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

29 August 2003

INITIAL ASSESSMENT REPORT

APPLICATION A495

POLYDEXTROSE AS DIETARY FIBRE

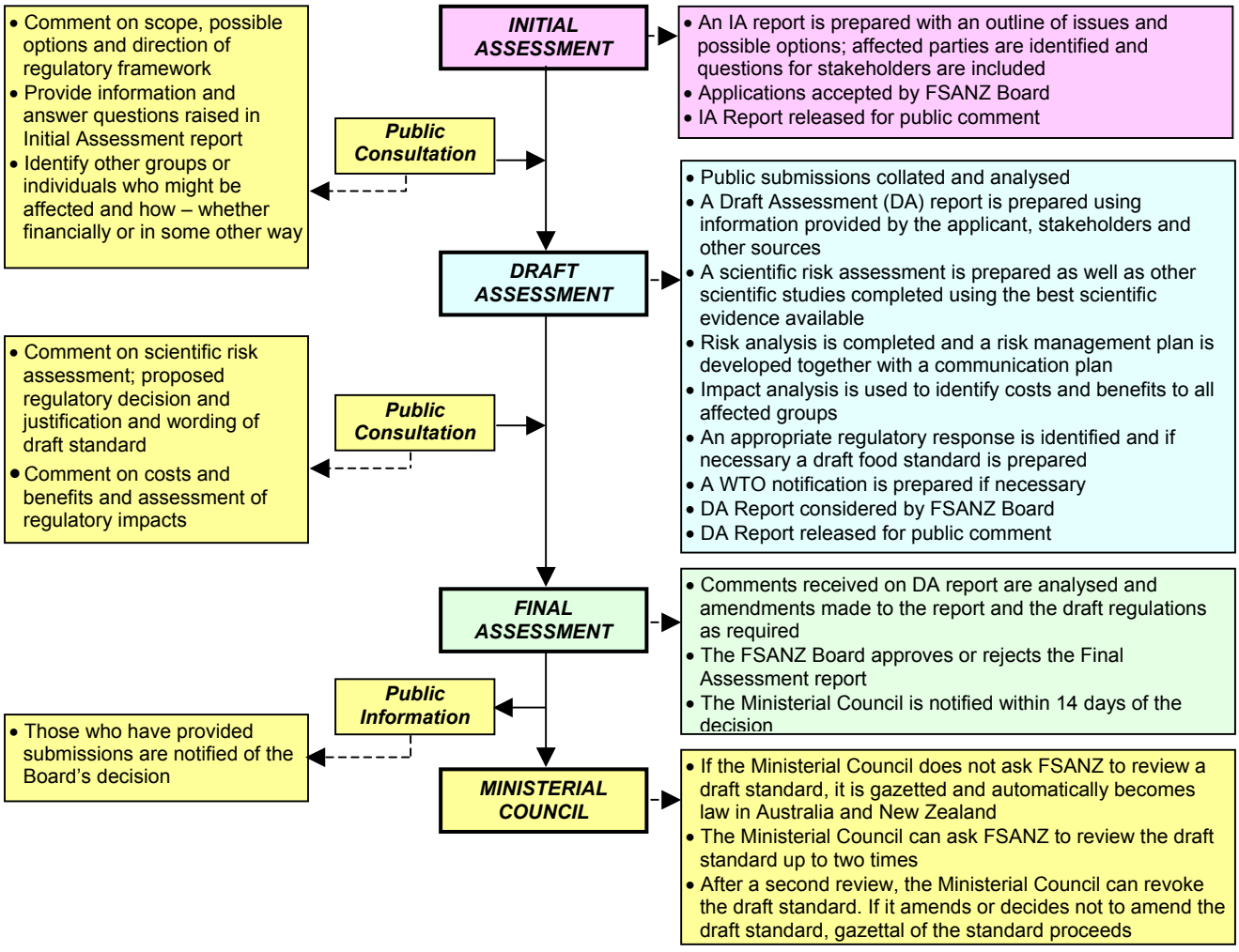
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A495, which includes the identification and discussion of the key issues.

FSANZ has decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (the Act) to omit to invite public submissions for the purposes of section 14 in relation to the Application prior to making a Draft Assessment.

FSANZ agreed to omit, pursuant to section 36 of the Act to invite public submissions 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.

CONTENTS

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Axiome 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 as a dietary fibre by including a specific method of analysis for dietary fibre in foods containing Polydextrose (AOAC method 2000.11). This Application has been accepted on the FSANZ Work Plan as Application number A495.

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 in the calculation of total dietary fibre content.

Issues

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

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

- *Criteria for determination of physiological effect (of dietary fibre)*
  The development of quantified criteria for the determination of physiological effect is paramount to determining if a substance should be considered dietary fibre.

- *Dietary issues*
  Polydextrose can be used in a wide variety of foods at concentrations ranging from 2% –30% and 95% in the case of confectionary. If AOAC 2000.11 is accepted as a method of analysis, 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.

Regulatory options and impact analysis

Two options are being considered for progressing A495 at Initial Assessment:

1. Maintain the status quo by not including a new method of analysis for dietary fibre in Standard 1.2.8; or

2. Include specific regulation for the method of analysis of Polydextrose in Standard 1.2.8 and implement any appropriate risk management strategies subject to a safety assessment to be conducted at Draft Assessment.

For each regulatory option, an impact analysis has been undertaken to assess the potential costs and benefits to various stakeholder groups associated with its implementation.

Conclusion and recommendation

This Application has been assessed against the requirements of section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Accordingly it is recommended that this Application should be accepted and progressed to Draft Assessment subject to payment of fees assessed pursuant to section 66 of the FSANZ Act and the Regulations.

FSANZ has decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* to omit to invite public submissions for the purposes of section 14 in relation to the Application prior to making a Draft Assessment.

In assessing the Category for this Application, and taking into account the regulations under the FSANZ Act, FSANZ has come to the view that the Category for this Application should be set at Category 2. The Regulations, Schedule 3, Part 1 – Categories of Assessment defines Category 2 paid Applications as:

Category 2 — for an Application requiring only an updating of the standard methods for analysis set out in the Code in relation to a food.

1. Introduction

1.1 Nature of Application

Food Standards Australia New Zealand (FSANZ) received an Application from Axiome on behalf of Danisco A/S on 28 March 2003 seeking to amend Standard 1.2.8 – Nutrition Information Requirements of the Code to recognise Polydextrose as a form of dietary fibre by including a specific method of analysis for dietary fibre in foods containing Polydextrose, the AOAC method 2000.11. This Application has been accepted on the FSANZ Work Plan as number A495.

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. Polydextrose has an average degree of polymerisation of 12 and an average molecular weight of 2000.

The Applicant has advised that Polydextrose has similar technological properties to sugar and functions in food as a humectant, bulking agent, stabiliser and texturiser. Polydextrose is only partially metabolised in the large intestine. It is used as a replacement for sugar and/or starch to provide a technological function in food where lower energy content is desired. Polydextrose is permitted in the Code under Standard 1.3.1, schedule 2 -Miscellaneous Additives and is permitted in accordance with Good Manufacturing Practice (GMP) in processed foods specified in Schedule 1 of the Standard.

2. Regulatory Problem

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 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."

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 fructooligosaccharide	Section 997.08 of the AOAC, 17th Edition (2000).
Inulin	Section 999.03 of the AOAC, 17th Edition (2000).

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 is one such substance. The Applicant has therefore applied to have the Polydextrose recognised as a dietary fibre and to subsequently amend the Table to subclause 18(1) of Standard 1.2.8 of the Code to include a new method of analysis for Polydextrose in foods.

In considering the regulatory problem, this paper will therefore assess the issues of how Polydextrose meets the definition of dietary fibre in Standard 1.2.8, and whether Polydextrose can be quantified using the 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 three 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 consumers can make informed choices about the dietary fibre content of foods containing Polydextrose.

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 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 of the Code.

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 24th session of this Committee (2002) that the Delegation of France was to prepare a discussion paper for further discussion, 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 in the US is based on methods of analysis. The US Food and Nutrition Board has 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.'

Polydextrose has obtained Generally-Recognised-As-Safe (GRAS) status in the United States and is permitted for use in food with no limitation other than current GMP (21 CFR – 170.36).

4.2.3 Japan

According to the Applicant, in Japan, Polydextrose is considered to be 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 make 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, Egypt, Indonesia, Japan, Korea, Poland and Taiwan.

4.3 Work Plan Classification

This Application had been identified as Application A495, rated as complexity Category 2, and placed in Group 3 on the FSANZ Standards Development Work Plan. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

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

- behaviour of Polydextrose in the small intestine;
- determination of whether Polydextrose should be considered as dietary fibre;
- development of quantified criteria for the determination of physiological effect, to aid in determining if a substance should be considered dietary fibre;
- appropriateness of the method of analysis;
- nutritional issues associated with dietary fibre; and
- dietary consideration of Polydextrose in food.

5.1 Polydextrose in the small intestine

Determination of whether Polydextrose 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 the definition for dietary fibre in clause 1 of Standard 1.2.8 of the Code; there must be a demonstration that it is indigestible in the human small intestine; and can promote at least one of the following physiological effects: laxation, a reduction in blood cholesterol, or modulation of blood glucose.

In support of the classification of Polydextrose as dietary fibre, the Applicant has cited information indicating that the majority of Polydextrose is indigestible, with approximately 1.5% being hydrolysed in the small intestine. Proposal P177, Derivation of Energy Factors completed by FSANZ's predecessor in 1999, also concluded that 1.5% of Polydextrose is digested in the small intestine[1]. Because AOAC method 2000.11 measures the entire Polydextrose content of a food, it also measures the 1.5% of Polydextrose that is subject to enzymatic degradation and therefore it would not strictly meet the definition of dietary fibre.

The Applicant argues that Polydextrose is used in small amounts in foods, and that describing the 1.5% of digestible Polydextrose as fibre is within the limits of analytical and methodological error. Furthermore, Polydextrose is used in nominally small amounts in foods and the result of assuming that Polydextrose is 100% fibre as opposed to 98.5% fibre, would relate to mislabelling of fibre content by an average of 0.1g per serve of food per 5 grams added Polydextrose. Standard 1.2.8 states that values in the nutrition information panels should be declared to no more than three significant figures. There are no requirements for minimum decimal places.

5.2 Polydextrose in the large intestine

In addition to being resistant to digestion and absorption in the small intestine, dietary fibre is 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 being excreted in stools.

The largest human study conducted to investigate the effects of Polydextrose on physiological function was by Jie *et al*[2] 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 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.

[1] Derivation of Energy Factors; Full Assessment Report; Proposal P177, ANZFA, 1999, pg 35
[2] 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 Dec 72 (6): 1503-9

Wang and Gibson's[3] 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).

5.3 Criteria for determination of physiological effect

The definition of dietary fibre in Standard 1.2.8 of the Code 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 the time, with other criteria to be developed as the need arose. The laxation effect defined in Application A277 was more than 1g of faecal wet weight increase per gram ingested in either 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 weight increase/g FOS ingested at intakes 15-40 g/day), and were subsequently regarded as dietary fibre for nutrition labelling and associated purposes.

Inulin and FOS were assessed as types of dietary fibre only on the basis of meeting the physiological effect of laxation. Therefore, to meet the definition of dietary fibre in Standard 1.2.8, Polydextrose need only display similar characteristics without having to exhibit the other stated physiological effects. However, clarification of the underpinning criteria for these two physiological effects may assist in determining if Polydextrose and future substances are forms of dietary fibre.

The Applicant states that Polydextrose promotes the beneficial physiological effects referred to in the definition of dietary fibre. Copies and summaries of a number of studies investigating the potential beneficial physiological effects of Polydextrose, specifically on laxation, reduction in blood cholesterol have been provided in support of these arguments.

5.3.1 Laxation

The laxation effect defined in Application A277 was more than 1 g of faecal wet weight increase per gram ingested in either food matrix or supplementary form. Changes in gastrointestinal function are most pronounced for non-soluble fibres. As Polydextrose is soluble, it is not expected that there will be a significant effect from its ingestion on gastrointestinal function.

There have been only a few studies investigating the laxative effect of Polydextrose. Jie *et al*[2] 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 1g per gram 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 days –4 to –1 and 26-28. Wet stool weight was increased by more than 2 g/g ingested Polydextrose in all groups.

[3] 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

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 increase or discuss if the weights were dry or wet faecal weight[4]. A second study where seven subjects consumed 30 g of Polydextrose a day over two seven-day periods showed an increase in daily faecal weight of more than 30 g[5]. Endo *et al*[6] 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.

5.3.1.1 Summary

One study of 120 participants demonstrated an increase in dry faecal weight of at least 1 g/g of ingested Polydextrose, and in 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. Unfortunately neither of these latter studies quantified the increase in weight using grams.

5.3.2 Blood cholesterol

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

Saku *et al* [7]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[8]. 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.

5.3.2.1 Summary

There is no conclusive evidence as the effect of Polydextrose on serum cholesterol.

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[4] 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

[5] 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

[6] 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

[7] Saku K, Yoshinaga K, Okura Y et al . Effects of Polydextrose on serum lipids, lipoproteins and apolipoproteins in health subjects. Clinical Therapeutics 1991 13(2) 254-258

[8] 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) 1-12

5.3.3 Blood glucose

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

McMahon[9] 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 50 g of Polydextrose with either 50 g or 100 g of glucose. There was no effect from Polydextrose on insulin or glucose kinetics.

5.3.3.1 Summary

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

5.3.4 Conclusion

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

5.4 Method of Analysis

The Applicant claims that the Prosky method (AOAC 985.29) prescribed in the Table to subclause 18(1) measures 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. Craig[10] 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. Prosky[11] states that a number of substances, including Polydextrose, 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) to measure a specific dietary fibre (Polydextrose) content of foods for the purposes of the nutrition information labelling of dietary fibre.

[9] 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)
[10] Graig S, Holden J, Khaled M. (2001) Determination of Polydextrose in Foods by Ion Chromatography: Collaborative Study. Journal of AOAC International 84:2, 472-478.
[11] Prosky L (2000), *What is dietary fibre?* Journal of AOAC International, 83:4, 985-7.

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[3], which has been adopted as First Action by AOAC International.

The literature states that the AOAC 2000.11 method can be used as an adjunct to the AOAC 985.29 method of analysing dietary fibre. The method involves extracting the Polydextrose 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.

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 content. In order to determine the fibre content of foods from sources other than Polydextrose, another method such as the AOAC 985.29 would be necessary. If the value obtained from the additional step in this method of analysis 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.

5.4.1 Collaborative study

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 content of seven foods, typical to Polydextrose use[12]. 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 percent of recovery was 94%. The associate referee to the paper recommended that the method be adopted to first action as a result of this study.

5.5 Nutrition Issues

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

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

[12] Craig SAS, Holden JF, Khaled MY. Determination of Polydextrose in foods by ion chromatography: collaborative study. Journal of AOAC International 2001 84(2)472-478

The Applicant argues that Polydextrose will not compromise nutrient intake in this manner, and has provided evidence to this effect[13,14].

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 products 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.

Polydextrose is already permitted and used as an additive in a wide range of foods.

5.6 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 below.

Table 1

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 applications and use levels stated above were supplied by the Applicant who notes that they are based on formulations developed by the manufacturer and although they provide guidance on potential food applications and use levels, they do not necessarily represent Polydextrose-containing food products on the market.

[13] Bamba T, Fuse K, Chun W, Hosoda S. Polydextrose and activities of brush boarder enzymes of small intestine in rats and glucose absorption in Humans. Nutrition 1993 9(3) 233-236

[14] Giblert McMahon F, 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)

Furthermore, in commercial food products, Polydextrose is often used in combination with other food ingredients such as polyols and consequently the levels used in these cases 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".

If a method of analysis for Polydextrose is included in Standard 1.2.8, it is likely that the number of food products containing dietary fibre would increase in Australia and New Zealand, due to the ability to declare Polydextrose as dietary fibre in the current range of foods containing Polydextrose, as well as in new products in both nutrition information panels, and where eligible, as dietary fibre content claims. 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, including Polydextrose in these foods may also provide an alternative means of increasing the population intake of dietary fibre separate from other existing public health strategies.

6. Regulatory Options

Two options are being considered for progressing Application A495 at Initial Assessment:

1. *Maintain the status quo by not including a new method of analysis of Polydextrose 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 would not be recognised as dietary fibre for nutrition labelling purposes.

2. *Include specific regulation for method of analysis of foods containing Polydextrose in Standard 1.2.8, and implement any appropriate risk management strategies subject to a safety assessment to be conducted at Draft Assessment.*

Under this option, Polydextrose would be recognised as dietary fibre for labelling purposes, by the recognition of the 'AOAC Official Method 2000.11– Polydextrose in Foods By Ion Chromatography' as an acceptable method for determining the Polydextrose content in 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**; 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 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 minor. The restriction of current regulatory arrangements that prevent manufacturers from claiming Polydextrose as a source of dietary fibre is unlikely to be known by consumers.

However, the scope for adding dietary fibre to a food may be restricted under this option, thus limiting the range of foods available to consumers that have a high dietary fibre content.

Consumers may benefit from the minimal changes in nutrition education messages on dietary fibre that will occur under this option.

7.2.1.2 Food Industry

There is a potential disadvantage to industry in not permitting Polydextrose as a potential claimable source of dietary fibre in foods. Those manufacturers whose products contain Polydextrose will incur a cost through a lost marketing potential. The extent of this potential loss is, however, unclear.

Some sectors of the food industry may also incur a cost through the inability to use Polydextrose as a source of dietary fibre, by virtue of the inability to reflect the addition of Polydextrose in a product's fibre content.

7.2.1.3 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 Option 2 - Include specific regulation for method of analysis of foods containing Polydextrose in Standard 1.2.8

7.2.2.1 Consumers

There is a potential benefit to consumers under this option, as they may have access to a wider choice of products containing dietary fibre, potentially resulting in an increased dietary fibre intake. A new range of food products containing Polydextrose may, however, create a level of consumer confusion with respect over 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.

If manufacturers incur costs from using Polydextrose in products that have not traditionally contained added forms of dietary fibre, then there is also the potential for this option to create an additional cost to consumers through increased product prices.

7.2.2.2 Food Industry

Industry may potentially benefit from broadening the permissions on sourcing added dietary fibre, and by allowing for the presence of Polydextrose to be claimed as a source of dietary fibre.

A prescribed method of analysis that incorporates Polydextrose 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.

7.2.2.3 Government

Nutrition education messages may need to be modified to allow for the classification of Polydextrose as a form of dietary fibre, creating a cost for government agencies and institutions. This may result in an increased complexity of messages and may add to consumer confusion and cynicism with regard to nutrition messages. However, in terms of public health, there may be an overall net benefit to Australian and New Zealand governments from an increased dietary fibre intake across their respective populations.

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

8.1 Release for Public Consultation

FSANZ has 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 omitting to invite public submissions prior to making a Draft Assessment would not have an adverse effect on anyone's interests and 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.

8.2 World Trade Organization

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, is unlikely to have a significant effect on international trade as Polydextrose is currently permitted for use in the majority of imported foods, and is recognised as a source of dietary fibre in many overseas nations.

The impact on international trade will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) Agreement. This will enable other WTO member countries to comment on the proposed changes where these changes may have a significant impact on their markets.

9. Conclusion and Recommendation

This Application has been assessed against the requirements of section 13 of the FSANZ Act. Accordingly it is recommended that this Application should be accepted and progressed to Draft Assessment subject to payment of fees assessed pursuant to section 66 of the Act and the Regulations.