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

12/03
8 October 2003

DRAFT ASSESSMENT REPORT

APPLICATION A495

POLYDEXTROSE AS DIETARY FIBRE

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
19 November 2003
(See 'Invitation for Public Submissions' for details)

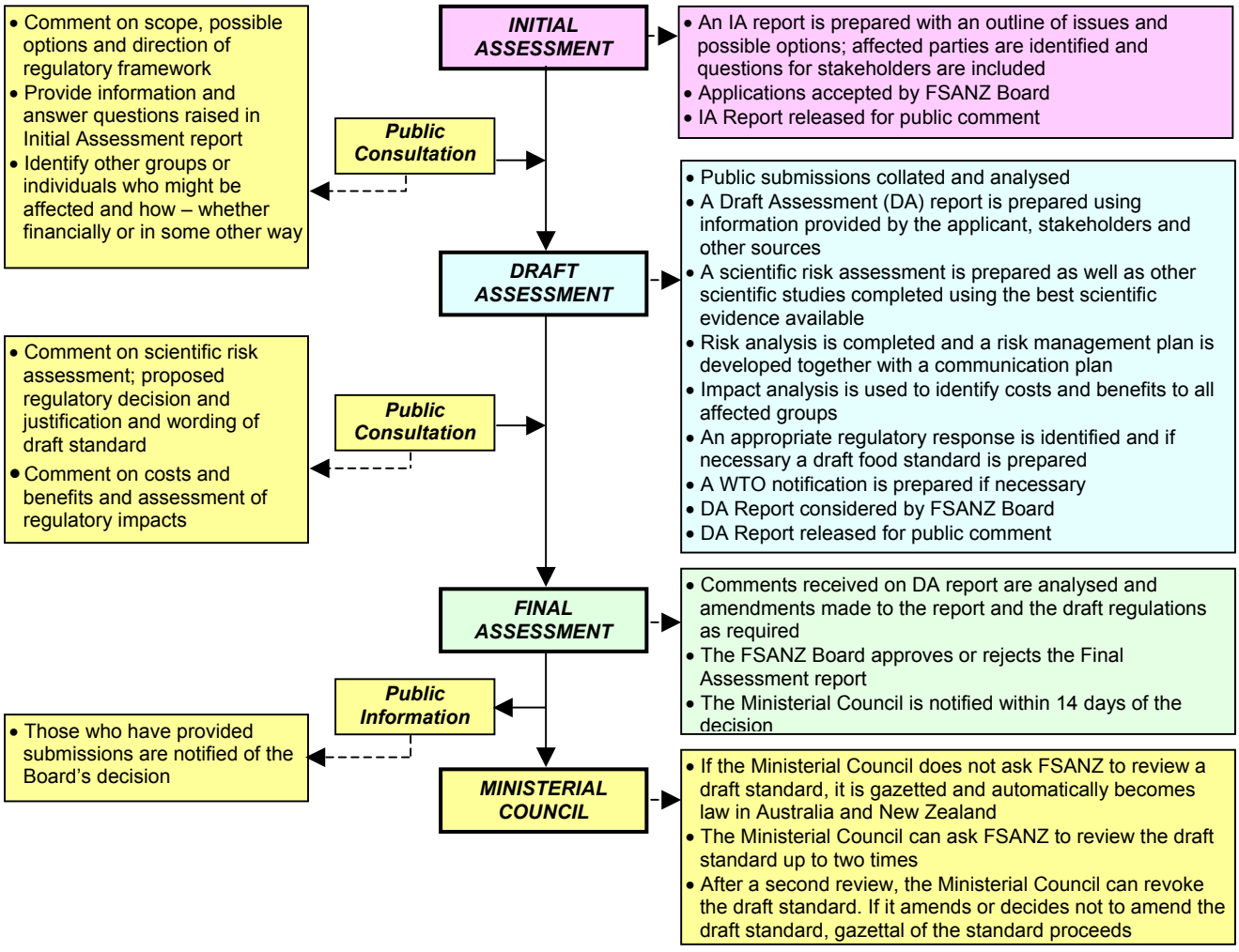
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 a Draft Assessment Report of Application A495; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 19 November 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

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). 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 polymer 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 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.

- *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 confectionery. 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 Draft 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 polymer in Standard 1.2.8 and implement any appropriate risk management strategies subject to a safety 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.

Consultation

Under section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) the Authority decided to omit to invite public submissions after accepting the Application at Initial Assessment. The Initial Assessment Report has been posted on FSANZ's website.

Conclusion and Statement of Reasons

FSANZ recommends the approval of this Application 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;
   - is partially fermented in the large intestine; and
   - promotes the physiological effect of laxation.

2. Polydextrose is listed as a permitted additive in Schedule 2 - Miscellaneous Additives in accordance with Good Manufacturing Practice (GMP) in Processed Foods specified in Schedule 1 of the Standard. Polydextrose is thus considered safe and of negligible risk to public health.

The proposed drafting for the amendment to Standard 1.2.8 – Nutrition Information Requirements, is at Attachment 1 of this Draft Assessment Report.

1. Introduction

1.1 Nature of Application

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* to recognise Polydextrose polymer as a form of dietary fibre by including a specific method of analysis for dietary fibre in foods containing Polydextrose, the AOAC Official Method 2000.11– Polydextrose in Foods By Ion Chromatography. This Application has been accepted on the FSANZ workplan as Application 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. 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.

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 permitted in the Code 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.

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 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 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 of the Code 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 how Polydextrose polymer meets the definition of dietary fibre in Standard 1.2.8, and whether it can be quantified using the methods of analysis listed in the Table to Subclause 18(1) of Standard 1.2.8.

It is obviously important that dietary fibre claims are substantiated and provide reliable information to consumers.

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 are adequately informed about the dietary fibre content of foods containing Polydextrose polymer.

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 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 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 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.

5. Relevant Issues

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

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

5.1 Polydextrose in the Small Intestine

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 the definition for dietary fibre in clause 1 of Standard 1.2.8;
- demonstrate that it is indigestible in the human small intestine; and
- demonstrate promotion of at least one of the following physiological effects: laxation, a reduction in blood cholesterol, or modulation of blood glucose.

The ingredient Polydextrose contains a small amount of glucose and sorbitol as bi-products to the manufacturing process as shown in the certificate of analysis in Attachment 2. Studies of the digestive fate of Polydextrose are often unclear as to whether the Polydextrose investigated is the commercial ingredient or a more purified substance 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, the Applicant has cited information indicating that the vast majority of Polydextrose is indigestible with up to 1.5% hydrolysed in the small intestine. Proposal P177 – Derivation of Energy Factors, completed in 1999, also concluded that 1.5% of Polydextrose 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 free glucose present in the commercial Polydextrose product. 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[3]. 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.

The Applicant believes that this is the case and that the Polydextrose polymer itself is totally unabsorbable. 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. The Applicant also argues that 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.

5.1.1 Summary

It is unclear whether Polydextrose is totally resistant to absorption in the small intestine. The literature suggests that between 0.03 - 1.5% Polydextrose is digestible in the small intestine

[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

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. Also uncertain is whether this absorbable fraction contributes to the results of analysis by the proposed method of analysis. However, due to the generally small amounts of Polydextrose currently used in foods and the limitations of the performance of the analytical method, FSANZ considers that for all practical purposes, Polydextrose polymer satisfies the criteria that requires dietary fibre to be indigestible in the human small intestine.

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*[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 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).

5.2.1 Summary

Polydextrose has been shown in both *in vitro* and *in vivo* studies to be at least partially fermented in the large intestine.

5.3 Criteria for Determination of Physiological Effect

The definition of dietary fibre in clause 1 of 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.

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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

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 ingested 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 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 polymer 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 polymer and future substances are forms of dietary fibre.

The Applicant states that Polydextrose polymer 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 polymer, 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 a 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 polymer. 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. 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 faecal weight of more than 30 g[8].

[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

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.

5.3.1.1 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.

Question: Do these studies provide evidence of a sufficient laxation effect from Polydextrose?

5.3.2 Blood cholesterol

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

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.

5.3.2.1 Summary

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

5.3.3 Blood glucose

[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 faeces in healthy volunteers. Bifidobact. Microflora. 1991, 10: 53-64

[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

The glycaemic index (GI) of Polydextrose was measured by Jie *et al* 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 related to delayed gastric emptying that Polydextrose promotes, due to increased bulking and viscosity in the bowel.

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.

5.3.3.1 Summary

Polydextrose appears to be non-glycaemic. Evidence suggests that it also results in a concomitant 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) 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. Craig[13] 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[14] 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 (Polydextrose polymer) 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

[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)
[13] Craig S, Holden J, Khaled M. Determination of Polydextrose in Foods by Ion Chromatography: Collaberative Study. Journal of AOAC International. 2001, 84: 472-478.
[14] Prosky L. What is dietary fibre? Journal of AOAC International. 2000, 83: 985-7.

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 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 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 polymer content of seven foods, typical to Polydextrose use[15]. 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%. This is consistent with the Applicant's claim that Polydextrose is only between 90 and 95% pure (see Attachment 2). The associate referee to the paper recommended that the method be adopted to First Action as a result of this study.

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

Question:
Should AOAC 2000.11 be permitted as a regulatory method for analysing the individual fibre content of a food from Polydextrose?
In considering these questions you may like to consider:

- **the simplicity and rigour of the method for use by food manufacturers;**
- **the cost of conducting an analysis using the method;**
- **whether the method measures what it is purported to measure; and**
- **the reproducibility and precision of the method.**

5.5 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 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. 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.

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

- **Submitters are invited to comment or provide data relevant to the effect of Polydextrose on nutrient absorption and bioavailability in the gastrointestinal tract.**

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.

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	Icecream/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 for a food to make 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 would be assessed in accordance with the New Zealand Fair Trading Act (1986).

The Australian CoPoNC criteria for making source claims for fibre are:

- Fibre content greater than 1.5 g per serve permits a source claim;
- Fibre content greater than 3 g per serve permits a good source claim; and
- Fibre content greater than 6 g per serve permits an excellent source claim.

Based on Table 1 above, any product with a serve size of more than 100g, 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.

If a method of analysis for Polydextrose is included in the Table to subclause 18(1) in Standard 1.2.8, it is likely that the number of food products claiming to contain dietary fibre would increase in Australia and New Zealand, due to the 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 separate from other existing public health strategies.

Submitters are invited to comment or provide data relevant to the use of Polydextrose in foods and/or patterns and levels of consumption of Polydextrose and respond to the following questions:

- **Are you aware of any additional, or more specific data on the use of Polydextrose by the Australian and New Zealand food industry?**
- **Are you aware of any data regarding the patterns and/or levels of consumption of Polydextrose in Australia, New Zealand or overseas markets?**
- **Are there any concerns about the impact on nutrition education messages or the food supply as a whole, if manufacturers were provided with an incentive to add Polydextrose to foods and were permitted to use 'source' or 'good source' of fibre claims for foods that are not traditional sources of dietary fibre?**

6. Regulatory Options

Two options are being 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, and implement any appropriate risk management strategies subject to a safety assessment.*

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 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 adding dietary fibre to a food may be restricted under this option, thus limiting the range of high fibre foods available to consumers. Nevertheless consumers currently benefit to some degree from the dietary fibre functionality of Polydextrose that is present in some foods.

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 identifying foods that contain Polydextrose as containing dietary fibre. However, there will be no requirement to modify current public health education messages to address the potential of number of foods that are traditionally poor sources of dietary fibre that, through the addition of Polydextrose, 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.

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 causes to 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.

Question: Are there any other potential costs and benefits to consumers, industry, public health professionals or government or any other stakeholders not identified in this Draft Assessment?

8. Consultation

8.1 Release for Public 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. The Initial Assessment Report is posted on FSANZ's website. FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received.

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.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for a review of FSANZ's decision may be made to the Administrative Appeals Tribunal by a person whose interests are significantly affected by the decision to omit to invite public submissions in relation to the Application.

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. Polydextrose is currently permitted for use in the majority of imported foods, and Polydextrose polymer is recognised as a source of dietary fibre in many overseas nations and thus it is not proposed to notify this draft amendment.

9. Conclusion and Recommendation

FSANZ recommends the approval of this Application to amend the Table to sub clause 18(1) of 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– Polydextrose in Foods By Ion Chromatography) for the following reasons:

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

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

2. Polydextrose is listed as a permitted additive in Schedule 2 - Miscellaneous Additives in accordance with GMP in Processed Foods specified in Schedule 1, of Standard 1.3.1. It is also recognised as a food ingredient when present in significant quantities. Polydextrose is thus considered safe and of negligible risk to public health.

The proposed drafting for the amendment to the Table to subclause 18(1) of Standard 1.2.8 – Nutrition Information Requirements, is at Attachment 1 of this Draft Assessment Report.

10. Implementation and Review

Following the consultation period for this document, the Final Assessment of the Application will be undertaken. Following the preparation of the Final Assessment Report and consideration by the FSANZ Board, a notification will be made to the Ministerial Council and it is anticipated that the notification will be made by the end of the 2nd quarter 2004. Subject to the outcome of the Ministerial Council process, an amendment to Standard 1.2.8 – Nutrition Information Requirements would come into effect upon gazettal.

Attachments

1. Draft Variation to Standard 1.2.8 of the *Australia New Zealand Food Standards Code*
2. 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

Certificate of Analysis for Polydextrose

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			
Odourless	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