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13 August 2003

INITIAL ASSESSMENT REPORT

APPLICATION A491

RESISTANT MALTODEXTRIN AS DIETARY FIBRE

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

24 September 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

The Authority has prepared an Initial Assessment Report of Application A491, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* (the Code) for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991*. 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

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 the Authority **by 24 September 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.

Further Information

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

Food Standards Australia New Zealand
PO Box 7186
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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from the Authority's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Matsutani Chemical Industry Co Ltd on 17 January 2003 seeking to amend Standard 1.2.8 – Nutrition Information Requirements of the *Australia New Zealand Food Standards Code* (the Code) to recognise resistant maltodextrin (RMD) as a dietary fibre and to include a specific method of analysis for dietary fibre in foods containing RMD. This Application has been accepted on the FSANZ workplan as number A491.

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. This Standard does not permit a nutrition information statement to recognise RMD in the calculation of total dietary fibre content.

Objective

The specific objectives of A491 are to:

- protect public health and safety through appropriate regulation of RMD, including safety considerations on the addition of RMD to foods; and
- ensure that consumers can make informed choices about the dietary fibre content of foods containing RMD.

Issues

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

- *Classification of Resistant Maltodextrin as dietary fibre*
Consideration of whether RMD 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.
- *Method of analysis*
The method of analysis, ‘AOAC Official Method 2001.03 – Total Dietary Fibre in Foods Containing Resistant Maltodextrin’, is an extension of the AOAC 985.29 method currently prescribed in Standard 1.2.8. Of relevance to this issue is a determination of not only the appropriateness of including AOAC 2001.03 in Standard 1.2.8, but also how it applies to the analysis of various dietary fibre components.

- *Safety of RMD*
FSANZ has identified several safety concerns regarding the use of RMD in foods. A safety assessment will be conducted during the Draft Assessment of A491 based on available information. The safety assessment will consider:
 - the altered chemical structure of the product compared to traditional maltodextrin,
 - the potential for high levels of consumption of the product, and
 - the physiological effects of a poorly digested fibre on the gastrointestinal tract.
- *Nutrition issues*
The Applicant has highlighted the potential nutritional benefits of RMD, in that it does not form viscous solutions associated with other forms of soluble dietary fibre, and thus the consumption of RMD containing food will not compromise nutritional intake.
- *Dietary issues*
RMD can be used in a wide variety of foods at concentrations ranging from 0.2 –30%. If AOAC 2001.03 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 A491 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 RMD 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* (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.

For both the Issues and Impact Analysis sections in this Report, a number of questions have been posed to facilitate consideration of this Application. Public comment is invited on these questions, the proposed regulatory options, and the Report as a whole.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an application from Matsutani Chemical Industry Co Ltd on 17 January 2003 seeking to amend the Table to Subclause 18(1) of Standard 1.2.8 of the Code to include another method (AOAC 2001.03) for the measurement of dietary fibre in particular foods. If this amendment is allowed, it will enable resistant maltodextrin (RMD) to be included in the calculation of total dietary fibre content for the purposes of nutrition labelling, provided RMD meets the definition of dietary fibre as specified in Clause 1 of Standard 1.2.8.

RMD has been categorised by the Applicant as starch hydrolysates (e.g. dextrin and maltodextrin) that contain indigestible components. Other categorisation has been made by the United States (US) Institute of Medicine, where RMD is referred to as a mixture of oligosaccharides and polysaccharides manufactured by pyrolysis and subsequent enzymatic treatment of cornstarch.¹

Matsutani Chemical Industry Company has developed a RMD (named Fibersol-2), which is composed of the $\alpha(1-4)$ and $\alpha(1-6)$ glucosidic bonds normally found in the native starch, but also contains $\alpha/\beta(1-2)$ and $\alpha/\beta(1-3)$ linkages and levoglucosan². Due to this altered structure, Fibersol-2 contains branched particles that are only partially hydrolysed by human digestive enzymes. Information provided by the Applicant indicates that Fibersol-2 contains approximately 90% of indigestible components². RMD is also known as indigestible dextrin.

The Applicant has advised that RMD can be added to any type of food that is currently formulated with maltodextrin, suggesting that the addition of RMD to these types of foods fulfils the normal technological function of maltodextrin in foods.

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;

¹ Institute of Medicine (2001), *Dietary Reference Intakes: Proposed Definition of Dietary Fibre*, National Academies Press, Washington DC.

² Ohkuma K & Wakabayashi S, (2001), *Fibersol-2: A Soluble, Non-digestible, Starch-derived Dietary Fibre*, in McCleary B.V & Prosky L (Eds) *Advanced Dietary Fibre Technology*, Blackwell Science, Oxford, pp. 509-23.

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. RMD is such a substance. The Applicant has therefore applied to have the Table to subclause 18(1) of Standard 1.2.8 of the Code amended to include a new method of analysis for dietary fibre in foods containing RMD.

In considering the regulatory problem, this paper will therefore assess the issues of how RMD meets the definition of dietary fibre in Standard 1.2.8, and whether RMD 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 objectives of A491 are to:

- protect public health and safety through appropriate regulation of RMD, including safety considerations on the addition of RMD to foods; and
- ensure that consumers can make informed choices about the dietary fibre content of foods containing RMD.

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 and a general definition was thus developed through the process of A277 and included in Standard 1.2.8.

4.2 International Background

The Applicant states that Fibersol-2 has approval as a dietary fibre according to AOAC Official Method 2001.03 in Japan, Korea, the United States, the United Kingdom, other European Union countries, Taiwan, and is pending approval in Canada and China.

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.’

Maltodextrin 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 good manufacturing practice (GMP) (21 CFR – 184.1444). No GRAS status has been given specifically to RMD, however the Applicant has indicated that Fibersol-2 meets the US GRAS requirements for maltodextrin.

4.2.3 Japan

Japan has regulations for Foods for Specified Health Use (FOSHU). FOSHU products can make specific health claims. According to the Applicant, FOSHU products containing indigestible dextrin as the effective ingredient in beverages, powdered beverages, cookies and sausages; has been approved and is marketed in Japan.

4.3 Novel Food Considerations

As RMD is a relatively new substance to be added to foods, its status under Standard 1.5.1 – Novel Foods has been assessed at Initial Assessment.

Standard 1.5.1 requires FSANZ to consider the safety of those non-traditional foods and food ingredients that are considered ‘novel’ before they are made available for retail sale. A non-traditional food or food ingredient is regarded as ‘novel’ if there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account:

- (a) the composition or structure of the product;
- (b) the level of undesirable substances in the product;
- (c) known potential for adverse effects in humans;
- (d) traditional preparation and cooking techniques; and
- (e) patterns and levels of consumption of the product.

A ‘non-traditional food’ means a food that does not have a history of significant human consumption by the broad community in Australia or New Zealand.

In order to determine whether RMD is a non-traditional food, and possibly a novel food, FSANZ requested further information from the Applicant on the extent of use of RMD in Australia and/or New Zealand. In response to this request, the Applicant provided some generic information related to the use of Fibersol-2, but was unable to provide specific information on its availability in Australia and New Zealand.

It is possible, however, that foods imported into Australia and New Zealand may contain Fibersol-2, due to the number of overseas countries in which it is used and the wide range of food applications in these countries including: beverages, cultured dairy products, cereals, frozen desserts, processed meats and baked goods. It is not possible to determine whether Fibersol-2 is present in imported foods of this nature, as it would be referred to as ‘dextrin’ or ‘maltodextrin’ in Australia and New Zealand.

According to the Applicant, it is likely that Fibersol-2, and therefore RMD has been present in imported foods on the Australian and/or New Zealand market for many years. Therefore, it is not practical to consider RMD under Standard 1.5.1 as a novel substance.

4.4 Work Plan Classification

This Application had been identified as A491, 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 RMD regulation have been identified:

- determination of whether RMD 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;
- consideration of the novel status of RMD;
- nutritional issues associated with dietary fibre; and
- dietary consideration of RMD in food.

5.1 Resistant Maltodextrin as dietary fibre

Determination of whether RMD 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 dietary fibre under the definition in Clause 1 of Standard 1.2.8 of the Code, there must be a demonstration that it is indigestible in the human 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 RMD as dietary fibre, the Applicant has cited an *in vivo* study indicating that RMD is indigestible in the human body³. This study observed that with an increase in the proportion of RMD in three manufactured fibre products, the blood glucose and insulin concentrations of five human males did not significantly increase ($p < 0.01$) after ingestion, when compared to the ingestion of either glucose or maltodextrin. The product containing the highest proportion of RMD – Fibersol-2 at 90% – only produced a very small rise in blood glucose and insulin concentrations over a 150-minute period.

³ Ohkuma K, Matsuda I, Katta Y, and Hanno Y (1990), *Pyrolysis of Starch and Its Digestibility by Enzymes – Characterisation of Indigestible Dextrin* Denpun Kagaku 37: 107-114.

However, there was no statistical or laboratory determination in this study as to whether the digestible carbohydrate fractions of these products were responsible for the reported increases in blood glucose and insulin concentrations above a fasting level, a potentially confounding factor of the results. Despite such an omission, the study does indicate that the RMD in these products, as analysed by AOAC 2001.03, contributes significantly to their indigestibility when assessed *in vivo*.

The Applicant has further argued that RMD promotes all three 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 RMD, specifically on laxation, reduction in blood cholesterol and modulation of blood glucose have been provided in support of these arguments. These studies and other information will be investigated further during the Draft Assessment.

Submitters are invited to comment or provide relevant data on the characteristics of RMD with respect to the definition of dietary fibre and the following question:

- Does RMD display the necessary characteristics to meet the definition of dietary fibre as provided in Clause 1 of Standard 1.2.8?

5.2 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 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, RMD 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 RMD, and future substances, are forms of dietary fibre.

Submitters are invited to comment or provide relevant data on the development of quantified eligibility criteria for dietary fibre and the following questions:

- Would it be advantageous to develop quantified criteria in order to demonstrate the magnitude of the beneficial physiological effects listed in the definition of dietary fibre in Standard 1.2.8?
- If so, what measurable levels would be appropriate in the criteria for demonstration of each physiological effect?

5.3 Method of Analysis

The Applicant claims that the Prosky method (AOAC Official Method 985.29) prescribed in the Table to subclause 18(1) only measures 40% of Fibersol-2 as dietary fibre, and that the true total dietary fibre content of a food can not be determined by this method. Prosky⁴ states that a number of substances, including RMD, meet the AOAC physiological definition of dietary fibre⁵ (including resistance to digestibility in the small intestine and faecal bulking) yet are not analysed as dietary fibre by AOAC 985.29.

The Applicant proposes that a new method of analysis be included in the Table to Subclause 18(1) to measure the total dietary fibre content of foods for the purposes of the nutrition information labelling of dietary fibre. The proposed new method is known as “AOAC Official Method 2001.03 – Total Dietary Fibre in Foods Containing Resistant Maltodextrin”. The Applicant has provided information on an AOAC collaborative studies conducted to validate this method^{6,7}, which has been adopted as First Action by AOAC International. The Applicant has indicated that this method is likely to be adopted as Final Action by AOAC International during 2003.

The AOAC 2001.03 method is an extension of, and includes AOAC 985.29. The AOAC 2001.03 method initially analyses food for indigestible dietary fibre and high molecular weight soluble dietary fibre that is precipitated in ethanol, according to the AOAC 985.29 method. However, in addition, the desalted filtrate is then analysed. A liquid chromatography determination is conducted on the filtrate to obtain the quantity of low molecular weight RMD that did not precipitate in the 78% alcohol preparation. The two values are summed to obtain the total dietary fibre content of the food.

The Applicant has requested that AOAC 2001.03 be permitted as a method for only calculating the total dietary fibre content of foods containing RMD. As it is the prerogative of manufacturers to determine which method of analysis to use for calculating total dietary fibre content of a food, positioning AOAC 2001.03 as a general method of analysis for

⁴ Prosky L (2000), *What is dietary fibre?* Journal of AOAC International, 83:4, 985-7.

⁵ The AOAC definition is stated as: “Dietary fibre consists of the remanants of plant cells, polysaccharides, lignin, and associated substances resistant to hydrolysis by the alimentary enzymes of humans”. Reference: Cho S, DeVries J, Prosky L (1997), *Dietary Fiber Analysis and Applications*. AOAC International, Maryland USA.

⁶ Ohkuma K, Matsuda I, Yasuo K, Tsuji K (2000), *New Method for Determining Total Dietary Fibre by Liquid Chromatography*. J AOAC International, 83(4): 1013-1019.

⁷ Gordon DT and Okuma K (2002), *Determination of Total Dietary Fibre in Selected Foods Containing Resistant Maltodextrin by Enzymatic-Gravimetric Method and Liquid Chromatography: Collaborative Study*. J AOAC International, 85(2): 435-444.

dietary fibre is a viable approach, should its inclusion in Standard 1.2.8 be assessed as acceptable.

However, there is the possibility of also permitting the use of the proposed new method for determining the total dietary fibre content in any food, not just those containing RMD. Foods that do not contain RMD would only obtain a total dietary fibre value from AOAC 2001.03 similar to that obtained with the currently permitted methods of analysis for total dietary fibre, as the additional procedure in AOAC 2001.03 would only produce a negligible RMD value for these foods.

Submitters are invited to comment on the method of analysis of RMD as dietary fibre and the following question:

- Is the ‘AOAC Official Method 2001.03 – Total dietary Fibre in Foods Containing Resistant Maltodextrin’ suitable for inclusion in the Table to Subclause 18(1) of Standard 1.2.8 as a regulatory method of analysis of total dietary fibre content?

In considering this question 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;
- the reproducibility and precision of the method; and
- whether the method can apply to foods that do not contain RMD.

5.4 Safety considerations of Resistant Maltodextrin

RMD is not easily distinguished from traditional maltodextrin, and it is not immediately evident that there is sufficient knowledge in the broader community to ensure safe use. Therefore, a number of safety concerns exist in relation to RMD, which will require further consideration at Draft Assessment. These concerns include:

- the altered chemical structure of the product compared to traditional maltodextrin;
- the potential for high levels of consumption of the product; and
- the physiological effects of a poorly digested fibre on the gastrointestinal tract.

The Applicant has provided copies and summaries of relevant information on the safety of RMD and Fibersol-2 as follows:

- safety and efficacy studies conducted in experimental animals and humans;
- the chemical composition and structure of Fibersol-2;
- intended physiological effects of the deliberate modification of structure in Fibersol-2 in comparison with maltodextrin generally; and
- concentrations in various food products, which ranges from 0.2% to 30% in most food applications, but is as high as 99% in tabletop sweeteners (since the product comprises intense sweetener and maltodextrin only).

FSANZ will consider the safety data on RMD at Draft Assessment, which at present is specific only to the information on Fibersol-2 as provided by the Applicant.

Submitters are invited to comment or provide additional data relevant to the safety of RMD. Consideration should be given to the following:

- The potential effects on the gut associated with foods containing high levels of RMD.
- The potential for RMD to inhibit or reduce the absorption of nutrients.
- Any other relevant safety concerns.

5.5 Nutrition Issues

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 can also impair nutrient absorption by forming viscous solutions and gels, a process that has been shown to reduce nutrient absorption by delaying stomach emptying and digestion. As a soluble fibre derived from starch, the Applicant has argued that RMD does not form a highly viscous gel and therefore will not compromise nutrient intake in the typical manner of such fibre types. Some evidence has been provided in support of this argument⁸.

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 RMD 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.

Submitters are invited to comment or provide data relevant to the effect of RMD on nutrient absorption and bioavailability in the gastrointestinal tract, and the following questions:

- Will the use of RMD in foods avoid or minimise the impact on nutrient bioavailability that occurs with other forms of dietary fibre, as argued by the Applicant?

5.6 Dietary considerations

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

⁸ Matsuoka A, Saito M, Nagano S (1992), *Continuous Administration Tests of Indigestible Dextrin; 1: Study on the effects of the improvement of fat metabolism in healthy volunteers*, J Jpn Clin Nutr 80(2): 167-172.

Table 1: Potential level of use for RMD in various foods

Food category	Specific food items	Level of RMD use (%)
General Processed Foods	<ul style="list-style-type: none"> - Sauces/ Dressings/ Soups (retorted, dry)/ Gravies - Canned goods (fruit, vegetables, meats, pasta) - Frozen foods 	3 - 30
Beverages	<ul style="list-style-type: none"> - Dairy - Juice - Soy formulated smoothies - Fortified waters - Sports drinks - Other beverages 	1 - 10
Cultured Dairy Products	<ul style="list-style-type: none"> - Cup yogurts - Yogurt drinks - Cultured dairy beverages - Pro-biotic products - Sour cream 	1 - 5
Cereals	<ul style="list-style-type: none"> - Hot cereal - Ready-to-eat (RTE) - Flaked - Extruded 	1 - 10
Frozen Dairy Desserts	<ul style="list-style-type: none"> - Ice creams - Sorbets - Frozen yogurts - Novelties - Other frozen dairy 	1 - 5
Confectionery Products	<ul style="list-style-type: none"> - Hard and soft candies - Chocolate - Coatings - Compounded flavourings 	5 - 30
Snack Foods	<ul style="list-style-type: none"> - Extruded (hot and cold) - Baked - Fried 	1 - 5
Baked Goods	<ul style="list-style-type: none"> - Yeast raised and chemically leavened breads - sweet biscuits - crackers 	1 - 10
Processed Meats	<ul style="list-style-type: none"> - Ground meats - Emulsion type products - Coarse ground products - Injected or recombined whole muscle foods 	1 - 10
Dry Mixes	<ul style="list-style-type: none"> - Beverages - Baked goods - Supplements - Formulated meal replacements 	1 - 30
High Intensity Sweetener	<ul style="list-style-type: none"> - Tabletop sweeteners (intense sweetener and maltodextrin only) 	99
Nutritional/Functional Foods	<ul style="list-style-type: none"> - Energy / nutrition bars - Reduced / low / no fat foods - Reduced / low / no calorie foods - No sugar added foods - Foods for special medical purposes (currently the subject of Proposal P242) 	1 - 30
Dietary Supplements (both food and therapeutic types)	<ul style="list-style-type: none"> - Dry mixes - Fluid beverages - Prepared meals - Bars - Snacks - Tablets - Capsules 	1 - 100

It is not possible to determine current patterns and levels of consumption of RMD in Australia and New Zealand. It is possible that some imported food products may contain RMD, however it can only be referred to as “dextrin” or “maltodextrin” in Australia and New Zealand, because it is not recognised as dietary fibre for nutrition labelling purposes. The patterns and levels of consumption of RMD will be investigated at Draft Assessment as part of the safety assessment.

If a method of analysis for RMD is included in Standard 1.2.8, it is likely that the number of food products containing higher levels of dietary fibre would increase in Australia and New Zealand, due to the ability to include RMD in dietary fibre nutrition information values. This incentive for adding RMD 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; however, including RMD 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 RMD in foods and/or patterns and levels of consumption of RMD and the following questions:

- Are you aware of any additional, or more specific data on the use of RMD by the Australian and New Zealand food industry?
- Are you aware of any data regarding the patterns and/or levels of consumption of RMD 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 RMD to foods that are not traditional sources of dietary fibre?

6. Regulatory Options

Two options are being considered for progressing A491 at Initial Assessment:

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

To maintain the *status quo* by not including a new method of analysis would mean that RMD would not be recognised as dietary fibre for nutrition labelling purposes. It is possible that RMD will be present in imported food products but not readily identifiable because it can only be referred to as ‘dextrin’ or ‘maltodextrin’.

2. *Include specific regulation for method of analysis of foods containing RMD 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, RMD would be recognised as dietary fibre for labelling purposes, by the recognition of ‘AOAC Official Method 2001.03 – Total Dietary Fibre in Foods Containing Resistant Maltodextrin’ as an acceptable method for determining the dietary fibre 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 RMD and foods containing RMD who make up the **industry**; and the **governments** of New Zealand, Australian States and Territories, and the Commonwealth of 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 RMD and products containing RMD under Option 2.

7.2.1 Option 1 – Status Quo

Consumers

The impact on consumers from this option is likely to be minor. The restriction of current regulatory arrangements that prevent manufacturers from claiming RMD 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.

Food Industry

There is a potential disadvantage to industry in not permitting RMD as a potential claimable source of dietary fibre in foods. Those manufacturers whose products contain RMD 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 RMD as a source of dietary fibre, by virtue of the inability to reflect the addition of RMD in a product's fibre content.

There is some potential for industry innovation to be restricted in the area of developing new types of RMD for use as a source of dietary fibre.

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 RMD in Standard 1.2.8*

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 RMD may, however, create a level of consumer confusion with public health nutrition education messages on 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 RMD 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.

Food Industry

Industry may potentially benefit from broadening the permissions on sourcing added dietary fibre, and by allowing for the presence of RMD to be claimed as a source of dietary fibre. RMD may be used in foods that are currently formulated with maltodextrin, so permitting the labels on these foods to contain a nutrient content claim for dietary fibre will potentially benefit industry.

A prescribed method of analysis that incorporates RMD 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.

Government

Nutrition education messages may need to be modified to allow for the classification of RMD 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 with regard to nutrition messages. However, government public health strategies for increasing population dietary fibre intakes may indirectly benefit to from this option, through a potential increase in the range of foods available on domestic markets that contain higher levels of dietary fibre, or are identified as sources of dietary fibre.

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.

Are there any other potential costs and benefits to consumers, industry or government or any other stakeholders not identified in this Initial Assessment?

8. Consultation

8.1 Release for Public Consultation

The Initial Assessment Report will be released for a six-week consultation period. The views of the submitters will be incorporated into the development of the Draft Assessment Report. Further public comment will be sought on the Draft Assessment Report in late 2003, which will include a proposed regulatory approach.

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 RMD, is unlikely to have a significant effect on international trade as RMD is currently permitted for use in the majority of imported foods, and is recognised as a source of dietary fibre in the majority of 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) or Sanitary and Phytosanitary Measure (SPS) Agreements. 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.

For both the Issues and Impact Analysis sections in this Report, a number of questions have been posed to facilitate consideration of this Application. Public comment is invited on these questions, the proposed regulatory options, and the Report as a whole.

Subject to further payment by the Applicant to progress A491 as a Group 3 Application, responses to this Initial Assessment Report will be used to further assess A491 including the undertaking of any risk assessments and development of draft amendments to the Code.