally fermented in the large intestine, and to have a laxation effect (1-2 g faecal wet weight increase/g FOS ingested at intakes 15-40 g/day), and were subsequently regarded as dietary fibre for nutrition labelling and associated purposes.

To meet the definition of dietary fibre in Standard 1.2.8, it need only be demonstrated that Polydextrose polymer can promote one of the required physiological effects; it is unnecessary for Polydextrose polymer to demonstrate a promotion all three physiological effects.

The Applicant states that Polydextrose polymer promotes the beneficial physiological effects referred to in the definition of dietary fibre. A number of studies investigating the potential beneficial physiological effects of Polydextrose polymer, specifically on laxation, reduction in blood cholesterol and modulation of blood glucose have been provided in support of these arguments. These studies are examined below.

5.1.4.1 Laxation

Currently, the following foods containing Polydextrose are required to carry an advisory statement to the effect that excess consumption of the food may have a laxative effect:

- foods containing Polydextrose in amounts greater than 25 g/100 g; or
- foods containing Polydextrose in addition to Lactitol, Maltitol, Maltitol syrup, Mannitol or Xylitol in combined amounts at a level of or in excess of 10 g/100 g.

The criterion for laxation effect defined for FOS in Application A277 for dietary fibre, was more than 1 g of faecal wet weight increase per gram ingested in either a food matrix or supplementary form. Changes in gastrointestinal function are most pronounced for non-soluble fibres.

There have been only a few studies investigating the laxative effect of Polydextrose polymer. Jie *et al*[5] investigated the effects of Polydextrose ingested at levels of 0, 4, 8 and 12 g/day over 28 days. Each group had 30 participants. Dry stool weight was increased by more than 1 g/g of ingested Polydextrose in all three study groups when compared to baseline. Diets were provided and eaten at the study clinic during the study on pre-intervention days – 4 to – 1 and during the study on days 26-28. Wet stool weight was increased by more than 2 g/g ingested Polydextrose in all groups. In another study of 12 people consuming 30 g/day Polydextrose for 10 days results displayed a significant increase in faecal weight compared to the control period ($p<0.05$) however the authors did not provide actual weight increases or discuss if the weights were dry or wet faecal weight[7]. A second study where seven subjects consumed 30 g of Polydextrose a day over two seven-day periods showed an increase in daily dry faecal weight of more than 30 g[8]. Endo *et al*[9] investigated the effects of 15 g/day Polydextrose ingestion on dry faecal weight. The results showed a significant increase in dry stool weight when ingesting Polydextrose compared to baseline, but did not quantify the absolute measure of the increase in weight.

5.1.4.1.1 Submitter comments

The submission to the Draft Assessment Report from the Applicant points out that 18 human clinical studies on the physiological effect of Polydextrose have been undertaken with nine of these studies having been published. Many of these studies discuss laxation as being an observed side effect of Polydextrose intake, however, other than broad comments suggesting a laxation effect, only the three of the four studies cited above discuss the effects in any quantifiable detail. The Applicant also suggests that, as Standard 1.2.3 of the Code requires all foods containing Polydextrose where the concentration is greater than 25 g/100 g, either alone or in combination with some polyols, to carry an advisory statement about laxative effects, FSANZ must have been previously satisfied that Polydextrose does promote laxation.

5.1.4.1.2 Assessment

One study of 120 participants demonstrated an increase in dry faecal weight of at least 1 g/g of ingested Polydextrose, and wet faecal weight of at least 2 g/g of ingested Polydextrose. The results of this study were confirmed by two smaller studies that also showed a significant increase in faecal weight as a result of Polydextrose ingestion. Polydextrose therefore meets the criteria of an increase in laxation as originally established in Application A277.

5.1.4.2 Blood cholesterol

Two studies into the effects of Polydextrose on serum cholesterol levels show apparently conflicting results.

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[7] Tomlin J, Read N. A comparative study of the effect on colon function by feeding ispaghula husk and Polydextrose. Aliment Parmacol Therap. 1988, 2: 513-9

[8] Achour L, Flourie B, Briet F et al. Gastrointestinal effects and energy values of Polydextrose in healthy non-obese men. Am J Clin Nutr. 1994, 59: 1362-8

[9] Endo K, Kumemera M, Nakamura K et al. Effect of high cholesterol diet and Polydextrose supplementation on the microflora, bacterial enzyme activity, putrefactive products, volatile fatty acid (VFA) profile, weight and pH of the feces in healthy volunteers. Bifidobact. Microflora. 1991, 10: 53-64

Saku *et al* [10]gave subjects 15 g/day of Polydextrose for two months. They measured serum cholesterol fractions at baseline, months one and two, and at month three after a wash out period. Results showed no effect on serum total cholesterol, serum LDL cholesterol or triglycerides after two months of Polydextrose ingestion. A significant decrease in serum HDL cholesterol, Apo A-I, and Apo A-II ($p<0.01$) were observed during the ingestion periods with levels normalising to baseline after the one month washout period.

The only other study found investigating the effects of Polydextrose on blood cholesterol in humans is written in Chinese, with an English abstract and tables[11]. The abstract states that a decrease in total cholesterol and LDL cholesterol was observed in 10 healthy university students after 18 days of consuming 10 g of Polydextrose ($p<0.05$). Serum triglycerides were not changed. No details were available as to the methodology of the research due to their being no English interpretation.

5.1.4.2.1 Submitter comments

None of the submissions made to the Draft Assessment commented on whether Polydextrose affects blood cholesterol levels.

5.1.4.2.2 Assessment

There is no conclusive evidence of an effect of Polydextrose on serum cholesterol, and for the purposes of Application A495, Polydextrose can thus be assessed as not promoting a decrease in blood cholesterol.

5.1.4.3 Blood glucose

The glycaemic index (GI) of Polydextrose was measured by Jie *et al*[5] in 30 subjects each consuming 0, 4, 8 and 12 g Polydextrose with 50 g of glucose. The GI from ingestion of 4 g was 101. Ingestion of 8 g resulted in a GI of 95, and of 12 g a GI of 88. The authors concluded that Polydextrose is non-glycaemic. They suggested that ingestion of Polydextrose results in a reduction in glucose absorption from the intestine, possibly resulting from increased bulking and viscosity in the bowel and a subsequent delay in gastric emptying.

McMahon[12] investigated the effects of Polydextrose on plasma insulin and glucose kinetics in 10 subjects with non insulin dependent diabetes. Standard glucose tolerance tests were administered after ingestion of 0 and 50 g of Polydextrose with either 0, 50 or 100 g of glucose. There was no effect from Polydextrose on insulin or glucose kinetics.

[10] Saku K, Yoshinaga K, Okura Y et al . Effects of Polydextrose on serum lipids, lipoproteins and apolipoproteins in health subjects. Clinical Therapuetics. 1991, 13: 254-258

[11] Liu S, Tsai C. Effects of biotechnically synthesized oligosaccharides and Polydextrose on serum lipid in the human. Journal of the Chinese Nutrition Society. 1995, 20: 1-12

[12] McMahon G. Tulane University School of Medicine (1974): Study number III (unpublished) – To examine the effects of modified Polydextrose on plasma insulin and glucose kinetics in maturity onset diabetes during the standard glucose tolerance test. (vol 10, Pfizer Food Addition Petition to FDA 1979)

5.1.4.3.1 Submitter comments

Two submitters (one industry, one health professional) commented on the value of Polydextrose in the manufacture of low GI foods. The Applicant advised in their submission that the ingredient Polydextrose has a glycaemic index (GI) of between 4 and 7 (compared to glucose having a GI of 100) when tested at Sydney University's Glycaemic Index Research Services. Two submitters agreed that Polydextrose does have a place in the manufacture of low GI foods.

5.1.4.3.2 Assessment

Polydextrose appears to be non-glycaemic. Evidence suggests that ingested Polydextrose also produces a concomitant reduction of glucose absorption in the small intestine..

5.1.4.4 Conclusion

The definition of fibre requires a food to show at least one of several physiological effects. Polydextrose meets the criteria determined for laxation, and in doing so fulfils this requirement of the definition of dietary fibre.

5.1.5 Overall Conclusion on Polydextrose and the Definition Of Dietary Fibre

FSANZ has determined that Polydextrose is a synthetic analogue made from glucose and sorbitol that is resistant to absorption in the small intestine, promotes laxation and is an oligosaccharide with a degree of polymerisation greater than two. As such, Polydextrose fulfils all parts of the definition of dietary fibre as described in Standard 1.2.8.

5.2 Method of Analysis

The Applicant claims that the Prosky method (AOAC 985.29) prescribed in the Table to subclause 18(1) of Standard 1.2.8 measures significantly less than 10% of Polydextrose as dietary fibre, and that the true total dietary fibre content of a food containing Polydextrose cannot be determined by this method. Prosky[13] states that a number of substances, including Polydextrose polymer, meet the AOAC physiological definition of dietary fibre (including resistance to digestibility in the small intestine and faecal bulking), yet are not analysed as dietary fibre by AOAC 985.29, due to a failure to measure substances with 10, 11 and 12 degrees of polymerisation.

The Applicant proposes that a new method of analysis be included in the Table to subclause 18(1) of Standard 1.2.8 to measure a specific dietary fibre (Polydextrosepolymer) content of foods for the purposes of the nutrition labelling of dietary fibre. The proposed new method is known as 'AOAC Official Method 2000.11 – Polydextrose in Food by Ion Chromatography'. The Applicant has provided information on an AOAC collaborative study conducted to validate this method[4], which has been adopted as First Action by AOAC International (discussed in detail in the sections below).

[13] Prosky L. What is dietary fibre? Journal of AOAC International. 2000, 83: 985-7.

AOAC 2000.11 method can be used as an adjunct to the AOAC 985.29 method of analysis of dietary fibre. The method involves extracting the Polydextrose polymer from foods with hot water. After centrifugation and filtration, the filtrate is treated with an enzyme mixture to remove any oligosaccharides that can interfere with the analysis. High-pressure anion exchange chromatography with electrochemical detection (HPAEC-ED) is then used to quantitate a molecular weight fraction of Polydextrose polymer.

It is not possible for manufacturers to use the proposed new method to determine the total dietary fibre content of any food: only the Polydextrose polymer content. In order to determine the fibre content of foods from sources other than Polydextrose polymer, another method such as the AOAC 985.29 would be necessary. If the value obtained from the AOAC 2000.11 method was added to other values for the total dietary fibre content of a food, then a true result would be obtained for nutrition information purposes. However, as with other calculations for individual dietary fibre components, the prohibition against the double counting of dietary fibre components would apply as detailed in subclause 18(2) of Standard 1.2.8.

Craig[14] states that Polydextrose gives no significant total dietary fibre value by AOAC methods other than AOAC 2000.11. Therefore, the value obtained from the AOAC 2000.11 method can be added to the total dietary fibre value determined by current AOAC methods of measuring dietary fibre without concern of double counting.

5.2.1 AOAC method validation program

The AOAC International administer an Official Method Program for validation of methods of analysis. Typical validation processes take at least 12 months and between eight and 10 independent laboratories are required. Methods are submitted together with the collaborative study protocol to the AOAC. The AOAC then appoints a study director and who sends the protocol out to independent referees and the AOAC methods committee for review. As required revisions are made and the study protocol is resubmitted. Once accepted the study director conducts the collaborative study, and forwards the study results to the Method Committee. The committee makes comments and the committee chair summarises these for the study director. Finally the method is either rejected or approved as First Action by the Methods committee[15].

Methods that are approved as First Action are listed in the 'Official Methods of Analysis of AOAC International' publication, currently in its 17th edition. Once listed in this publication, methods are approved by the AOAC for widespread use.

Two years after completion of the First Action status, the method is reassessed for adoption as Final Action. Final Action status can only be given if the AOAC has not received any information regarding significant problems with the practical implementation of the method, and is subject to a two-month period of public comment. First Action methods are rarely denied Final Action status: it is only where there is evidence of a serious failure in the methods implementation that Final Action status is denied[16]. Such methods are repealed by the AOAC and removed from Official Methods listings. Evidence of minor problems will usually result in a correction of the method and subsequent approval as Final Action.

[14] Craig S, Holden J, Khaled M. Determination of Polydextrose in Foods by Ion Chromatography: Collaberative Study. Journal of AOAC International. 2001, 84: 472-478.
[15] www.aoac.org/vmeth/oma_program.htm
[16] Ladeji O (18/2/2004); Program Manager - Method Validation, AOAC International; personal communication.

5.2.1.1 Collaborative study for AOAC method 2000.11

In order to meet the requirements of the AOAC, methodologies are required to undergo a collaborative study. Eight laboratories used the AOAC 2000.11 assay to measure the Polydextrose polymer content of seven foods, typical to Polydextrose use[17]. Duplicate paired samples containing between 2 and 95% Polydextrose were blinded and given to the laboratory along with a standard. In addition to Polydextrose, ingredients known to interfere with other methods (inulin, maltodextrin and pectin) were incorporated into the test foods. Repeatability standard deviations ranged from 3.93 to 9.04%; reproducibility standard deviations ranged from 4.48 to 14.06%. The average percentage of recovery was 94%. This is consistent with the Applicant's claim that Polydextrose is between 90 and 95% pure (see Attachment 3). The associate referee to the paper recommended that the method be adopted to First Action as a result of this study.

5.2.1.2 Final Action

The AOAC 2000.11 method was due to have Final Action status granted in 2004. However, AOAC International has deferred a decision on the Final Action status of AOAC 2000.11 (and a number of other dietary fibre related methods) until 2005 so that an expert panel can be convened to review the general approach to analysing dietary fibre. Final Action status is given after two years of First Action Status as a means of reviewing the method in question, with the principal aim of assessing it practical implementation. As no problems have been reported with the practical application of AOAC 2000.11 since its approval as First Action, it is highly unlikely that Final Action status will be denied once the AOAC International resumes its discussions on the method[16]. AOAC has advised that deferral of consideration of Final Action should not be regarded as a negative reflection on the functioning of the method.

5.2.2 Submitter comments

The New Zealand Food Safety Authority (NZFSA) commented in their submission that in their view the collaborative process is not yet complete and thus that it would be inappropriate for the AOAC 2000.11 method to be included Standard 1.2.8.

5.2.3 Conclusion

FSANZ considers the AOAC validation program to be sufficiently rigorous to permit the use of methodologies in the Code after First Action status has been conferred and indications of untroubled laboratory implementation.

5.3 Safety Issues

The submission from the NZFSA expressed the view that another round of public comment should be undertaken that includes a safety assessment and dietary intake risk assessment. The submissions from the Australian Food and Grocery Council and Unilever commented that a safety assessment was unnecessary due to the assessments undertaken in the initial approval of Polydextrose use.

[17] Craig SAS, Holden JF, Khaled MY. Determination of Polydextrose in foods by ion chromatography: collaborative study. Journal of AOAC International. 2001, 84: 472-478

On consideration, FSANZ has determined that a safety assessment of Polydextrose is not necessary. During the development of the joint Code, Proposal P150 – Australian New Zealand Standard for Food Additives – considered the safety of all additives permitted in the Code. Safety assessments were not undertaken for those additives for which an acceptable daily intake level (ADI) had previously been established. Polydextrose had previously been allocated an ADI 'not specified' by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA)[18]. The Committee defines this term to mean that, on the basis of the available data (chemical, biochemical, toxicological, and other), the total intake of the substance, arising from its use at the levels necessary to achieve the desired effect does not represent a hazard to health. On this basis, polydextrose is included in Schedule 2 in Standard 1.3.1 – Food Additives – and has broad permissions in a variety of foods. No further review of its safety is considered necessary as part of this application.

5.3.1 Conclusion

No safety assessment has been undertaken for Polydextrose as it had previously been considered by FSANZ and deemed safe for use with an ADI 'not specified'.

5.4 Nutrition Issues

The digestibility and beneficial effects of Polydextrose polymer and dietary fibre are discussed earlier in this report. Dietary fibre has been shown to alter the bioavailability of nutrients during digestion, especially the minerals calcium, iron and magnesium where a reduced absorption has been observed[19].

Soluble dietary fibres such as pectins and gums form viscous solutions and gels, which can delay stomach emptying and digestion; these have been shown to reduce absorption of some nutrients including glucose. The Applicant has provided evidence that Polydextrose polymer, as a soluble fibre derived from starch, does not form a highly viscous gel and therefore will not compromise nutrient intake in the typical manner of such fibre types.

Phytates and oxalates are found within plant foods at various levels, and thus commonly associated with dietary fibre. These substances can influence the digestive process through their property of binding to, and thus impairing the absorption of various nutrients. The phytate and oxalate content of manufactured Polydextrose is unknown, however as processed and refined substances it is expected that they only contain minor amounts of phytates and oxalates, if any at all.

5.4.1 Conclusion

It is not expected that Polydextrose will have any adverse effects on the nutrition of consumers.

[18] WHO Geneva 1987, Evaluation of certain food additives and contaminants, Technical report series 759.
[19] Wisker E, Nagel R, Tanudjaja T, Feldheim W. Calcium, magnesium, zinc and iron balance in young women: effects of a low-phytate barley-fibre concentrate. Am J Clin Nutr 1991, 54(3) 553-9

5.5 Dietary Considerations

Polydextrose has been used in a wide variety of products internationally. Information from the Applicant indicates that it is possible to add Polydextrose to foods as illustrated in Table 1.

Table 1 Potential foods and levels of use of Polydextrose

Food Category	***Specific Food Item***	***Typical use level %***
Baked Goods	Muffins	2%
	Cup cakes	12%
	Cookies	14%
	Muesli bars	Up to 30%
Dairy Products	Ice cream/frozen desserts	3%
	Low fat yoghurt	3%
	Fromage fraise	2%
	Soft serve	7%
	Whipping cream	4%
	Low fat chocolate milk	2%
Confectionery	Sugar based high-boil	Up to 95%
	Chocolate/products	5%
	Other confectionery products	Up to 30%
Other Products	Fruit spreads	13%
	Barbecue/fruit sauces	16%
	Beverages	Up to 10%

The Applicant notes that the details shown in Table 1 are based on formulations developed by the manufacturer and, although these details provide guidance on potential food applications and use levels, they do not necessarily represent Polydextrose-containing food products on the market. Furthermore, Polydextrose is often used in combination with other food ingredients such as polyols in commercial food products and consequently the levels used may be significantly lower than some of the levels indicated above. This is particularly relevant for confectionery products and baked goods.

The Applicant also states that 'since Polydextrose was originally approved in Australia and New Zealand, food products containing Polydextrose that have become commercially available include cake mixes, fruit pies, ice cream, chocolate, jellies (soft confectionery), toppings, fruit spreads and muesli bars. The actual use levels in these products are not available but would be consistent with the levels indicated above. Some of these products have since been withdrawn from the market'.

Should this Application be approved, the Polydextrose polymer content of foods could be taken into account when determining a food's eligibility to bear a label claim referring to dietary fibre content in accordance with the Australian Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC, 1995). In New Zealand, there are no regulations in food law that determine the eligibility of a food to carry a dietary fibre claim. Previously claims were regulated under the New Zealand Food Regulations 1984, however these Regulations were repealed on 20 December 2002 when the Code solely came in to effect. Claims are now assessed in accordance with the New Zealand *Fair Trading Act 1986*.

The Australian CoPoNC criteria for claims for a source of fibre are:

- Fibre content not less than 1.5 g per serve permits a source claim;
- Fibre content not less than 3 g per serve permits a good source claim; and
- Fibre content not less than 6 g per serve permits an excellent source claim.

Claims relating to fibre under CoPoNC criteria are discouraged on foods having a significant fat content. Where 30% or more of the food energy is derived from fats, there must be a statement on the label drawing attention to the fat content of the food in the nutrition information panel.

Based on Table 1 above, any product with a serve size of more than 100 g, could qualify for at least a 'source of fibre' claim. Some products with smaller serve sizes could also qualify to make these claims, depending on the level of use of Polydextrose, and the actual serve size. Standard recipe ice-cream and chocolate are not eligible to make fibre claims under the CoPoNC criteria.

In December 2003 the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) released policy guidelines for nutrition, health and related claims. FSANZ is commencing implementation of the new policy in the Code via the food standards setting process. Issues relating to the conditions or criteria that determine the eligibility to bear nutrient content claims, including for dietary fibre, will be addressed as part of the development of regulation of nutrient claims. In assessment reports for Proposal P234 - 'Criteria and Conditions for Making Nutrition Content and Related Claims' previously released for public comment by FSANZ, the criteria for fibre claims were based on the CoPoNC criteria, with the addition of a clause that states 'nutrition claims must not be made in relation to the fibre content of a food unless a food derives less than 10 % of its average energy content from saturated fatty acids and trans fatty acids'.

If a method of analysis for Polydextrose is included in the Table to subclause 18(1) in Standard 1.2.8, it is possible that the number of food products claiming to contain dietary fibre would increase in Australia and New Zealand, due to the new ability to declare Polydextrose polymer as dietary fibre. This incentive for adding Polydextrose may also extend to foods that are not traditional or natural sources of dietary fibre. Such a modification to the food supply may have an impact upon nutrition education by expanding the concept of 'dietary fibre' for consumers and nutrition educators; however using Polydextrose in these foods may also provide an alternative means of increasing the population intake of dietary fibre (as described in the Code) separate from other existing public health strategies.

5.5.1 Submitter comments

Submitters were invited to comment or provide data relevant to the use of Polydextrose in foods and/or levels of consumption of Polydextrose. Four submitters, DAA, ACA, NZFSA and Queensland Public Health services, expressed concern regarding the potential impact on obesity if foods high in fat were permitted to carry a dietary fibre source claim. These submitters expressed concerns that high fat products would be marketed as being healthy and thus cause confusion amongst consumers. One of the four submitters expressed concern that the number of highly processed, energy dense foods claiming to be a source of dietary fibre would increase. Conversely, the Applicant stated in their submission that the number of foods containing Polydextrose is unlikely to increase as there are technical considerations when formulating foods with Polydextrose, and recipe formulation is often required.

Polydextrose is also unsuitable for use in all processed foods, and may not be present at minimum levels required for fibre claims. The Applicant is of the belief that approval of a fibre claim for Polydextrose would not result in a vast increase in general food fibre claims.

In their submission the DAA asked that FSANZ consider not permitting claims of any type until the Health and Nutrition Claims proposal has been finalised. Their interpretation is that the nutrition claim proposal may result in foods being permitted to make source claims only if such foods are a natural source of the nutrient. Proposal P234 Nutrient Claims, does not make reference to a food being a natural source of fibre for content claims unless the claims is a 'fibre increased', 'fibre enriched' or 'more fibre' claim in which case foods would be required to contain, prior to enrichment, at least 1.5 g of dietary fibre per serving.

5.5.2 Assessment

FSANZ will be developing regulation for nutrition content claims and the issue of conditions for nutrition-related claims will be considered as part of that process. Proposal P234 referred to by the DAA is likely to be abandoned with the recent policy guidance on health and nutrition related claims given by the ANZFRMC.

5.5.3 Conclusion

There is the potential for Polydextrose to be used in foods to a level that would qualify for a fibre content claim. However, due to the technological restrictions of using Polydextrose in a recipe, it is not expected that it will be used as an ingredient in a wide number of foods. Currently there is no regulation of the use of nutrient and health claims and manufacturers often use the Australian CoPoNC criteria as a guideline. These criteria disencourage the use of a fibre claim on a food that has an undesirable fatty acid composition. FSANZ notes that several submitters did have concern over the integrity of the food supply as a result of this application, the perceived number of foods in which Polydextrose can be, and the potential confusion to consumers as Polydextrose is not a 'natural' fibre.

6. Regulatory Options

Two options were considered for progressing Application A495 at Draft Assessment:

1. *Maintain the status quo by not including a new method of analysis of Polydextrose polymer as dietary fibre in Standard 1.2.8.*

To maintain the *status quo* by not including a new method of analysis would mean that Polydextrose polymer would not be recognised as dietary fibre for nutrition labelling purposes.

2. *Include specific regulation in Standard 1.2.8 for a new method of analysis of dietary fibre specifically for foods containing Polydextrose.*

Under this option, Polydextrose polymer would be recognised as dietary fibre for labelling purposes, by recognition of the 'AOAC Official Method 2000.11– Polydextrose in Foods By Ion Chromatography' as an acceptable method for determining the Polydextrose polymer content of foods.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this Application are: **consumers**; Australian and New Zealand importers and manufacturers of Polydextrose and foods containing Polydextrose who make up the **industry**; Australian and New Zealand **public health officials/professionals**; and the **Governments** of New Zealand and Australia.

7.2 Cost-Benefit Assessment of the Regulatory Options

This analysis assesses the immediate and tangible impacts of current food standards under Option 1, and the potential for growth in the market for Polydextrose and products containing Polydextrose under Option 2.

7.2.1 Option 1 – Status quo

7.2.1.1 Consumers

The impact on consumers from this option is likely to be neutral. The restriction of current regulatory arrangements that prevent manufacturers from claiming Polydextrose polymer as a source of dietary fibre is unlikely to be known by consumers.

However, the scope for claiming dietary fibre content of a food may be restricted under this option, thus limiting the range of increased fibre foods recognised by consumers. Nevertheless consumers currently benefit to some degree from the dietary fibre functionality of Polydextrose that is present in some foods.

The AFGC considers that this option will mean that consumers will not be able to easily identify all agreed sources of fibre.

7.2.1.2 Food industry

There is a potential disadvantage to industry in not permitting Polydextrose polymer as a potential claimable source of dietary fibre in foods. Those manufacturers whose products contain Polydextrose will incur an opportunity cost through a lost marketing potential. The extent of this potential loss is, however, unclear and could be quite small, particularly when the lack of a dietary fibre claim has not restricted the use of Polydextrose in a range of foods.

7.2.1.3 Public health professionals/officials

The impact on public health professionals and officials from this option is likely to be neutral. Public health professionals currently have the option of acknowledging to the public the fibre content of foods manufactured using Polydextrose. Also there will be no need for public health education strategies to address the potential of number of foods that are traditionally poor sources of dietary fibre that may be eligible to make fibre content claims.

7.2.1.4 Government

There are no identified impacts for government agencies and institutions from not including a new method of analysis for dietary fibre, as this option maintains the *status quo*.

7.2.2 Include specific regulation in Standard 1.2.8 for a new method of analysis of dietary fibre specifically for foods containing Polydextrose

7.2.2.1 Consumers

Consumers will benefit under this option, as they will have access to a wider choice of products containing dietary fibre, potentially resulting in an increased dietary fibre intake. It is also possible that a new range of food products containing Polydextrose may create a level of consumer confusion with respect to current public health nutrition education messages regarding sources of dietary fibre, particularly if foods that are traditionally poor sources of dietary fibre were to be considered otherwise. Overall, the net-benefit to consumers is likely to be small.

7.2.2.2 Food industry

Industry will benefit from broadening the permissions on sourcing added dietary fibre, and by allowing for the presence of Polydextrose polymer to be claimed as a source of dietary fibre in the existing range of products. Industry will benefit further with the capacity to innovate and develop new products aimed at exploiting the dietary fibre niche.

A prescribed method of analysis that measures Polydextrose polymer will be a potential benefit for both industry and consumers by providing a level of consistency in the estimation, and thus labelling, of the dietary fibre content in foods containing Polydextrose.

7.2.2.3 Public health professionals/officials

Public health professionals will have a wider range of foods to recommend to those people who require an increased fibre intake. The possibility of a wider range of foods using Polydextrose and subsequently permitted to make fibre claims may increase. Some of the foods may not be considered traditional sources of dietary fibre and public health messages may be required to address the potential confusion this might create for consumers.

7.2.2.4 Government

Enforcement agencies may benefit from the inclusion of the proposed prescribed method of analysis for dietary fibre, through the improved clarity and straightforward regulation on dietary fibre claims.

8. Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act to omit to invite public submissions in relation to the Application prior to making a Draft Assessment.

FSANZ made its decision under section 36 because it was satisfied that the Application raised issues of minor significance or complexity only.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of FSANZ's decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

The Draft Assessment Report for A495 was available for public consultation from 9 Oct 2003 until 26 November 2003. A total of 14 submissions were received, with 11 of these from Australia, three from New Zealand.

Of these 14 submitters, 10 unconditionally supported Option 2 (amend the Code as originally requested by the Applicant and include specific regulation in Standard 1.2.8 for a new method of analysis of dietary fibre specifically for foods containing Polydextrose), two submitters opposed the Application in its entirety (support for Option 1, maintain the status quo). One submitter considered that there should be another round of public comment on the completion of a safety assessment report, one submitter considered it appropriate to hold a decision around the Application until the policy for health claims had been released.

8.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards pertaining to the classification of dietary fibre, and determination of its content in foods. However, amending the Code to allow for the inclusion of a specific method of analysis for the total dietary fibre content of foods containing Polydextrose was considered to not have a significant effect on international trade since Polydextrose was already permitted in foods by the Food Standards Code as in many overseas countries. Polydextrose polymer is also recognised as a source of dietary fibre in many overseas nations and therefore the amendment was not notified.

9. Conclusion and Recommendation

FSANZ approves the draft variation to Standard 1.2.8 for a new method of analysis of dietary fibre specifically for foods containing Polydextrose and in doing so permitting foods containing Polydextrose the eligibility to bear a label claim referring to dietary fibre content in accordance with the Australian Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC), 1995, for the following reasons:

- The AOAC 2000.11 method for determination of Polydextrose by Ion Chromatography is considered to be eligible for inclusion in Standard 1.2.8 because Polydextrose polymer meets the general definition of dietary fibre as developed by FSANZ and contained in Standard 1.2.8 of the Code.

- Polydextrose is already considered a food and permitted under Good Manufacturing Practice, with no prescribed ADI.

- The inclusion of AOAC method 2000.11 in Standard 1.2.8 would potentially provide consumers with additional and/or alternative food sources of dietary fibre.

- Standard 1.2.3 currently requires all food containing more than 25 g Polydextrose and some polyols either singularly or in combination per 100 g of food to carry an advisory statement regarding the laxative effects of the food.

The proposed drafting of the Code is at Attachment 1 of this Final Assessment Report.

10. Implementation and review

Approval of the Application will result in the proposed variation to Standard 1.2.8 commencing on gazettal.

ATTACHMENTS

1. Draft variation or standard to the *Australia New Zealand Food Standards Code*
2. Summary of issues raised in public submissions from the Draft Assessment Report
3. Certificate of Analysis for Polydextrose

ATTACHMENT 1

Draft Variation to the *Australia New Zealand Food Standards Code*

To commence on gazettal

[1] ***Standard 1.2.8.*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to subclause 18(1) –

Polydextrose	Section 2000.11 of the AOAC, 17th Edition, 1st Revision (2002)

ATTACHMENT 2

Summary of submissions

No	Submitter	Submission comments
1	Food Technology Association of Australia David Gill	**Supports Option 2**
2	New Zealand Food Safety Authority Carole Inkster	Oppose continuation to final assessment until gaps in scientific assessment are addressed. Believe that there should be another round of public consultation that includes a safety assessment and dietary intake risk assessment. Method of analysis: appears that collaborative process is not yet complete – would not be appropriate to insert the AOAC method. Concerned re high intake by children – particularly of confectionary products. Asked what levels of consumption there would be a safety concern – advisory statement. Consumers choosing foods with a dietary fibre claim usually do so to obtain a source of a faecal bulking agent. Concern over the nutritional make up of some foods that will be permitted to make a claim (high sugar/fat foods) and in doing so is perceived as being healthy.
3	Queensland Government Public Health Services Kerry Bell	**Supports Option 1** Express concern that the application allows for the potential for foods such as ice cream and confectionary to be, and claim to be, a good source of dietary fibre. This result in confusion in consumers and would require re adjustment of nutrition education tools. Poses potential risk to public health and safety related to risk of increasing over weight and obesity related chronic diseases.
4	Australian Consumers' Association Clare Hughes	**Supports Option 1** Believe that Polydextrose doses not meet the definition of dietary fibre…*the fraction of the edible part of plants or their extracts, or synthetic analogues tha*t….Polydextrose is derived from starch by chemical treatment leading to extensive degradation of the original amylase and amylase pectin….it is a polysaccharide with a radically different structure from starch, not a synthetic analogue of any naturally occurring plant fraction. Consumers look for dietary fibre with expectation of positive health outcomes. Does not believe that sufficient scientific evidence to support Polydextrose as a dietary fibre.

		DAR states the Application is of minimal benefit to consumers. ACA is concerned that option 2 would increase the number of foods permitted to make dietary fibre claims and thus increase the number of highly processes, energy dense foods claiming to be a source of dietary fibre, which is inconsistent with the advice given in the Dietary Guidelines for Australian Adults. Status quo result in loss of marketing opportunities for food manufacturers – ACA is of opinion that loss of marketing opportunities is not enough to warrant a change in the food code- esp. when there is no benefit to consumers. Weighing up the costs and benefits – Status Quo loss to industry and diff to consumers, change in code – gain to industry – potential undermining of public health attempts to encourage healthy diets. ACA supports status quo.
5	Info Med systems John Birkbeck	**Supports Option 2** Indicates strong support for the application. Polydextrose has low GI and the benefit of lowering the GI of some foods. Question of analysis of Polydextrose should not arise as it is deliberately added to food. – Mentions that defining the fibre in the lab is still a problem Considers the narrow foods in which Polydextrose is used in more than small amounts is limited and thus does not believe that result will be confusion amongst consumers.
6	Dietitians' Association of Australia	**Supports Option 2 with conditions** DAA believe that the applicant has provided sufficient information to include Polydextrose as a dietary fibre. DAA believes that the permission for fibre claims be prohibited until draft proposals for health and nutrition claims has been finalised. DAA believes that the Nutritional claim proposal will not permit a food with Polydextrose to make source claims unless they are a natural source of a nutrient. DA requests that FSANZ looks into the US Food and Nutrition Board definition for total dietary fibre as part of the risk management strategies, and consider its inclusion in the NIP.
7	New Zealand Dairy Foods Hamish Conway	**Supports Option 2** Useful food ingredient that provides a number of technical functions in proceed Food Standards Australia New Zealand Particularly useful for foods with reduced and low energy contents and low GI foods.

8	Axiome Pty Ltd David Bill	**Supports Option 2** *Laxation effect:* 3 studies were cited in the DAR but total of 18 human clinical studies have been undertaken – 9 of these studies unpublished. Standard 1.2.3 of the Food code makes reference to laxation effect of Polydextrose by requiring foods containing Polydextrose to carry an advisory statement around laxation effects. *Method of analysis* Collaborative study confirms the method of analysis. The method is specific to Polydextrose. *Nutrient absorption/bioavailability* 3 animal studies all report an increased absorption of calcium in foods containing Polydextrose. *Polydextrose use levels/patterns of use;* When formulating foods with Polydextrose there are technical considerations that need to be considered….recipe reformulation is required. Polydextrose is not suitable for addition to all processed foods, nor necessarily at levels that would be required for fibre claims. Thus the approval of a fibre claim for Polydextrose would not result in a vast increase in general food fibre claims. Polydextrose use in studies – reference to DAR section 5.1 – unless stated otherwise it can be assumed the Polydextrose used in these studies was commercial Polydextrose – this is particularly relevant to toleration studies. Section 5.3.3 – blood glucose – Sydney Universities Glycaemic Index Research Services tested Polydextrose and demonstrated a GI value of 4-7 compared to 100 for glucose.
9	Healthy Snack Sam Briskin	**Supports Option 2**
10	Anadis Fred Mears	**Supports Option 2** R and D company who use Litesse – prepared to add additional details incidence if required.
11	Masterfoods Australia Ambrose Glass	**Supports Option 2**
12	Australian Food and Grocery Council	**Supports Option 2** AFGC considers that there are only two issues that need to be considered: • does Polydextrose fit definition of dietary fibre in S1.2.8; and • is the AOAC method 2000.11 a suitable method of analysis Considers that the fact that Polydextrose fit the first part of the definition (ia a polysaccharide) then it should be considered at fibre. AFGC supports FSANZ conclusion that Polydextrose satisfies the criteria for dietary fibre, how ever does not necessarily support the way in which it reached the decision. AFGC considers the studies quoted as being evidence of sufficient laxation effect based on the outlined criteria.

		AFGC considers that FSANZ wasted its own time investigating the effect of Polydextrose on blood cholesterol and blood glucose when the criterion for laxation was meet. AFGC considers that the method of analysis AOAC 200.11 should be permitted as a regulatory method for analysing the individual fibre content of food from Polydextrose. Considers than this application has nothing to do with health and safety and that in previously approving Polydextrose use, the appropriate safety assessment was carried out. Considers that there is not need for a safety assessment in option 2 as this should already have been undertaken in permitting Polydextrose initially. AFGC agrees with the cost benefit analysis but adds that option 1 will mean that consumers will not easily be able to identify sources of fibre.
13	Unilever Australia Julie Newlands	**Supports Option 2** Fully supports the AFGC submission
14	Confectionery Manufacturers Association Jennifer Thompson	**Supports Option 2** In addition to supporting option 2 would like confirmation that the declared energy value of Polydextrose will not be changed as a result of the proposed amendment.

ATTACHMENT 3

Danisco USA Inc.
PO Box **8266**
Terra Haute IN 47808

Certificate of Analysis

Litesse® Powder - 25 Kg Bag

Material 104705
Lot number V37210S

Characteristic	Lower Limit	Upper Limit	value	Unit
Appear-White to cream powder	Passes Test			
Odorless	Passes Test			
FCC Identification Test	Passes Test			
Polydextrose Assay '*'	90.0	-	93.5	%
Anhydro-D-Glucoses (Levogluc)*	-	4.0	2.4	%
Glucose *	•	4.0	2.8	%
Sorbitol *	-	2-0	1.7	%
Water Content	-	4.0	0.6	%
High Molecular Wt. Limit	Passes Test			
5-Hydroxymethylfurural *	-	0.10	0.03	%
Lead (0.5 ppm Maximum)	Passes Test			
Heavy Metals (5 ppm Maximum)	Passes Test			
pH (10% Solution)	3.0	4.5	3.5	pH
Residue on Ignition		0.30	0.00	%
Acidity, Anhydr. Basis (meq/g)	-	0.030	0.013	meg
Standard Plate Count - Aerobic	-	10	0	cfg
Yeast and Mold	-	10	0	cfg
Salmonella - Negative to test	Passes Test			
E.Coli - Negative to test	Passes Test			
Staph aureus Negative to test	Passes Test			

* Anhydrous, ash-free basis
Storage - Avoid **excessive** beat and humidity-

This product **has** been evaluated and **is** released for use. It is FCC grade and is manufactured under a quality
management system certified as compliant with the requirements of **ISO** 9001:2000 and ISO 14001.

This certificate is electronically generated, thereby not requiring a signature.

A. F. GOSSMANN, Quality Manager

07/29/2003