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

6-04
4 August 2004

FINAL ASSESSMENT REPORT

APPLICATION A491

RESISTANT MALTODEXTRIN AS DIETARY FIBRE

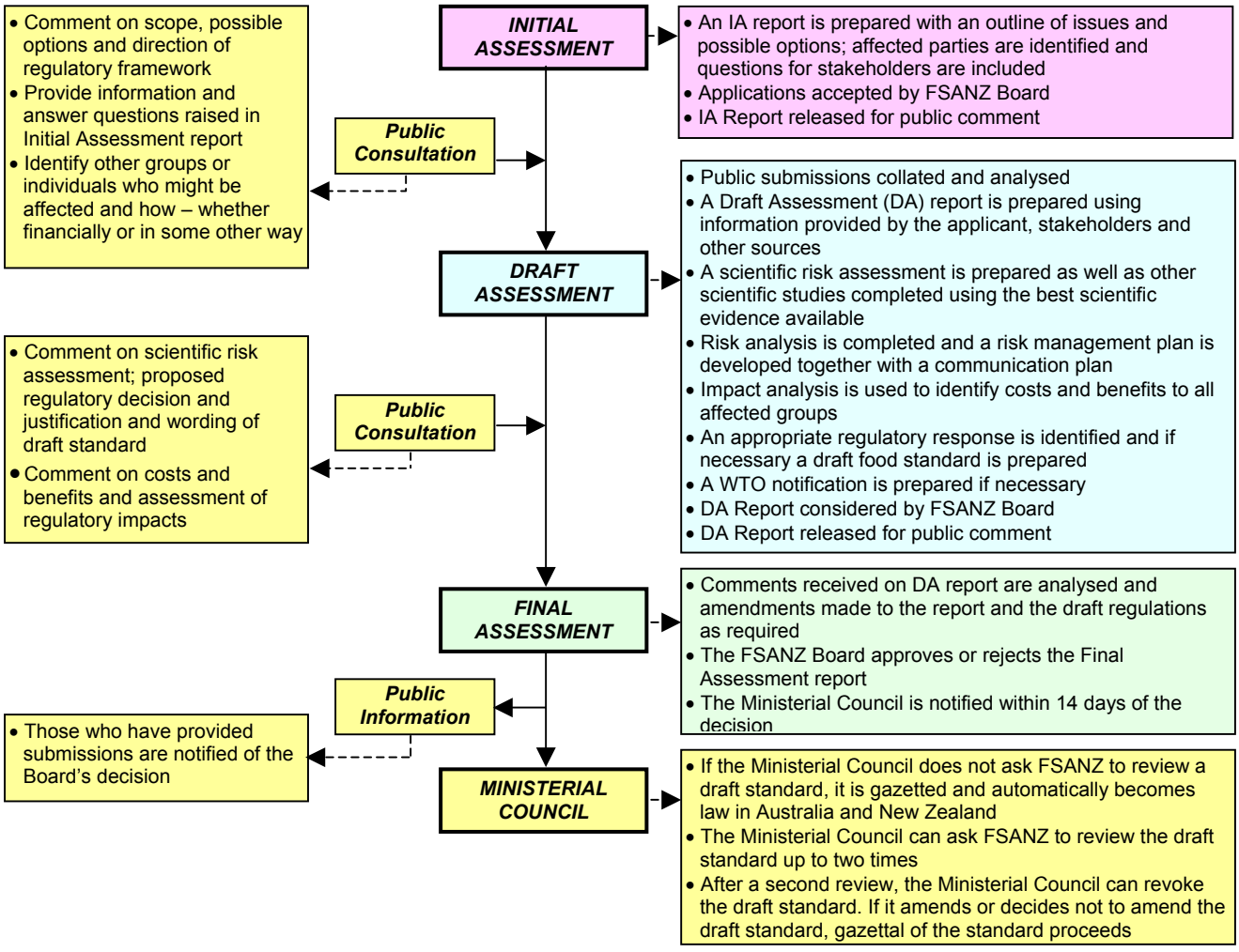
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

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

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

Further Information

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

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

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application from Matsutani Chemical Industry Co Ltd on 17 January 2003, seeking to amend the Table to subclause 18(1) of Standard 1.2.8 – Nutrition Information Requirements of the *Australia New Zealand Food Standards Code* (the Code) to include the method AOAC 2001.03 – 'Total Dietary Fibre in Foods Containing Resistant Maltodextrin' for the measurement of dietary fibre in foods containing resistant maltodextrins. If this amendment is approved, it will enable resistant maltodextrins (RMD) to be included in the calculation of total dietary fibre content for nutrition labelling purposes.

The Applicant has stated that the current methods of analysis for dietary fibre prescribed in the Table to subclause 18(1) can accurately measure only up to 50% of any RMD that are present in a food. The method AOAC 2001.03 however, is reported to quantify close to 100% of the RMD that are in a food.

In assessing the Applicant's request, it is noted that the scope of Application A491 will not address whether RMD should be permitted for addition to foods. RMD are considered ingredients (i.e. maltodextrins) and are therefore already permitted for use in the manufacture of foods, subject to any public health and safety considerations.

Objectives

The specific objectives of Application A491 are to:

- enable consumers to make informed choices about the dietary fibre content of foods, by reviewing the list of approved methods for dietary fibre analyses to reflect available analytical techniques, and to reflect current scientific understanding on the status of RMD as dietary fibre; and

- protect public health and safety through an assessment of the safety, nutritional and technical issues associated with RMD.

Issues

Submissions to the Draft Assessment for Application A491 made comments on a number of topics that can be broadly categorised into three main issues:

- the relationship between RMD and the definition of dietary fibre;
- implications for population nutrition and dietary patterns, including the potential impact on consumer confusion; and
- the potential for RMD to contribute to dietary fibre claims.

Each of these issues has been addressed at Final Assessment. In considering these issues, FSANZ recognises that it is impractical to apply AOAC 2001.03 to all types of RMD, as it is unknown whether assessments based on the Applicant's Fibersol-2 product can apply to other types of RMD. Therefore, requirements have been established as part of the proposed amendment to the Code for the use of the AOAC 2001.03 method.

Regulatory Options and Impact Analysis

There are two options for addressing this Application:

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

2. Include specific regulation in Standard 1.2.8 for a method of analysis of dietary fibre in foods containing added RMD, and implement any appropriate risk management strategies.

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

Conclusion and Statement of Reasons

Option 2 has been identified as the preferred regulatory approach for Application A491. The considerations made in reaching this conclusion are as follows.

- RMD do not constitute any public health and safety concerns, and will not have a negative impact on the nutritional status of Australian and New Zealand populations, should they be recognised as dietary fibre. These findings are based on assessments of Fibersol-2 (Attachments 6 and 7).

- The method AOAC 2001.03 has been assessed as suitable for determining the total dietary fibre of foods containing RMD.

- Although Fibersol-2 was assessed as meeting the definition of dietary fibre (Attachment 5), there is insufficient scientific evidence to determine if those RMD without the chemical features of Fibersol-2 will also meet the definition of dietary fibre. Therefore, the use of AOAC 2001.03 will be restricted to foods that contain added forms of RMD only, with RMD further clarified as having characteristics based on the specifications for Fibersol-2.

- The implementation of Option 2 will impose some costs for affected parties; however, there will be an overall net benefit from proceeding with this option.

- If RMD are classified as a form of dietary fibre there is the potential for some increase dietary fibre content claims. However, health, nutrition and related claims are already under review, and it is not within the scope of this Application to address the broader framework that underscores dietary fibre content claims. Even so, any public comments made to Application A491 on this issue will be included within the process of reviewing health, nutrition and related claims.

AOAC Official Method 2001.03 – 'Total Dietary Fibre in Foods Containing Resistant Maltodextrin' is therefore recommended as a method of analysis for dietary fibre in the Table to subclause 18(1) of Standard 1.2.8 as detailed in Attachment 1 of this report.

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 – Nutrition Information Requirements of the Code to include the method AOAC 2001.03 – 'Total Dietary Fibre in Foods Containing Resistant Maltodextrin' for the measurement of dietary fibre. If this amendment is approved, it will enable resistant maltodextrins (RMD) to be included in the calculation of total dietary fibre content for nutrition labelling purposes.

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

2. Regulatory Problem

2.1 Current Standard

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 (e.g. inulin) content of food.

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

2.2 Requested Amendment to Standard 1.2.8

The Applicant has stated that the current methods of analysis for dietary fibre prescribed in the Table to subclause 18(1) of Standard 1.2.8 do not accurately measure the dietary fibre content of foods containing RMD. These methods can detect up to 50% RMD within their dietary fibre measurement, however they are not designed specifically for this purpose. Therefore, the Applicant has applied to amend the Table to subclause 18(1) of Standard 1.2.8 of the Code to include AOAC 2001.03 as a method of analysis, which is reported to measure close to 100% of the RMD present in a food.

In assessing the Applicant's request, it is noted that the scope of Application A491 will not address whether RMD should be permitted for addition to foods. RMD are considered ingredients (i.e. forms of maltodextrins) and are therefore already permitted for use in the manufacture of foods, subject to any public health and safety considerations. The focus of Application A491 will therefore extend only to the recognition of RMD as forms of dietary fibre, their inclusion in calculations of a food's dietary fibre content, and the insertion of the AOAC 2001.03 method in Standard 1.2.8.

3. Objectives

The purpose of this Application is to determine whether it would be appropriate to amend the Code and permit the inclusion of AOAC 2001.03 in the Table to subclause 18(1) of Standard 1.2.8. Such an amendment to the Code will need to be assessed by FSANZ in a manner consistent with three primary objectives as stated in section 10 of the FSANZ Act.

Section 10 of the FSANZ Act lists the primary objectives as:

- 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.

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 Application A491 that reflect these statutory requirements are:

- to enable consumers to make informed choices about the dietary fibre content of foods; and
- the protection of public health and safety through an assessment of the safety, nutritional and technical issues associated with RMD.

4. Background

4.1 The History of Dietary Fibre Regulation in Australia and New Zealand

Prior to 1995, both Australia and New Zealand recognised dietary fibre as carbohydrate substances that could be measured only by the Prosky method (AOAC 985.29 Official Method).

In 1995, FSANZ received Application A277 – Inulin and Fructo-oligosaccharides as Dietary Fibre, requesting amendments that would allow for the recognition of inulin and fructo-oligosaccharides (FOS) as forms of dietary fibre, substances that could not be measured by the Prosky method. These amendments were subsequently approved in the year 2000, and resulted in the addition of new AOAC methods into Standard 1.2.8.

Because there was no existing definition of dietary fibre in the Code at that time, a general definition of dietary fibre was also developed and included in Standard 1.2.8.

4.2 International Regulations on Dietary Fibre

The Applicant has provided written statements from United States (US) and Japanese authorities, which indicate that these countries have no objection to Fibersol-2 and Fibersol-2B resistant maltodextrin products being recognised as forms of dietary fibre. The Applicant has also informed FSANZ that Korea, Taiwan, the United Kingdom, and other European Union countries also recognise Fibersol-2 and Fibersol-2B as sources of dietary fibre, and that requests have been made of Canada and China to recognise Fibersol-2 and Fibersol-2B as sources of dietary fibre.

4.2.1 Codex Alimentarius

Codex defines 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'[1]. The Codex definition does not specify any analytical methods for the determination of dietary fibre for nutrition labelling.

The Codex definition is currently under review as part of an assessment of the *Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents* (CX/NFSDU 02/3). This review is being conducted by the Codex Committee on Nutrition and Foods for Special Dietary Uses, which has not as yet agreed upon a suitable definition. A proposed definition and list of appropriate analytical methods was circulated the 25th session of this Committee (2003), however a consensus was not reached. Further discussions are scheduled for the 26th session in 2004.

4.2.2 United States

In the United States, dietary fibre is not explicitly defined in legislation, although 'fiber' can be calculated using an official AOAC method (including AOAC 2001.03).

The United States (US) Institute of Medicine (IOM) has developed a definition for total dietary fibre based on methods of analysis as part of the development of the US Dietary Reference Intakes series. The proposed US definition of dietary fibre[2] 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.'

This definition is not currently included in the US *Code of Food Regulations*, and therefore will not have an impact on nutrition labelling within the US. The definition has, however, been used by the IOM to delineate sources of dietary fibre and associated potential health benefits when developing a recommended intake for total dietary fibre, although recommended intakes specific to each of the three dietary fibre types were not developed.

Maltodextrin has Generally-Recognised-As-Safe (GRAS) status in the US, and is permitted for use in food under the US *Code of Federal Regulations*[4] with no limitation other than current good manufacturing practice (GMP). No GRAS status has been specifically given to the overall category of RMD, however the Applicant has provided information demonstrating that US GRAS status has been specifically applied to its RMD product, Fibersol-2.

As RMD can be measured by the AOAC 2001.03 method, they can be fully included in dietary fibre content declarations on the labels of US foods. This also allows RMD to fully contribute to labelling of dietary fibre claims in the US.

4.2.3 Japan

Japan has regulations for Foods for Specified Health Use (FOSHU). FOSHU products can carry specific health claims including those relating to dietary fibre. According to the Applicant, FOSHU products containing RMD have been approved and marketed in Japan where RMD are ingredients in beverages, powdered beverages, cookies and sausages. In Japan, RMD are recognised as forms of dietary fibre under FOSHU regulations and are included in dietary fibre content declarations.

4.3 Substances Categorised as 'Resistant Maltodextrins'

RMD are a subset of the general category of 'maltodextrins' for which there is no single chemical structure. Maltodextrins are derived from starches, and because starches can assume a wide variety of chemical structures, the actual chemical nature of maltodextrins – and thus RMD – is poorly understood. However, RMD can be identified and separated into three broad categories on the basis of their manufacture:

- *Added forms of RMD:*
  These types of maltodextrins are deliberately manufactured for use as a form of dietary fibre. The Applicant's Fibersol-2 product is an example of this category.

- *Traditional maltodextrins that are 'resistant':*
  Some maltodextrins currently in use may have a chemical structure that provides them with resistance to human digestion. These products may or may not have the additional physiological effects associated with dietary fibres, and are added for a technological purpose rather than as a deliberately added form of dietary fibre.

- *Inadvertent production of RMD:*
  Some manufacturing processes (e.g. extrusion) can cause starch or digestible maltodextrins to gain resistance to digestion, and thus result in the appearance of RMD in a food. Further details of this process can be found in the Food Technology report that was provided at Draft Assessment (Attachment 4). It is unlikely that a manufacturer would be aware of the development of these particular RMD.

5. Relevant Issues

The Draft Assessment Report for Application A491 investigated and made assessments on the following issues:

- the substances that are considered to be RMD;
- whether RMD meet the definition of dietary fibre;
- the regulatory appropriateness of the AOAC 2001.03 method of analysis;
- the technological functions associated with RMD;
- the nutritional issues for RMD including the impact on nutrient absorption and availability, the dietary fibre claims made on labels, and the impact on consumers' understanding of dietary fibre;
- the safety of RMD;
- the dietary exposure to RMD; and
- the overall risk associated with the recognition of RMD as dietary fibre.

The consideration of these issues was based on the comments made by submitters to the Initial Assessment (see Attachment 3), and on various technical and safety assessments conducted at Draft Assessment (available at Attachments 4-7). The Draft Assessment made the conclusions on these issues that:

- any recognition of RMD as a source of dietary fibre will not constitute a risk to public health and safety, and will not adversely affect the dietary patterns or nutrient intakes of Australian and New Zealand populations;
- RMD meet the definition of dietary fibre as outlined in Standard 1.2.8;
- recognition of RMD as sources of dietary fibre will not be misrepresentative, nor will the general public be misled by the full inclusion of RMD values in total dietary fibre content declarations on a food label; and
- the AOAC 2001.03 method identified by the Applicant is an accurate and appropriate method for analysing the RMD content of a food for this purpose.

Following the Draft Assessment for Application A491, submitters have made further comments (see Attachment 2) on a number of topics that can be broadly categorised into three main issues:

- the conformance of RMD to the definition of dietary fibre;
- implications for population nutrition and dietary patterns, including the potential impact on consumer confusion; and
- the potential for RMD to contribute to dietary fibre claims.

These three issues will be assessed below in light of the new comments made by submitters, and in the context of the previous safety and technical assessments undertaken at Draft Assessment.

5.1 Resistant Maltodextrins and the Definition of Dietary Fibre

Consideration of RMD as dietary fibre is fundamental to the assessment of this Application, as it will determine whether AOAC 2001.03 can be included in Standard 1.2.8.

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'.

At Draft Assessment, the characteristics of RMD were compared to each part of the definition, and found to be consistent with its requirements.

5.1.1 Submitter Comments

There were no submissions that commented on the Draft Assessment's comparison of RMD against the definition of dietary fibre, however the *Food Technology Association of Victoria Inc.* and *Matsutani Chemical Industry Co. Ltd.* raised issues about whether it is appropriate to categorise RMD as dietary fibre.

Food Technology Association of Victoria Inc. indicated that the definition itself should be reviewed to determine what substances are categorised as dietary fibre. Alternatively, *Matsutani Chemical Industry Co. Ltd.* supported the definition and its application to RMD, although it was mentioned that Fibersol-2 was the only substance evaluated against the physiological criteria of the definition. *Matsutani Chemical Industry Co. Ltd.* therefore recommended that RMD should be further defined in the Code as applying to 'polysaccharides composed of α(1-4), α(1-6), α/β(1-2), and α/β(1-3) glucosidic bonds and levoglucosan'.

5.1.2 Assessment

With the different chemical arrangements that maltodextrins can assume to achieve an indigestible structure (see section 4.3 above), applying the definition of dietary fibre to the entire class of substances termed 'resistant maltodextrins' creates a risk that certain maltodextrins may be recognised as having the characteristics of dietary fibre, when this is not the case. Although all RMD may be indigestible (and can thus be analysed by AOAC 2001.03), without evidence to indicate otherwise, it is unlikely that many of the RMD that are not deliberately intended for use as forms of dietary fibre would meet the physiological requirements of the dietary fibre definition.

Therefore, FSANZ has reviewed the recognition of RMD as forms of dietary fibre since Draft Assessment, and concluded that restricting the categorisation of RMD to substances with the chemical features of Fibersol-2 is the most appropriate means of addressing the lack of evidence. The assessment of RMD against the dietary fibre definition (Attachment 5) was based on Fibersol-2 only, and cannot be applied to other RMD with certainty.

A separate definition for RMD in the Code is no longer considered to be the best means of capturing the assessment made on Fibersol-2. Instead, the most accurate arrangement is to refer to RMD as having a set of specifications based on Fibersol-2 (see Table 1 below) as a requirement for using AOAC 2001.03. Foods containing added RMD that meet these specifications will be eligible for analysis by the AOAC 2001.03 method, thus eliminating the risk that AOAC 2001.03 may capture RMD with substantially different properties to those of Fibersol-2. These specifications will be placed in Standard 1.3.4 – Identity and Purity, as is typically done with other specifications.

Table 1: Specifications for Fibersol-2 that will be applied to resistant maltodextrins

Characteristic		**Details for Fibersol-2**
Chemical structure		Glucopyranose linked by α(1-4), α(1-6), α/β(1-2), and α/β(1-3) glucosidic bonds, and levoglucosan.
Dextrose equivalent		8-12
Appearance		Free-flowing fine powder
Colour		White
Taste/odour		Slightly sweet/odourless
Solution		Clear
pH (in 10% solution)		4-6
Moisture (%)		max. 5
Ash (%)		max. 0.2
Arsenic (ppm)		max. 1
Heavy metals (ppm)		max. 5
Microbiological	Standard plate count (cfu/g)	max. 300
	Yeast and mould (cfu/g)	max. 100
	Salmonella	Negative to test
	Coliforms	Negative to test

5.1.3 Conclusion

Fibersol-2 has been concluded as meeting the definition of dietary fibre as provided in Standard 1.2.8. While it is possible that other types of RMD may also meet the definition, there is no currently available evidence that can demonstrate such an outcome. To ensure that any permission to use AOAC 2001.03 recognises only those types of RMD that have been assessed by FSANZ for conformity to the dietary fibre definition, the proposed amendment to the Code will specify that AOAC 2001.03 can only be used for foods that contain added RMD with specifications based on Fibersol-2.

5.2 Nutrition and Dietary Issues

There are two main nutritional/dietary issues that require further consideration at Final Assessment: the potential for a shift in consumer dietary behaviour away from traditional sources of dietary fibre to processed foods with added fibre, and the impact of this shift on consumers' understanding of dietary fibre.

5.2.1 Submitter Comments

Queensland Health has commented that there is a potential for Application A491 to negatively impact on dietary patterns, by recognising a form of dietary fibre that can be added to processed foods. In support of these comments, two pieces of literature were cited which indicated that a general trend in consumption patterns towards more processed foods has already commenced[4,5]. *Queensland Health* also acknowledged that an increase in dietary fibre intake would be beneficial for population nutrition, however any such benefits are negated if the increase in dietary fibre intake is also accompanied by an increase in saturated fat, sugar and salt intakes.

Queensland Health further stated that FSANZ's own research shows that consumers are confused about nutrition information and have difficulty interpreting such material.

5.2.2 Assessment

The issues raised by *Queensland Health* were previously addressed at Draft Assessment, where it was assessed that approval or disapproval of Application A491 will not affect the broader regulatory arrangement where dietary fibre content calculations are based on the use of a definition in conjunction with various methods of dietary fibre analysis. Furthermore, it was established that the current regulation of dietary fibre claims is the main driving force behind any shift in the addition of dietary fibre to non-traditional food sources, and not the approval of specific methods for analysing dietary fibre.

Consumer confusion over dietary fibre was recognised as a real and possible outcome of Application A491 at Draft Assessment. The literature cited by *Queensland Health* reinforces this concern, by demonstrating that consumers are becoming more exposed to processed foods that challenge the traditional concept of nutrition and dietary sources of nutrients. This problem is also in part affected by the regulatory uncertainty that exists at an international level over the classification of substances as dietary fibre[6]. However, it is not within the scope of this Application to address the regulatory framework for recognising and claiming sources of dietary fibre, only to operate within its boundaries, and to assess the public health impacts from an increased number of foods with novel forms of dietary fibre.

Therefore the only option available within this Application is to recognise consumer confusion as a cost arising from the implementation of the proposed amendments, and to give this cost due consideration.

5.2.3 Conclusion

The potential for increased consumer confusion with identifying sources of dietary fibre is a likely outcome of this Application. This cost has been recognised by FSANZ within the impact analysis at Section 7.

5.3 Dietary Fibre Claims

Should this Application be approved, RMD could be fully taken into account when determining a food's eligibility to bear a dietary fibre content claim in accordance with the Australian Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC, 1995).

In New Zealand, there are no regulations in food law that determine the eligibility of a food to carry a dietary fibre content claim. Instead, such claims are assessed in accordance with the New Zealand *Fair Trading Act, 1986*.

The Australian CoPoNC criteria for dietary fibre content claims discourage foods with a high fat content from carrying these claims. Where 30% or more of the food energy is derived from fats, there must be a statement on the label drawing attention to the fat content of the food in the nutrition information panel.

In December 2003 the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) released policy guidelines for nutrition, health and related claims. FSANZ is commencing implementation of the new policy within the Code via the food standards setting process, and it is intended that the eligibility criteria (and any other relevant regulatory aspects) for all nutrition content claims will be addressed via this process.

At Draft Assessment, it was recognised that of those foods with added RMD at levels sufficient to make a dietary fibre claim in Australia, additional restrictions could apply either from FSANZ's implementation of ministerial policy guidance, or through CoPoNC requirements on fat content. In New Zealand, compliance with the *Fair Trading Act, 1986* adds a layer of protection against inappropriate claims on trivial amounts of dietary fibre content. Furthermore, it was assessed that Application A491 is likely to increase dietary fibre contents across the food supply to a limited degree only, and thus have a limited impact on dietary fibre claims.

5.3.1 Submitter Comments

Queensland Health was the only submitter to comment on the issue of dietary fibre claims at Draft Assessment. *Queensland Health* stated that CoPoNC regulations are not enforceable, and are therefore inadequate when addressing potential dietary fibre claims made for RMD. However, it was recognised Application A491 does not have the scope to address the eligibility criteria for dietary fibre claims, and that there is already a process underway to revise health, nutrition and related claims. Therefore, *Queensland Health* has requested a guarantee from FSANZ, that eligibility criteria will be included as part of this revision process.

5.3.2 Assessment

FSANZ has not identified additional evidence since Draft Assessment that could further inform the previously determined impact on dietary fibre content claims, nor have submitters to the Draft Assessment presented any such material. Therefore, FSANZ continues to hold the position that the proposed amendment to the Code will only increase the numbers of foods carrying dietary fibre claims by a limited amount.

Concerns with the impact on dietary fibre claims are not unique to Application A491. Similar issues have been raised previously as part of Application A495 – Polydextrose as Dietary Fibre, which reviewed an amendment to permit the use of a new method of analysis for dietary fibre. Australian and New Zealand Health Ministers met during May 2004 to discuss, amongst other matters, the impact of Application A495.

Health Ministers did not request a review of the decision by FSANZ to accept Application A495, however they stated that the consequences for nutrition education and consumer understanding on dietary fibre should be given further consideration during the implementation of the health, nutrition and related claims policy.

FSANZ concurs with the comments made by both the Health Ministers on Application A495, and by submitters to Application A491; that the impacts from recognising methods of analysis for dietary fibre require further assessment during the development of a standard for health, nutrition and related claims. FSANZ will therefore incorporate the deliberations of this Application into the standard development process.

5.3.3 Conclusion

The recognition of RMD as dietary fibre will increase the numbers of foods carrying dietary fibre claims by a limited amount only. The comments on dietary fibre claims made during this Application (to both the Initial and Draft Assessments) are more appropriate for the health, nutrition and related claims revision process (Proposal P293), and will be incorporated into its assessments on nutrition claims.

6. Regulatory Options

Two options have been considered for progressing A491 at Draft 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 foods as there are no current prohibitions on their addition to, or presence in foods, but the full quantity of RMD will not be included in dietary fibre calculations. Under this Option it is recognised that current methods of analysis for dietary fibre can include approximately 50% of the RMD within a food as part of dietary fibre calculations.

2. *Include specific regulation for a method of analysis of dietary fibre in Standard 1.2.8 for foods containing RMD, and implement any appropriate risk management strategies.*

Under this option, the full RMD content of a food would be included in calculations of dietary fibre, 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. Foods containing RMD would therefore be able to include 100% of these substances in dietary fibre content declarations (e.g. nutrition information panels).

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**; the **governments** of New Zealand, Australian States and Territories, and the Commonwealth of Australia; and **public health officials/professionals** responsible for the nutrition education of Australian and New Zealand populations.

7.2 Impact Analysis

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

7.2.1 Option 1 – Status Quo

7.2.1.1 Consumers

The impact on consumers from this option is minor. Consumers are unlikely to know that manufacturers cannot include all of the RMD in a food within dietary fibre content declarations. However, under this option, the lack of an industry incentive is likely to keep added amounts of dietary fibre within current boundaries, thus limiting consumer choice on foods that contain high amounts of dietary fibre.

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

7.2.1.2 Food Industry

There is a potential disadvantage to industry in not permitting the AOAC 2001.03 method, as RMD would represent potential claimable sources of dietary fibre in foods. Those manufacturers whose products currently contain RMD may incur a cost through a lost marketing potential, however as up to 50% of the RMD in a food can be captured by current methods, the extent of this potential loss would be minimal.

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

7.2.1.3 Government

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

7.2.1.4 Public Health Officials/Professionals

As the main disseminators of nutrition education, public health officials/professionals may benefit from the minimal changes in nutrition education messages on dietary fibre that will occur under this option.

7.2.2 Include specific regulation for a 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.

7.2.2.1 Consumers

There are potential benefits to consumers under this option, as they may have access to a wider choice of products containing dietary fibre and will have access to more accurate nutrition information on the total dietary fibre content of foods containing RMD. A new range of food products containing RMD may, however, create a level of consumer confusion on sources of dietary fibre. This is particularly true if foods that are traditionally poor sources of dietary fibre were to contain added RMD as a means of increasing their dietary fibre content.

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

7.2.2.2 Food Industry

Industry may potentially benefit from broadening the types of substances considered as dietary fibre, and by allowing for the presence of all RMD to be included in dietary fibre content values. Through the ability to recognise a higher dietary fibre content on a product's label, manufacturers would be able to increase the marketing potential of products by:

- including 100% of current RMD levels in dietary fibre calculations,
- adding RMD to a product as a substitute for digestible forms of maltodextrin, or
- adding RMD as an innovative form of dietary fibre.

Industry could, however, incur some costs from Option 2, as AOAC 2001.03 includes an additional analytical step beyond those of other analytical techniques. However, these costs would only apply to those sections of the industry that choose to use AOAC 2001.03 in preference to other methods of calculating total dietary fibre content. These sections of the industry are also likely to be those who will receive the greatest benefits from Option 2.

7.2.2.3 Government

Nutrition education messages may need to be modified to allow for the classification of RMD as forms 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 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.

7.2.2.4 Public Health Officials/Professionals

Nutrition education messages may need to be modified to allow for the classification of RMD as forms of dietary fibre, creating a cost for public health officials/professionals. The potential for consumer confusion also represents a potential cost, as nutrition education activities will need to be changed to accommodate the general public's additional education requirements.

8. Consultation

8.1 Public Consultation

In March 2004, FSANZ released a Draft Assessment Report on Application A491 for public consultation. In response, 3 submissions were received: two submitters supported Option 1, and one supported Option 2. A summary of submitter comments can be found in Attachment 2.

8.2 World Trade Organization (WTO)

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

WTO member nations were notified of Application A491 on 10 March 2004. No comments were received in response to this notification.

9. Conclusion and Recommendation

The assessments outlined at Draft Assessment indicated that any recognition of RMD as a source of dietary fibre would not constitute a risk to public health and safety, and would not adversely affect the dietary patterns or nutrient intakes of Australian and New Zealand populations. RMD were also assessed as meeting the definition of dietary fibre as outlined in Standard 1.2.8, and that the AOAC 2001.03 method identified by the Applicant is an accurate and appropriate method for analysing the RMD content of a food for this purpose.

However, these assessments were based on scientific literature that was specific to the Applicant's RMD product (Fibersol-2). This is a particular problem for comparing RMD against the definition of dietary fibre, as there is no other scientific evidence that can confirm whether all RMD will have similar dietary fibre properties to those identified with Fibersol-2.

Therefore, at Final Assessment it is proposed that while the AOAC 2001.03 method is acceptable for determining the total dietary fibre content of foods containing RMD, additional requirements are needed for this purpose. These requirements include restricting AOAC 2001.03 to foods that only contain added forms of RMD, with RMD further clarified as having characteristics based on the specifications for Fibersol-2. These restrictions will ensure that AOAC 2001.03 will capture those RMD with the characteristics of Fibersol-2 (and thus having similar dietary fibre properties), and no others.

The costs and benefits remain substantially unchanged from those identified at Draft Assessment when consideration is given to the revised amendments as mentioned above, and to other issues that have been identified at Final Assessment.

On the basis of the above considerations, Option 2 is the preferred regulatory approach for Application A491. AOAC Official Method 2001.03 – 'Total Dietary Fibre in Foods Containing Resistant Maltodextrin' is recommended for listing as a method for analysing dietary fibre in the Table to subclause 18(1) of Standard 1.2.8 as detailed in Attachment 1.

10. Implementation

The Ministerial Council will be notified of the recommendations from this Final Assessment Report. Should the Ministerial Council accept the recommended draft variations to the Code without further review, they will come into effect shortly thereafter upon gazettal.

A transition period is not required for the implementation of the proposed draft variations, as manufacturers will have the choice as to whether or not they wish to use the AOAC 2001.03 method of analysis. Current stock will also be unaffected, as existing methods of analysis for dietary fibre will continue to remain in force.

Reference List

1. Codex Alimentarius (1995); *'Guidelines on Nutrition Labelling'*; CAC/GL 2-1985.
2. Institute of Medicine (IOM) (2001); '*Dietary reference intakes*: *Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, protein and Amino Acids'*; National Academy Press, Washington DC.
3. United States Code of Federal Regulations Title 21 *'Food and Drugs'*, Section 184.1444 *'Maltodextrin'*.
4. Cook, Rutishauser, Seelig (2001); *'Comparable data on food and nutrient intake and physical measurements from the 1983, 1985 and 1995 national nutrition surveys'*; Australian Food and Nutrition Monitoring Unit, AusInfo, Canberra.
5. Bonner G, Warwick H, Barnardo M, Lobstein T (1999); *'Fortification Examined'*; Food Commission (UK) Ltd, London.
6. Duxbury D (2004); *'Dietary Fiber: Still No Accepted Definition'*; Food Technology, 58(5): 70-80.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions to the Draft Assessment
3. Summary of Submissions to the Initial Assessment
4. Food Technology Report – Conducted at Draft Assessment
5. Assessment of Resistant Maltodextrins Against the Definition of Dietary Fibre – Conducted at Draft Assessment
6. Safety Assessment Report – Conducted at Draft Assessment
7. Dietary Exposure Assessment Report – Conducted at Draft Assessment

ATTACHMENT 1

Draft Variations 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 –*

[1.1] *inserting in the* Table to subclause 18(1) –

Total dietary fibre (including resistant maltodextrins)	Section 2001.03 of the AOAC, 17th Edition, 1st Revision (2002)

[1.2] *inserting in the* Editorial note *after* subclause 18(2*)* –

Total dietary fibre as determined by Section 985.29, or Section 991.43 of the AOAC, 17th Edition (2000) may include resistant maltodextrins. However, these methods cannot fully determine resistant maltodextrins as total dietary fibre, and should not be used for this purpose. Section 2001.03 of the AOAC, 17th Edition, 1st Revision (2002) is an accurate method for determining resistant maltodextrins as dietary fibre, and should be used to ascertain total dietary fibre content where full analysis of resistant maltodextrins is required.

Added resistant maltodextrins must comply with Standard 1.3.4 – Identity and Purity

[2] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Schedule –

Specification for resistant maltodextrins

Chemical structure		Glucopyranose linked by α(1-4), α(1-6), α/β(1-2), and α/β(1-3) glucosidic bonds; and contains levoglucosan.
Dextrose equivalent		8-12
Appearance		Free-flowing fine powder
Colour		White
Taste/odour		Slightly sweet/odourless
Solution		Clear
pH (in 10% solution)		4-6
Moisture (%)		max. 5
Ash (%)		max. 0.2
Arsenic (ppm)		max. 1
Heavy metals (ppm)		max. 5
Microbiological	Standard plate count (cfu/g)	max. 300
	Yeast and mould (cfu/g)	max. 100
	Salmonella	Negative to test
	Coliforms	Negative to test

Attachment 2

Application A491 – Resistant Maltodextrin as Dietary Fibre
Summary of Submissions to Draft Assessment

LIST OF SUBMITTERS

A public consultation period occurred from the 17 March 2004 to the 28 April 2004 for the Draft Assessment of Application A491. During this period, three separate submissions were received by FSANZ. A list of the submitters that provided comment on the Draft Assessment Report is provided below.

Submitter	*Abbreviation*
• Food Technology Association of Victoria	FTAV
• Matsutani Chemical Industry Co. Ltd	MCI
• Queensland Health	QH

COMMENTS MADE ON THE DRAFT ASSESSMENT FOR APPLICATION A491 – RESISTANT MALTODEXTRIN (RMD) AS DIETARY FIBRE

Preferred Regulatory Option

Option	Submitters Supporting Option	Comments
1 – Maintain Status Quo	FTAV, QH	• QH stated that until a new national nutrition survey is completed and provides data that can assess shifts in population nutrition [such as from traditional sources of dietary fibre to processed food sources], the recognition of RMD as dietary fibre will not be supported.
2 – Inclusion of AOAC Official Method 2001.03 in the Code	MCI	• As the Applicant for Application A491, MCI supports the inclusion of AOAC 2001.03 in Standard 1.2.8.

Method of Analysis

- MCI indicated that the AOAC 2001.03 method measures a whole range of indigestible oligosaccharides and polysaccharides in foods. AOAC methods quantify certain substances, and the physiological actions of such substances are not measured or implied. Therefore the scientific and technical assessments of Application A491 that measure dietary fibre characteristics can only apply to Fibersol-2.

Definition of Dietary Fibre

- FTAV was concerned at exactly what is defined as 'fibre' for human consumption. The whole definition of dietary fibre needs to be reviewed to determine what foods and or food ingredients/components fall into this category.
- FTAV mentioned that there is a lot of confusion on what is permitted for use and designated as 'fibre' within the food industry and amongst consumers.
- MCI stated that the assessment of RMD against the physiological effects criteria applies to Fibersol-2 only, and that other types of RMD will have different constituents.
- MCI recommends that RMD should be defined in the Code as applying to 'polysaccharides composed of α(1-4), α(1-6), □/□(1-2), and □/□(1-3) glucosidic bonds and levoglucosan'. MCI acknowledged that AOAC 2001.03 quantifies other types of small molecular weight soluble dietary fibre that cannot be recovered by the alcohol precipitation of AOAC 991.43.

Nutritional and Dietary Issues

- FTAV did not consider there to be a demonstrated health benefit associated with RMD.
- QH submitted the following material in support of an already existing shift in consumption patterns towards a more highly processed diet:

  - Cook, Rutishauser, Seelig (2001); *'Comparable data on food and nutrient intake and physical measurements from the 1983, 1985 and 1995 national nutrition surveys'*; Australian Food and Nutrition Monitoring Unit, AusInfo, Canberra; and
  - A report by the United Kingdom Food Commission on a survey of 260 foods containing added vitamins and minerals, which shows that 75% of these foods were high in fat, sugar or salt.

  QH stated that although the submitted material is not specific to RMD, the addition of RMD to foods such as confectionary, frozen dairy desserts, and dips etc, is a form of fortification and the results can therefore be considered relevant.

- QH agreed with comments made at the Draft Assessment by other submitters, stating that an increase in dietary fibre intake would be beneficial for population nutrition. However, any such benefits are negated if the increase in dietary fibre intake is also accompanied by an increase in saturated fat, sugar and salt intakes.

Dietary Fibre Claims

- QH commented that the 'Australian Code of Practice on Nutrient Claims in food label and advertising' (CoPoNC) is not enforceable, and is therefore inadequate when addressing potential dietary fibre claims made for RMD.
- QH recognise that addressing the eligibility criteria underpinning the permissions for dietary fibre claims is outside the scope of Application A491. A guarantee that eligibility criteria will be revised as part of the current health, nutrition and related claims revision process would be appropriate to allay any concerns on this issue.

Consumer Confusion

- QH stated that FSANZ's own research indicates that consumers are confused by the nutrition information provided on food labels and have difficulty interpreting this information. It is unlikely that RMD will be exempt from this confusion, especially when added to products such as chocolate, sour cream and ice cream.

Attachment 3

Application A491 – Resistant Maltodextrin as Dietary Fibre
Summary of Submissions to Initial Assessment

LIST OF SUBMITTERS

A public consultation period was made available from the 13 August 2003 to 3 October 2003 for the Initial Assessment of Application A491. During this period, seven separate submissions were received by FSANZ. A list of the submitters that provided comment on the Initial Assessment Report is provided below.

Submitter	Abbreviation
• Australian Consumers' Association	ACA
• Australian Food and Grocery Council	AFGC
• Prof. Dennis T. Gordon	
• Dietitians' Association of Australia	DAA
• Food Technology Association of Victoria	FTAV
• New Zealand Food Safety Authority	NZFSA
• Queensland Health	QH

COMMENTS MADE ON THE DRAFT ASSESSMENT FOR APPLICATION A491 – RESISTANT MALTODEXTRIN AS DIETARY FIBRE

Preferred Regulatory Option

Option	Submitters Supporting Option	Comments
1 – Maintain Status Quo	ACA, DAA	• The ACA does not support the inclusion of RMD in the *Food Standards Code* (the Code) unless sufficient evidence is provided to demonstrate that RMD carries the same health benefits of other types of dietary fibre. • DAA supports Option 1 until further information is provided to suggest otherwise.
2 – Regulation by a discreet standard in the FSC	AFGC, Prof. Gordon, FTAV.	• The AFGC supports Option 2, contingent on the outcomes of a safety assessment. It is stated that nutritional and dietary considerations indicate a net benefit, as does the 'costs and benefits' analysis. • Prof. Gordon mentioned that the method should be included in the Table to subclause 18(1) of Standard 1.2.8. • The FTAV Technical Subcommittee agrees with Option 2.

The Position of Other Submitters on Proposed Regulatory Options:

- NZFSA made no comment on the regulatory options.
- QH did not take a position on the regulatory options at the Initial Assessment stage of A491, and awaits the results of a safety assessment before doing so.

Definition of Dietary Fibre

Issue	Comments
Whether RMD meets the definition of dietary fibre	• The ACA mentioned that RMD should not be included in the Code under the definition of a dietary fibre, as this would be misleading to consumers. • Prof. Gordon stated that the American Association of Cereal Chemists definition of dietary fibre (which forms the basis of the dietary fibre definition in Code) was designed to include food ingredients such as RMD, polydextrose, low molecular weight fructans, FOS and GOS. • The AFGC states that, in the absence of information to the contrary, the information presented at Initial Assessment supports RMD being considered as dietary fibre.
The manner in which RMD does or does not comply with the definition of dietary fibre	• The ACA views RMD as a substance with a structure radically different to starch, having been derived from a process of chemical alteration. It is not a synthetic analogue of any naturally occurring plant fraction [as required in the definition for dietary fibre]. • Prof. Gordon mentioned that RMD is a safe non-digestible food-based carbohydrate used as a source of dietary fibre in food. - RMD are not intended to be the sole source of fibre in the diet. They are intended to complement other types of dietary fibre to help individuals achieve the level of dietary fibre intake associated with better health and prevention of disease. - Approximately 50% of RMD in a food can be recovered by the current methods for analysing total dietary fibre. This alone already qualifies half of the RMD in a food as dietary fibre. • The AFGC was of the view that RMD satisfy: - part a) of the definition for dietary fibre as the IAR cited an *in vivo* study demonstrating the indigestibility of RMD in the human body, and mentions that RMD meets the AOAC definition of dietary fibre. - part b) the definition on the basis of the IAR statement that there appears to be enough evidence indicating that RMD promotes all three physiological effects. - the final line of the definition as the United States (US) Institute of Medicine has categorised RMD as types of oligosaccharides and polysaccharides. • DAA stated that further information is required before any determination is made as to whether RMD complies with the definition of dietary fibre.

Issue	Comments
Physiological Effects Criteria	• Prof. Gordon mentioned that it would be appropriate to develop criteria for the physiological effects listed in the definition of dietary fibre. However, in considering such an undertaking, it should be noted that there are no acceptable procedures or protocols from other regulatory agencies (e.g. USFDA or Health Canada) that measure the beneficial effects of any dietary fibre in humans. - An analytical method to measure the source of dietary fibre components, safety information, and a compilation of animal and human studies demonstrating the physiological effects, should be sufficient in the absence of accepted criteria. - There are various experiments that support RMD as promoting all of the physiological effects at a moderate level when compared to other known dietary fibres, however there are few foods or sources of dietary fibre that can accomplish all three effects. - The request to have RMD recognised as a source of dietary fibre should not be based solely on nutrition and/or health promoting properties. • DAA stated that there was insufficient information at Initial Assessment to determine the physiological effects of RMD.

Method of Analysis

Issue	Comments
The suitability of AOAC Official Method 2001.03	• Prof. Gordon made the following statements on the AOAC Official Method of Analysis 2001.03: - The method measures what it is purported to measure; - The method can apply to foods not containing RMD; and - The method was designed to recover all soluble components not recovered by the method for total dietary fibre [AOAC 985.29]. • The AFGC supports the inclusion of AOAC 2001.03 in the Table to subclause 18(1). - AOAC 2001.03 measures what it is purported to measure. - The method can act as an alternative to the other two methods for assessing total dietary fibre, and can thus apply to foods not containing RMD. - FSANZ will need to seek advice from enforcement agencies on the implications of including AOAC 2001.03 as a simple alternative method to the other two methods for total dietary fibre. A sample may need to be analysed by all three methods to ensure that a legal challenge could not claim that one of the other methods were more appropriate.
The cost to industry from using the new method	• Prof. Gordon indicated that AOAC 2001.03 is slightly more expensive and time consuming compared to the method for total dietary fibre, but is more exacting and accurate. This method could also be used to measure other soluble indigestible carbohydrates that escape current methods of analysis with time and patience. • The AFGC indicated that AOAC 2001.03 would be more expensive to carry out than AOAC 985.29 due to the additional procedures. Therefore industry is likely to use it only where RMD is present in the food and the optimum dietary fibre value is needed for claiming or for nutrition information purposes.

Safety of Resistant Maltodextrin

Issue	Comments
Conducting a Safety Assessment	• The NZFSA agrees that further work is required to assess the safety of RMD. • The AFGC supports the undertaking of a safety assessment, as it is consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991*.
Safety Issues	• QH views the safety concerns for RMD to be: - 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. • Prof. Gordon mentioned that he has no knowledge or experience of how RMD affects gut morphology or nutrient absorption, but does for other types of dietary fibre. It was stated that no other dietary fibre causes problems in these areas of physiology except for chitosan. - There is no evidence in the literature of RMD harming the intestine or adversely affecting nutrient bioavailability. • Prof. Gordon has data that indicates dietary fibre does not interfere with nutrient absorption (but not on every food or source of indigestible carbohydrate / RMD). - Safety concerns for RMD are the same as for other types of dietary fibre – flatulence and diarrhoea. The amount of RMD that is necessary to produce these effects are in excess of 1g/kg body weight consumed at one time, which is an unlikely scenario. - Prof. Gordon foresees no physiological problems or discomfort for individuals consuming RMD in the amounts listed in Table 1 of the IAR. • DAA stated that if RMD is allowed in the variety of foods listed in Table 1 of the Initial Assessment Report, there is potential for excessive intakes to occur. Upon evaluation of the safety, the following may be necessary: - advisory or warning statements, - restrictions on maximum amounts of RMD, - consideration of the impact on children and adolescent dietary and nutrient intakes, and - consideration of the impact on those with inflammatory bowel disease.
Assessment of safety by overseas jurisdictions	• The NZFSA requested that FSANZ checks on the regulatory status of RMD in overseas jurisdictions, to ensure that the statement made in the IAR of having overseas approval is correct. • The AFGC does not believe FSANZ will find RMD unsafe when other overseas jurisdictions have not reached this conclusion. - Another safety consideration is that RMD complies with the specifications of identity for maltodextrin in the Food Chemical Codex.

Nutritional and Dietary Issues

Issue	Comments
Impact of RMD on nutrients	• ACA - the Applicant promotes RMD as a form of soluble fibre that is functionally equivalent to pectin and other gums, but without the disadvantage of forming gels or very viscous solutions. Only one reference was provided to support these claims and ACA's own research has not identified further supporting evidence. • Prof. Gordon - Other ingredients in plant foods may impair nutrient absorption, but not dietary fibre itself; e.g. phytic acid and oxalic acid. Therefore, other sources of dietary fibre such as RMD could help increase dietary fibre intakes while diluting the levels of more deleterious components. • The AFGC has supplied evidence that magnesium absorption was enhanced through the consumption of fermentable oligo- or poly-saccharides by humans.
Impact on population nutrition	• QH would like the Draft Assessment Report to address the concern that A491 may further shift food consumption away from fresh foods to more processed foods. - Rather than aiding public health benefits by reducing chronic diseases, such a shift may do the opposite by reducing the consumption of fresh fruit and vegetables. • Prof. Gordon stated that there should be an encouragement to consume more fruit and vegetables in the diet, however there are nutritional and health values in processed foods that contain indigestible carbohydrates such as RMD. - States that processed foods may be 'sacrilegious' to many nutritionists, but they provide convenience and nutrition, and are what many people eat. - RMD is not a single source of dietary fibre, but rather part of a large dietary matrix of indigestible carbohydrates that help achieve the human dietary needs for this nutrient. • AFGC - on the basis of the information provided in the IAR, the AFGC considers that RMD will have minimal, if any negative nutritional impacts, and if displaces other forms of dietary fibre contain substances such as phytates and oxalates, then it may have a positive nutritional benefit. - An increase in dietary fibre consumption as the result of increased RMD use by industry would be consistent with the Dietary Guidelines. It is clear that the concept of dietary fibre is evolving, and that there is no reason why that [concept] of consumers should not evolve in the same way. - It is mentioned that the following should not be overestimated with RMD: * The potential for foods to contain higher levels of dietary fibre, with the potential for this increase to extend to non-traditional dietary fibre sources, and * The impact on nutrition education by expanding the concept of dietary fibre. • DAA is concerned that fibre supplements, such as RMD, may result in the substitution of fibre-rich foods such as fruit, vegetables and wholegrains. - Fibre supplements lack other beneficial components such as plant chemicals and antioxidants.

Consumer Issues

Issue	Comments
Consumers' understanding of dietary fibre	• The ACA indicated that consumers look for dietary fibre with the expectation that it will provide scientifically proven health benefits. A large body of evidence supports these heath benefits. • QH mentioned that consumer confusion on dietary fibre additions cannot be underestimated, and represents a significant cost to governments and providers of nutrition education. Consumers already struggle to understand basic nutrition. • Prof. Gordon commented that consumer information should be updated on a regular basis to relay the importance of dietary fibre for good health, the importance of fruit vegetables and cereals/grains as sources of dietary fibre, and that processed foods are a safe and nutritious source of dietary fibre.

Novel Food Status

Issue	Comments
Assessment of the novel food status of RMD	• The NZFSA is not convinced that RMD should be excluded from the novel standards process. - As RMD cannot be declared as dietary fibre in the domestic market, it is doubtful that it is currently used in the food supply. RMD could therefore meet the definition of a novel food.

Attachment 4

Application A491 – Resistant Maltodextrin as Dietary Fibre
Food Technology Report – Conducted at Draft Assessment

Introduction

The development of starches and maltodextrins that are resistant to digestion is a relatively new innovation in the food industry and there is little information available in the scientific literature on their structures and functions. This report provides a basic explanation of the chemistry of starch and the variability of starch derivatives such as maltodextrins (including resistant maltodextrins – RMD).

Starch

Starch is the starting material for the production of dextrins and maltodextrins. Starch occurs in plants as granules, with complex structures that contain mostly polysaccharides with some fats and proteins. The size and shape of starch granules vary from plant to plant. Starch composition varies greatly with the source. Much of the literature on the chemistry of starch relates to the starch produced from the wet milling of maize (corn), by a process that yields a starch of high purity. Starches obtained from other source materials or from dry milling processes may be more variable in composition.

For simplicity, starch molecules are usually considered to consist of two major polymers. Amylose exhibits a mainly linear structure, consisting of glucose linked by $\alpha(1,4)$ bonds, while amylopectin is considered as glucose chains more highly branched by $\alpha(1,6)$ linkages[1]. Starch from waxy maize consists almost entirely of amylopectin, while common yellow dent maize has 72%, potato starch about 79%, wheat approximately 72% and tapioca about 17%, with the remainder being amylose[2]. Along with some chemical differences, the amylose:amylopectin ratio impacts on the properties of the gelatinized forms of starch.

Maltodextrins

Maltodextrins are produced by partially hydrolysing starches with enzymes. The chemical structure of maltodextrins falls somewhere between the complex polysaccharide chains of starch and the simpler molecules of corn syrup solids or sugars[3]. Maltodextrins from sources other than corn differ not only in functional properties, but also with other characteristics, such as flavour. In addition, processing conditions affect the types of molecules that result. In acid hydrolysis, controlling pH, time and temperature influences the outcome. Because of the differences in properties of various starch sources, the dextrins and maltodextrins made from them can be expected to have different characteristics.

The Food Chemicals Codex (FCC) defines dextrin as follows:

'Dextrin is partially hydrolyzed starch converted by heat alone, or by heating in the presence of suitable food-grade acids and buffers, from any of several grain- or root-based unmodified native starches (e.g., corn, waxy maize, high amylase, milo, waxy milo, potato, arrowroot, wheat, rice, tapioca, sago, etc.).'[4]

The U.S. Food and Drug Administration (FDA) defines maltodextrin as;

'nonsweet nutritive saccharide polymer that consists of D-glucose units linked primarily by α(1,4) bonds and that has a dextrose equivalent (DE) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch or potato starch with safe and suitable acids and enzymes.'[5]

The FCC definition of dextrin relates specifically to the use of the food additive (INS 1400), whereas the FDA definition of maltodextrin relates to a US regulation. As both dextrins and maltodextrins can be considered as food ingredients in Australia and New Zealand, a variety of products that meet commercial specifications are available on domestic markets.

The food industry uses more maltodextrins than dextrins and often refers to corn-based products when referring to maltodextrins. In addition to corn-derived maltodextrins, some ingredient manufacturers also produce maltodextrins from other starchy sources, such as potato, rice and tapioca.

Depending on the starting material, maltodextrins may contain compounds other than glucose polymers, such as proteins. Even those products with the same DE may contain a different distribution of molecules - more medium-range molecules, and fewer larger molecules, for example. The process, its conditions, and the type of starch used as the starting material affect the exact composition and structure of the resulting glucose chains.

Dextrose Equivalence (DE)

DE indicates the degree of polymerization (DP) of the starch or dextrin molecules - the number of monosaccharide units in the molecules. DE is derived from the formula DE = 100 ÷ DP.

Glucose (dextrose) possesses a 100 DE; starch has an approximately zero DE.

Maltodextrins are usually classified by DE, indicating the amount of hydrolysis performed on a starch molecule. Most commercial maltodextrins are a mixture of different carbohydrate polymers.

The higher the DE, the higher the level of monosaccharides and short chain polymers. Because maltodextrins and other hydrolyzed starches consist of a mixture of polymer lengths, the DE is an average value (i.e. 5 DE does not mean 5% glucose content).

Since a maltodextrin with a low DE contains a larger amount of longer straight- and branched-chain units, it tends to exhibit characteristics more in line with those of starch, such as viscosity. As the DE increases and the level of lower molecular weight products increases, the maltodextrin tends to act more like a corn syrup solid. This means that a number of characteristics of maltodextrins are related to the DE.

As DE increases, so do the following characteristics:

- browning (due to the increased level of reducing sugars);
- hygroscopicity/humectant properties;
- plasticity;

- sweetness;
- solubility;
- osmolality.

As DE decreases, the following characteristics increase:

- molecular weight;
- viscosity;
- cohesiveness;
- film-forming properties;
- prevention of large sugar-crystal formation.

Most commercial maltodextrins are spray-dried and sold as powders, although some liquid maltodextrins are available. The spray-drying procedure and agglomeration influence the characteristics of a particular maltodextrin product.

Functions of Maltodextrins

Maltodextrins act as dispersing aids, flavour carriers, bulking agents, humectants, viscosifiers and other functional ingredients. They can work in a wide variety of applications - from dry mixes to fillings and sauces to beverages.

The functional characteristics related to DE help determine the applications where maltodextrins are used.

Because maltodextrins fall in the lower DE range, they supply little or no sweetness. They are fairly bland, although they sometimes provide a low level of flavour. They are relatively inert to heat, pH and other process conditions, such as shear.

Resistance to Digestion

Processed starch is usually considered to be a digestible polysaccharide, providing nutrition in the form of glucose that results from enzymatic and acid hydrolysis in human digestive processes. Starch and maltodextrins derived from starch can, however, be naturally resistant or they can be manufactured with increased resistance to human digestive processes.

Most polysaccharides pass into the large intestine more or less intact, as human gastrointestinal enzymes do not usually hydrolyze them. Ingested polysaccharides such as cellulose and gums have a beneficial effect in providing bulk for peristaltic action and by binding bile acids to lower cholesterol levels. Starch granules are also protected structurally from enzymic attack. Most vegetables and cereals must be processed in some way to yield digestible starch. Milling grains to flour, cooking, proofing and fermentation are examples of processes that make starch more available for digestion. Processing under high temperature and pressure, such as during extrusion, can modify some starches to make them more resistant to digestion.

Being a variety of maltodextrin, RMD exhibit all or nearly all of the technological properties listed above for digestible maltodextrins. Similar to digestible maltodextrins, the term RMD can encompass a variety of chemical substances that share certain characteristics, but with each having their own unique minor differences.

Conclusion

Starches from various sources and the maltodextrins produced from them (both digestible maltodextrins and RMD) are variable in structure and function. The Australia New Zealand *Food Standards Code* does not specify the source or the chemical structure of substances such as maltodextrin as they are treated as foods. Therefore, a wide variety of different maltodextrins could be detected by the AOAC 2001.03 method as 'resistant' and included in total dietary fibre content calculations.

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Attachment 5

Assessment of Resistant Maltodextrins Against the Definition of Dietary Fibre – Conducted at Draft Assessment

The aim of this Attachment is to determine whether RMD are capable of meeting the following definition of dietary fibre as provided in Standard 1.2.8 – Nutrition Information Requirements:

> **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.

Because up to 50% of the RMD in a food may appear in the residue of AOAC 985.29 (as they have a degree of polymerisation (DP) >12), they are already included in determinations of total dietary fibre. These RMD will continue to be included in determinations of dietary fibre content, even if it is concluded that RMD do not meet the definition of dietary fibre.

Assessment against Criterion 1 of the definition: the requirement to be an edible fraction of plants, their extracts, or synthetic analogues

RMD can be considered an extract of a plant. The word 'extract' indicates that the substance must have been separated out from a particular source. 'Extract' does not preclude the further modification of the plant substance in question, only that the final product has been derived from a plant source. This interpretation of Criterion 1 is consistent with a previous assessment made as part of Application A277 – Inulin and Fructo-oligosaccharides (FOS) as Dietary Fibre. During Application A277, it was recognised that inulin and FOS could be obtained from plant sources and thus conformed to the 'extract' part of the definition.

Therefore, as RMD are an extract of a plant material (starch) obtained by pyrolysis and enzyme treatments, they conform to the requirements of Criterion 1.

Assessment against Criterion 2 of the definition: indigestibility

In support of the classification of RMD as forms of dietary fibre, the Applicant has cited an *in vivo* study indicating that RMD are indigestible in the human body[1]. The results of this study can be found in Tables 1 and 2 below.

These results show 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 after ingestion when compared to the ingestion of either glucose or maltodextrin ($P<0.01$). 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.

Table 1: Blood glucose levels following the oral loading of glucose and various maltodextrins – Study by Ohkuma et al, 1990[1]

Time After Oral Loading (min)	Substance provided as oral bolus dose			
	Glucose (50 g)	Digestible Maltodextrin (20g)	Product 1 (contains 58% RMD)	Product 2 (contains 90% RMD)
0	82	82	82	82
30	143	134	120	83
60	150	130	118	83
90	118	105	100	81
120	100	90	82	80
150	80	82	82	80

Table 2: Blood insulin levels following the oral loading of glucose and various maltodextrins – Study by Ohkuma et al, 1990[1]

Time After Oral Loading (min)	Substance provided as oral bolus dose			
	Glucose (50 g)	Digestible Maltodextrin (20g)	Product 1 (contains 58% RMD)	Product 2 (contains 90% RMD)
0	4	4	4	6
30	36	26	26	8
60	42	15	21	6
90	33	8	14	4
120	20	8	8	4
150	10	4	8	4

These studies were undertaken using the Fibresol-2 product. During the production of the Fibresol-2 product it is expected that there will be a component of digestible manufacturing by-product. There was no statistical or laboratory determination in this study as to whether the digestible carbohydrate fractions of the Fibresol-2 products were responsible for the reported increases in blood glucose and insulin concentrations above a fasting level. Despite such an omission, the level of change in results from this study strongly indicate that RMD, as analysed by AOAC 2001.03, contribute significantly to their indigestibility when assessed *in vivo*.

There is also evidence from a study on rats by Tsuji and Gordon (1998)[2] that RMD are partially fermented to SCFA by bacteria upon reaching the large intestine. Tsuji and Gordon assessed the digestibility of Fibersol-2 in the short intestine and found that ~10% was digested (comparable with the fraction of digestible carbohydrate in Fibersol-2), while 38% of the ingested RMD appeared in faeces. From these results the authors inferred that the remaining RMD had been fermented in the large intestine, and further assessments of the rat caecum pH indicated that SCFA production had increased.

Assessment against Criterion 3 of the definition: promotion of beneficial physiological effects

The definition of dietary fibre in Standard 1.2.8 of the Code currently has no formal conditions that underpin the determination of laxation, a reduction in blood cholesterol, or modulation of blood glucose.

The Applicant has provided a number of studies supporting the position that RMD can produce the physiological effects detailed in the definition of dietary fibre. An assessment of this literature is provided below for each of the physiological effects of laxation, a reduction in blood cholesterol, and a modulation of blood glucose.

Quantitative Requirements Underpinning Criterion 3

A benchmark of more than 1g of faecal wet weight increase per gram of test fibre ingested in either a food matrix or supplementary form was established for laxation effects in Application A277, however this benchmark has not been further consolidated as a formal requirement.

Comments to the Initial Assessment were received from Prof. Gordon indicating that it would be ideal to develop criteria for the physiological effects listed in the definition of dietary fibre. However, there are no other regulatory agencies (e.g. USFDA or Health Canada) that currently measure the beneficial effects of dietary fibre, nor have any benchmarks been established in the scientific literature. Prof. Gordon commented that an analytical method measuring the source of dietary fibre components, safety information, and a compilation of animal and human studies demonstrating the physiological effects, should be sufficient in the absence of accepted standards.

On the basis of this information, it is recognised that the establishment of any baseline levels for criterion 3 will be arbitrary at best. Therefore, the scientific evidence on each of the physiological criteria will be assessed on merit; if there is a clear demonstration that an effect is promoted by RMD, the relevant criterion in the definition for dietary fibre can be considered fulfilled. An exception will be made for laxation as a means of maintaining consistency with past assessments; there must be a demonstration that RMD can at least produce the inulin/FOS level of laxation before the laxation requirement of criterion 3 is satisfied.

Laxation

The Applicant has supplied 12 studies[4-15] as evidence that RMD consumption produces a laxative effect. FSANZ has been unable to find any other studies that investigate this subject. Only Satouchi *et al*[4] assessed changes in faecal weight, and thus is the only study suitable for directly assessing the previously defined requirement for a laxation effect of 1 gram of faecal wet weight increase per gram of test fibre ingested.

The study by Satouchi *et al* is comprised of three separate experiments. The first examined the influence of various RMD amounts on stool appearance for the purposes of determining the safety of RMD. The third assessment was a randomised trial (blinding unknown) observing intakes of 10 g RMD/day to 5g RMD/day using self-reporting of stool frequencies, volumes, stool conditions and feeling after defecation.

Aside from the feeling after defecation, only the 10 g/day group experienced any significant change in the assessed variables.

Of importance for the determination of a laxation effect are the results from the second assessment of Satouchi *et al*, which was conducted as a crossover design to assess the influence of RMD intake on stool weights and frequencies. The results can be found in Table 3 below, and indicate a significant difference in the wet weight, dry weight and stool frequencies between the test diet containing 20 g/day RMD and the control diet, with the wet weight results reported as a mean increase of 1.18 g faecal wet weight/gram of RMD ingested/day (206.7 g increase in weight over the 5 test days).

Table 3: Results from Experiment 2 of Satouchi et al, 1993[4]

Study Design	RMD Administration	No. Subjects	Mean wet stool weight (g)	Mean dry stool weight (g)	Moisture (%)	Stool frequency (motions/week)
Double blind crossover	Test week	8	778.2±93.2*	180.5±12.9*	76.8±1.8	5.92±0.40*
	Control week	8	571.5±58.7	137.9±5.6	76.2±1.7	4.76±0.36

* Statistically significant to control week, $p<0.05$

The other 11 studies on laxation[5-15] used almost identical methodologies to each other, and reported very similar outcomes. The study designs were all crossover human trials examining the influence of a daily food/drink containing RMD, compared to a placebo food/drink with either a digestible form of maltodextrin or without RMD. The collections of results were conducted through the self-reporting of subjects, via questionnaires that examined stool frequency, stool volume, stool solidity, stool colour, stool odour and the clearance of bowels.

The majority of the 11 laxation studies[6-10,12-15] reported a significant increase in the frequency of bowel motions following the consumption of RMD compared to the placebo. Stool volumes were also reported to increase significantly[7-10,13,14] with RMD administration, however it is difficult to determine if such increases represent valid results, as all studies relied on the measurement of stool volumes in arbitrary units (e.g. eggs, ping-pong balls, or spheres). Only one study used a more object manner of assessing the volume of stools, where a visual guide was provided to subjects for reporting purposes. A few studies also identified significant changes in stool solidity as a result of RMD intake[5,13,15], however these results were based on subjective categorisation of stool solidity by subjects. None of the eleven studies reported any significant change in stool colour, stool odour and the clearance of bowels.

Overall, the evidence presented in these additional 11 studies reinforces the argument that RMD has an influence on laxation. However, the limitations in study designs are such that none of the studies are suitable for quantifying the impact of RMD on laxation. Therefore, these studies have been considered in Application A491 only to qualify the results on stool weights by Satouchi *et al*. The actual results of these 11 studies have not been provided within this Attachment due to the inconsistent and arbitrary nature of the study designs.

Evaluation

From the 12 studies presented by the Applicant, it is determined that RMD has some laxative properties such as promoting an increase in stool weight, stool frequency, and stool volume. However, of greatest significance is the study by Satouchi *et al*, which shows that an increase in faecal wet weight above a level of 1 gram per gram of ingested RMD can be achieved. Therefore, RMD can be considered capable of producing a laxative effect significant enough to fulfil this part of criterion 3.

Reduction in Blood Cholesterol

Seven studies have been identified that examine the effects of RMD intake[16-22] on blood lipid profiles. The only animal study identified as having assessed the influence of RMD on cholesterol levels in animals (rats)[16] is unsuitable for use in this report, as there was no indication within the study article as to whether blood samples were taken while the animal subjects were in a fasting state. Furthermore, it has been documented that the blood lipid profile of rats is more susceptible to dietary changes than humans[23]. Therefore, only the results from human studies have been used to assess the impact of RMD consumption on blood cholesterol.

A detailed analysis of the six human studies[17-22] and their results can be found in Table 4 (see the Appendix to this Attachment). From the results of these studies, the following changes from baseline readings were reported for doses between 30-60 g RMD / day (30 g/day was the commonly used dose) over a period of 4-16 weeks:

- a mean decrease in blood cholesterol levels from initial readings of 0.21% /day, and
- a mean decrease in blood triglyceride levels from initial readings of 0.39% /day.

Two of the six studies[18,21] reported a significant increase in HDL-cholesterol levels. However, the remaining studies are inconsistent with these reported outcomes; three studies reported no significant change in HDL-cholesterol levels[19,20,22], and one reported a significant decrease in HDL-cholesterol levels[17].

Evaluation

Overall, available evidence indicates that there is a noticeable and quantifiable lowering of major cholesterol biomarkers at doses of RMD that can be realistically obtained within normal eating patterns. As no evidence has been identified to contraindicate these findings, and FSANZ has not established an appropriate benchmark level in previous regulatory work, the reported changes in blood lipids are noted.

Modulation of Blood Glucose Levels

Both acute and long-term studies have been identified, which examine the impact of RMD intake on blood glucose levels. Because each methodology produces a different set of results, the relevant studies have been assessed in two separate groups. The majority of blood glucose studies are commonly conducted as acute trials using a bolus dose of RMD, and assess the postprandial change in blood glucose levels over a two-hour period as area-under-the-curve (AUC) values. Several human and animal studies also observe the regular consumption of a certain RMD dose over a long-term period.

These continuous administration studies do not involve AUC assessments, instead providing results as a difference between baseline and final readings. A detailed assessment of results from the studies cited below can be found in Tables 5 and 6 (see the Appendix to this Attachment).

Eight acute RMD studies have been identified that observe changes in blood glucose biomarkers[18,19,24-27]. These studies assess RMD at bolus doses of 1.5 g/kg body weight in rats, and a 1.5-10.0 g total intake in humans. Similar results were obtained in both rat and human studies, with RMD consumption producing a significantly lower postprandial rise in AUC values when compared to controls. Three exceptions were noted though:

- Uno *et al*. 1999[27] did not observe any significant lowering of postprandial blood glucose levels following the consumption of tofu containing RMD by humans;
- Wakabayashi *et al*. 1999[28] did not observe a significant decrease with the consumption of noodles and sweet rolls containing RMD by humans; and
- Wakabayashi *et al* 1995[29] did not observe a significant decrease when rats were fed glucose, fructose or lactose boluses combined with a RMD dose.

Two studies reported a significant decrease in the AUC for subjects with high fasting blood glucose levels, while subjects with fasting blood glucose levels within normal parameters did not experience a similar drop in the AUC[19,26]. Assessment of serum insulin levels (as AUC values) in two acute studies revealed a similar pattern of changes to those observed with blood glucose levels[28,29].

Four studies have assessed the effects of long-term consumption of RMD on blood glucose levels[17,18,19,22]. Two studies reported a significant decrease in blood glucose levels from baseline values over 12-16 week periods, and at doses of 13.7-30g/day in humans and 0.05 g/g bw/day in rats. One study by Mizushima *et al* 2000 reported a significant decrease in fasting blood glucose levels over 12 weeks, however when the RMD treatment was removed, blood glucose levels continued to decrease for eight weeks. Three studies (on humans)[18,19,22] also measured glycosylated haemoglobin (HbA1c) levels, which can quantify fluctuations in blood glucose over a three-month period. A decrease in these values was not observed.

Of all 10 blood glucose studies identified, only four assessed the consumption of RMD in food[18,19,22,28], while the remainder (the majority of short-term studies) assessed the consumption in drinks/fluids. The study by Fujiwara and Matsuoka[18] was the only one identified that observed the impact of RMD on humans with diabetes.

Evaluation

The reviewed evidence provides a distinct pattern of results. In both rats and humans, the postprandial levels of blood glucose are noticeably moderated by 5-10 g bolus doses of RMD, although several conflicting results did occur in some studies. However, continuous administration studies on humans do not reflect such changes in fasting blood glucose levels, and notably, the measurements of HbA1c levels in these studies remain unchanged.

It is therefore noted that RMD can produce postprandial changes in blood glucose levels, but do not modulate blood glucose levels over a prolonged period of time.

Conclusion for Criterion 3

It is concluded that there is sufficient evidence supporting the promotion of laxation; the impact on blood cholesterol levels is also noted. However, as criterion 3 requires the demonstration of only one physiological effect, it is determined that RMD meet this component of the definition for dietary fibre.

Criteria 4: The requirement to consist of polysaccharides, oligosaccharides (degree of polymerisation > 2) or lignins

RMD comply with the final sentence in the definition of dietary fibre, as demonstrated in a validation study[30] on the AOAC 2001.03 method of analysis that identifies RMD as comprising of polysaccharides and oligosaccharides, with an average molecular weight of 2000 daltons (DP = 12-13) and 60% of these substances having a DP >10.

Conclusion

It has been demonstrated in the available scientific literature that RMD is capable of meeting all components of the definition of dietary fibre as follows:

- RMD are an extract of a plant material (starch) obtained by pyrolysis and enzyme treatments;
- scientific material has been presented by the Applicant demonstrating that RMD are not digested by the human small intestine when assessed *in vivo*, and are partially fermented in the large intestine;
- there is sufficient evidence supporting the promotion of laxation. The promotion of one of the three listed physiological effects is sufficient to meet the requirements of the definition for dietary fibre; and
- RMD contain polysaccharides and oligosaccharides, with 60% of these substances having a DP >10.

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Results from Studies Cited in Attachment 2

Table 4: Human Studies on Resistant Maltodextrin and Blood Lipid Profiles

Study	**Study Period (weeks)**	**Number of Subjects**	**RMD Dose (g/day)**	**Results – Cholesterol**			**Results – Triglyceride**			**Results – HDL-cholesterol**		
				Baseline level (mg/dL)	*Final level (mg/dL)*	*Change (% of baseline /day)*	*Baseline level (mg/dL)*	*Final level (mg/dL)*	*Change (% of baseline /day)*	*Baseline level (mg/dL)*	*Final level (mg/dL)*	*Change (% of baseline /day)*
Nomura *et al*, 1992[17]	12	6	60	265±10	209±9	-0.25	243±34	176±42	-0.33	49±2	40±3	-0.22
Fujiwara and Matsuoka, 1993[18]	16	5	30	230±25	216±20	-0.05	285±60	159±40	-0.39	40±4	46±5	0.13
Kishimoto *et al*, 2000[19]	12	10	12	226±12	215±12	NS	186±16	145±18	-0.26	52±4	54±4	NS
Ohkuma and Wakabayashi, 2001[20]	8	Healthy = 10	30	226±10	199±10	-0.21	242±64	178±41	-0.47	47±4	49±4	NS
	8	Diabetic #1 =5	30	230±25	220±25	-0.07	285±60	244±45	-0.26	40±4	42±5	NS
	8	Diabetic #2 = 5	60	265±10	205±10	-0.41	243±30	148±11	-0.7	49±2	49±3	NS
Matsuoka *et al*, 1992[21]	4	10	30	213±10	198±10	-0.3	196±33	178±41	-0.33	45±3	48±4	0.25
Mizushima *et al*, 2000[22]	12	10	30	204±33	205±22	NS	186±97	152.4±83	NS	51.2	50	NS

NS = Not significant

Table 5: Bolus Dose Studies on Resistant Maltodextrin and Blood Glucose Levels

Study	No. and type of subjects		RMD Bolus Dose	Area Under the Curve (AUC) (mg min/dL)		
				Serum Glucose (mg min/dL unless otherwise stated)	*Serum Insulin (mmol/120 min)*	*Significant Difference ($p<0.05$)?*
Kishimoto *et al*, 2000[19]	Humans n=27, crossover design					
	All subjects	Control meal	0	graph	-	Yes; between the two meals
		Miso Soup	4.5g	graph	-	
	Subjects peak BSL > 150 mg/dL, n=12	Control meal	0	graph	-	Yes; between the two meals
		Miso Soup	4.5g	graph	-	
	Subjects peak BSL < 150 mg/dL, n=15	Control meal	0	graph	-	No
		Miso Soup	4.5g	graph	-	
Mizushima *et al*, 1999[24]	Humans n=22, crossover design					
	All subjects	Control: soft drink + food	0	34.2±31.6	-	Yes; between the two test drinks
		Test: RMD soft drink + food	9.8g	46.9±24.6	-	
	Subjects BSL > 140 mg/dL at 30 min, n=12	Control: soft drink + food	0	48.4±37.8	-	No
		Test: RMD soft drink + food	9.8g	62.9±26.3	-	
	Subjects BSL < 140 mg/dL at 30 min, n=10	Control: soft drink + food	0	22.3±20.2	-	No
		Test: RMD soft drink + food	9.8g	33.5±12.6	-	
Sinohara *et al*, 1999[25]	Humans n=39, crossover design					
	Subjects BSL > 155 mg/dL at 30 min, n=22	Control: green tea plus food	0	92.1±30.4	-	Yes; between the two test drinks
		Test: RMD green tea plus food	5g	81.3±27.9	-	
	Subjects BSL < 155 mg/dL at 30 min, n=13	Control: green tea plus food	0	96.1±22.8	-	No
		Test: RMD green tea plus food	5g	88.3±33.6	-	
Tokunaga and Matsuoka, 1999[26]	Humans n=40, crossover design					
	All subjects	Control: green tea plus food	0g	105.4±6.5	-	Yes; between the two test drinks
		Test: RMD soft drink plus food	1.5g	74.2±4.8	-	

Uno K et al, 1999[27]	Humans n=30, crossover design					
	All subjects	Control: tofu	0g	graph	-	No
		Test: RMD containing tofu	5g	graph	-	
	Subjects BSL > 155 mg/dL at 30 min, n=18	Control: tofu	0g	graph	-	No
		Test: RMD containing tofu	5g	graph	-	
	Subjects BSL < 155 mg/dL at 30 min, n=22	Control: tofu	0g	graph	-	No
		Test: RMD containing tofu	5g	graph	-	
Wakabayashi et al, 1999[28]	Humans, crossover design					
	10 healthy males	glucose	50 g	graph	graph	Serum glucose - no; Serum insulin – yes, between the two sugar loads
		glucose + RMD	50 g+ 10 g RMD	graph	graph	
	24 health males and females	sucrose	100g	graph	graph	Yes; between the two meals for both serum glucose and insulin
		sucrose + RMD	100g+ 10 g RMD	graph	graph	
	24 subjects BSL < 145 mg/dL at 30 min	digestible maltodextrin	50 g	graph	graph	Serum glucose - no; Serum insulin – yes, between the two sugar loads
		digestible maltodextrin + RMD	50 g + 10	graph	graph	
Wakabayashi et al, 1995[29]	Sprague-Dawley Rats, n=78					
	Glucose bolus	Without RMD, n=6	0	13.6±0.7 mmol/120 min	245±26	No
		With RMD, n=6	1.5g/kg bw	13.8±0.3 mmol/120 min	241±23	
	Fructose bolus	Without RMD, n=6	0	11.9±0.2 mmol/120 min	133±5	No
		With RMD, n=6	1.5g/kg bw	12.4±0.3 mmol/120 min	151±11	
	Sucrose bolus	Without RMD, n=10	0	13.5±0.1 mmol/120 min	248±22	Serum Glucose – Yes ($p<0.01$) Serum Insulin – Yes ($p<0.05$)
		With RMD, n=10	1.5g/kg bw	12.4±0.3 mmol/120 min	180±16	
	Maltose bolus	Without RMD, n=6	0	14.8±0.7 mmol/120 min	223±11	Serum Glucose – Yes ($p<0.05$) Serum Insulin – Yes ($p<0.05$)
		With RMD, n=6	1.5g/kg bw	12.8±0.6 mmol/120 min	164±21	
	Lactose bolus	Without RMD, n=5	0	12.9±0.5 mmol/120 min	177±35	No
		With RMD, n=5	1.5g/kg bw	12.3±0.2 mmol/120 min	198±34	
	Digestible maltodextrin bolus	Without RMD, n=6	0	14.5±0.4 mmol/120 min	304±17	Serum Glucose – Yes ($p<0.05$) Serum Insulin – Yes ($p<0.05$)
		With RMD, n=6	1.5g/kg bw	13.0±0.4 mmol/120 min	229±21	

	Rats fed for 2 weeks prior to bolus dose of glucose, n=26				
	Control feed n=6	0	13.0±0.6 mmol/120 min	253±27	Yes; each group is significantly different from the other for both glucose and insulin results ($p<0.05$)
	High sucrose feed n=12	0	16.7±0.6 mmol/120 min	620±37	
	High sucrose + RMD feed (1.5g/kg body weight) n=8	0	14.8±0.5 mmol/120 min	417±56	

graph = results were only displayed in graph format (were measured though)
- = variable was not assessed as part of the study

Table 6: Continuous Administration Studies on Resistant Maltodextrin and Blood Glucose Levels

Study	Study Period	No. and type of Subjects	RMD Dose	Fasting Blood Glucose (mg/dL)			HbA1c (%)		
				Baseline level	*Final level*	*Significant Difference ($p<0.05$)?*	*Baseline level*	*Final level*	*Significant Difference ($p<0.05$)?*
Nomura *et al*, 1992[17]	2 weeks	Rats, n=13							
		Control feed n=7	0	147±5	128±6	Yes; between the two groups by the end of the study period	-	-	-
		RMD feed n=6	0.05g/g body weight/day	140±5	106±10		-	-	
Fujiwara and Matsuoka, 1993[18]	16 weeks	Human, diabetics, n=5	30g/day	213±34	200±29	No	8.4±0.9	8.3±1.2	No
Kishimoto *et al*, 2000[19]	12 weeks	Human, n=10	13.7g/day	103±5.7	108.6±8.3	No	5.5±0.2	5.5±0.3	No
Mizushima *et al*, 2000[22]	12 weeks	Human, n=10, fasting serum glucose 110-126 mg/dL	30g/day	113.7±13.5	105.5±13.4*	Yes, over the study period	5.1±0.6	5.1±0.6*	No

- = variable was not assessed as part of the study

* = It should be noted that further assessment of fasting blood glucose and HbA1c were performed 8 weeks after cessation of the RMD dose. Although HbA1c results remained statistically unchanged (5.2±0.7%), the fasting blood glucose results continued to maintain the decreasing trend (103.9±13.9 mg/dL) at previous rates despite the absence of RMD consumption.

Attachment 6

SAFETY ASSESSMENT REPORT AT DRAFT ASSESSMENT ON FIBERSOL-2 AND FIBERSOL-2B (RESISTANT MALTODEXTRINS)

CONTENTS

1. Introduction

The purpose of this assessment is to determine the safety of resistant maltodextrins (RMD) in food for human consumption. RMD is a term used to describe starch hydrolysates (such as dextrin and maltodextrin) that contain indigestible components. The RMDs referred to by the Applicant is Fibersol-2 and Fibersol-2B, which are international trademarks. Fibersol-2 is known in Japan by the trademark 'Pinefiber C', while Fibersol-2B is known in Japan by the trademark 'Pinefiber'.

There are other similar RMD products available on the market. Hydrogenated RMD has been marketed in Japan and some other Asian countries, under the names of 'Fibersol-2H' and 'H-Fiber' ('MIXOL' for the international market). 'Pinefiber Bi' is also available in Japan only and has smaller molecules than Fibersol-2 or Fibersol-2B. A French company produces two RMDs: 'Nutriose FB' (very similar to Fibersol-2); and 'Lycasin' (very similar to MIXOL).

FSANZ has safety data for only Fibersol-2 and Fibersol-2B available for this assessment. It is likely that other RMDs have similar safety profiles because of the very similar structures and physiological properties. However, this safety assessment will only directly address Fibersol-2 and Fibersol-2B and the conclusions will not extend to addressing the safety of any other RMDs. Throughout the assessment, the names Fibersol-2 and Fibersol-2B will be used since these are the international trademarks.

1.1 Specifications for RMDs

The following specifications for the respective RMDs were provided by the applicant. The type of information provided by the applicant differs between the RMDs, for example, the test method is not provided in all cases and different characteristics are reported for different RMDs.

Table 1: Specifications for RMD products manufactured by the Applicant

Characteristics	Fibersol-2	Fibersol-2B	Fibersol-2H	MIXOL
Appearance	White free-flowing fine powder (by sensory test)	While free-flowing fine powder	White powder (by sensory test)	Clear, colourless, viscous liquid
Taste/odour	Slightly sweet/odourless (by sensory test)	Slightly sweet, odourless	Slightly sweet/odourless (by sensory test)	Slightly sweet/odourless
Solution	Clear (by sensory test)	Soluble in water, clear solution;		
Extraneous matter		Free from foreign material		
Moisture	5% maximum (by JAS method)	5% maximum		29-31% (Plastic film method)
Reducing sugars			0.5% maximum (by Bertrand method)	0.5% maximum (by Bertrand Method)

Characteristics		Fibersol-2	Fibersol-2B	Fibersol-2H	MIXOL
Sugar Alcohols				Sorbitol, maltitol and maltotritol: 10% maximum (by HPLC method)	Maltitol: 25-35% (Solid basis, HPLC analysis)
Indigestible Components		85-95% (by enzyme-HPLC method)	50% minimum by AOAC 2001.03	85-95% (by Enzyme-HPLC method)	45-55% (Solid basis, Enzyme-HPLC method); 10-20% (AOAC-Prosky method)
Loss of Drying				5% maximum (by 70oC reduced-pressure drying)	
Dextrose equivalent		8-12 (by WS method)			
pH (in 10% solution)		4-6 (by pH metre)	4-6		
Ash (% maximum)		0.2	0.2	0.2	0.2
Arsenic (ppm maximum)		1	1	2	2
Nickel (ppm maximum)				1	1
Heavy metals (ppm maximum)		5	5	5	5
Microbio -logical	Standard plate count	300 /g maximum	300 /g maximum	300 /g maximum	300 /g maximum
	Yeast and mould	100 /g maximum	100 /g maximum		100 /g maximum
	Salmonella	Negative /25g	Negative /25g		
	Coliforms	Negative /g	Negative /g	Negative /g	Negative /g

1.2 Generally Recognised as Safe (GRAS) status in the US

Fibersol-2 meets the requirements for US GRAS status as set out in 21 CFR 184.1444 Maltodextrin. This regulation requires that (1) the product be prepared from cornstarch with safe and suitable acids and enzymes and has a dextrose equivalent of less than 20 and (2) be of a purity suitable for its intended use. As such, there is no limitation on the amount of daily intake.

2. Review of available studies

2.1 *In-vitro* studies

2.1.1 In-vitro *digestion study (Wakabayashi et al., 1991)*

Purpose

A digestion test was performed in order to examine the resistance of Fibersol-2 and Fibersol-2B against successive digestion by salivary amylase, artificial gastric juice, pancreatic amylase and intestinal mucosal enzymes.

Study conduct

The salivary amylase used was Type IX-A of human origin, obtained from Sigma Co., artificial gastric juice was hydrochloric acid/potassium chloride solution at pH 2.0, pancreatic amylase was of porcine origin obtained from Behringer-Manheim Yamanouchi Pharmaceutical Co. Ltd., and intestinal mucosal enzymes were of rat origin obtained from Sigma Co. The resistance to successive digestions was examined by using the method described by Okada *et al*. (1990) and compared with maltodextrin (PDx#2, dextrose equivalent 10, Matsutani Chemical Industry Co., Ltd) that is an enzymatic hydrolysate of corn starch.

Results

Fibersol-2 and Fibersol-2B were partially hydrolyzed by salivary amylase, pancreatic amylase and intestinal mucosal enzymes and showed an increase in their reducing capacity but this increase was only marginal compared with maltodextrin. Fibersol-2 and Fibersol-2B were not digested by artificial gastric juice. Percentages of indigestible residue calculated by subtracting the increment of reducing sugar produced by successive digestion were 25.2% for maltodextrin, 61.4% for Fibersol-2B and 89.5% for Fibersol-2. Results are shown in Table 1.

Conclusions

The results indicate that the behaviour of Fibersol-2 and Fibersol-2B in the digestive trace is somewhat different from those of other soluble fibres such as pectin and guar gum. This is attributed to the solubility in water and low viscosity of Fibersol-2 and Fibersol-2B. It is estimated that approximately 90% of Fibersol-2 and approximately 60% of Fibersol-2B reaches the large intestine. Half of the resistant maltodextrin that reaches the large intestine is metabolised by intestinal bacteria, while the remainder is excreted in the faeces (Ohkuma and Wakabayashi, 2001).

Table 1: Successive digestion of Fibersol-2B, Fibersol-2 and maltodextrin *in-vitro*

Test medium	**Reducing sugar increased**[a]		
	Fibersol-2B	**Fibersol-2**	**Maltodextrin**
Salivary α-amylase	2.6	1.0	14.3
Artificial gastric juice	0.5	0.3	0.6
Pancreatic α-amylase	5.4	1.8	10.7
Intestinal mucosa[b]	38.6	10.5	74.8
Indigestible residue (%)[c]	61.4	89.5	25.2

a=increment of reducing sugar measured by Somogyi-Nelson method; b=rate of glucose formation measured by glucose oxidase method; c=percentage of indigestible residue calculated by the data from *in-vitro* successive digestion test.

2.2 Animal studies

2.2.1 Absorption, metabolism and excretion studies

Bile excretion and short-chain fatty acid production following ingestion of Fibersol-2 and Fibersol-2B has been measured in three studies reported in two separate publications.

Bile excretion and short-chain fatty acid production following Fibersol-2 and Fibersol-2B ingestion (Wakabayashi et al., 1991)

Test material:	Fibersol-2
Test species:	Rats, male Sprague-Dawley (Jcl:SD, CLEA Japan Inc.), 5 weeks old
Dose:	10% Fibersol-2: 90% tap water solution
Guidelines:	Not stated

Study conduct

5-week old rats were fed pellet food for 1 week and then distributed into 2 groups (6 rats per group, mean body weight of approximately 220g). After grouping, rats of group 1 received tap water (control) and rats of group 2 received 10% Fibersol-2 solution for 9 weeks, following which group 1 received Fibersol-2 solution and group 2 received tap water (control) for 2 weeks. All rats were allowed free access to food pellets and drinking water. Stools were collected daily for 1 week before the end of the experiment period and the dry weight was measured. The stools were freeze-dried, pulverized and bile acid was measured by the 3-α-hydroxysteroid dehydrogenase method (Wako Pure Chemical Ind. Ltd.) after extraction with chloroform and methanol. Deionised water (15 ml) was added to 1g of caecal content taken at the end of the experiment and the pH measured. For determination of short chain fatty acids, caecal content was added to isocupric acid and short chain fatty acids were extracted with chloroform-methanol mixture for analysis by gas chromatography. Acetic acid, propionic acid, butyric acid, isobutyric acid and valerianic acid were used as standards.

Results

There were no differences in body weight, feed efficiency and water consumption between the test (10% Fibersol-2 diet) and control groups. There was a non-significant increase in the caecum weight including caecal contents for the test group compared to the control group, but there were no other difference in weights of other organs or fatty tissues. Total short chain fatty acid excretion in the caecal content was significantly higher in the test group, especially for propionic acid, 5.86±0.9 mg/caecum/rat in the test group, compared with 2.46±0.46 mg/caecum/rat in the control group.

Bile excretion and short-chain fatty acid production following Fibersol-2 and Fibersol-2B ingestion (Wakabayashi et al., 1991)

Test material:	Fibersol-2B and Fibersol-2
Test species:	Rats, male Sprague-Dawley (Jcl:SD, CLEA Japan Inc.), 5 weeks old
Dose:	20% Fibersol-2B; 5, 10 and 20% Fibersol-2
Guidelines:	Not stated

Study conduct

Five-week old SD male rats (CE-s, Nippon Crea) were divided into 5 groups (8 rats per group) after pre-feeding with stock feed for 1 week. For the test period, Group 1 was fed with stock diet and tap water, Group 2 was fed with stock diet and 20% Fibersol-2B solution, Group 3 was fed with stock diet and 5% Fibersol-2 solution, Group 4 was fed with stock diet and 10% Fibersol-2 solution, and Group 5 was fed with stock diet and 20% Fibersol-2 solution.

Deionised water (15 ml) was added to 1g of caecal content taken at the end of the experiment and the pH measured. For determination of short chain fatty acids, caecal content was added to isocupric acid and short chain fatty acids were extracted with chloroform-methanol mixture for analysis by gas chromatography. Acetic acid, propionic acid, butyric acid, isobutyric acid and valerianic acid were used as standards.

Results

Weight of the caecum including the caecal contents increased significantly in the groups fed Fibersol-2 and Fibersol-2B compared with the control group. Dried faecal weight and total faecal bile acid excretion increased in the groups fed Fibersol-2 and Fibersol-2B compared with the control group, but not proportionate to the concentrations of Fibersol-2 and Fibersol-2B fed to the rats. Short-chain fatty acids in the caecal content was significantly higher in the rats fed Fibersol-2 and Fibersol-2B than in the control group and the increase was proportional to the concentrations of Fibersol-2 and Fibersol-2B fed to the rats. Acetic acid content was highest, followed by propionic acid and butyric acid. The caecal contents were weakly alkaline for the control group, while they were weakly acidic for both Fibersol-2 and Fibersol-2B, consistent with the increase in short-chain fatty acid production.

Bile excretion and short-chain fatty acid production following Fibersol-2 ingestion (Kishimoto et al., 1995)

Test material:	Fibersol-2
Test species:	Rats, male Sprague-Dawley, 6 weeks old
Dose:	5% Fibersol-2
Guidelines:	Not stated

Study conduct

3 week old SD rats were fed a high-carbohydrate diet containing sucrose, casein, corn oil, mineral mix (MM-2), vitamin mix (Harper), choline chloride, and vitamin E for 2 weeks. The rats were then divided into 4 groups: Group 1 was continued on the high-carbohydrate diet; Group 2 was fed 95% high-carbohydrate diet plus 5% Fibersol-2; Group 3 was fed 95% high-carbohydrate diet plus 5% citrus pectin (high viscosity fibre); and Group 4 was fed 95% high-carbohydrate diet plus 5% corn-fibre (insoluble fibre). Animals were given free access to feed. Caecal contents were weighed and the amounts of short-chain fatty acids produced were determined in the faeces for 3 days and bile acids were determined as outlined in Wakabayashi *et al*. (1991).

In this study, Fibersol-2, citrus pectin and corn fibre were also incubated together with rat caecal contents under static culture conditions, and examined for fermentation changes into short-chain fatty acids (acetate, propionate and butyrate) and lactate as their precursor.

Results

The amounts of short-chain fatty acids produced were greater in the rats fed Fibersol-2 or citrus pectin compared with the control, while production of short-chain fatty acids for the group fed corn fibre did not differ significantly from the control group.

Caecal propionate production was significantly correlated with serum total cholesterol implying that the propionate production may be involved in the regulation of serum cholesterol in the Fibersol-2 group ($p<0.001$) as well as in the citrus pectin group ($p<0.02$). A significant correlation was also obtained for the bile acid excretion and serum total cholesterol.

With respect to the incubation of rat caecal contents with Fibersol-2, citrus pectin and corn fibre, propionate production was higher for Fibersol-2, however, more short-chain fatty acids were produced from citrus pectin than from Fibersol-2 in 24 hours. The production of short-chain fatty acids from the insoluble corn fibre was extremely low.

Conclusions

These findings, together with the aforementioned *in-vivo* digestion study, indicate that Fibersol-2, and to a lesser extent, Fibersol-2B, escape digestion and absorption in the upper gastrointestinal tract. Upon reaching the large intestine, Fibersol-2 and Fibersol-2B are partially fermented by bacteria, producing short-chain fatty acids. It is estimated that approximately 90% of Fibersol-2 and 60% of Fibersol-2B reach the large intestine. Intestinal bacteria ferment approximately half of the resistant maltodextrins that reaches the large intestine primarily into acetate, propionate and butyrate. The remaining resistant maltodextrins are excreted.

2.2.2 Acute toxicity studies

Two acute toxicity studies are described below, one has Fibersol-2 as the test material, while the other uses Fibersol-2B.

Acute toxicity of Fibersol-2B (Matsutani Chemical Industry Co. Ltd. ed.: Review: Safety of Pinefibre, 1990)

Test material:	Fibersol-2B
Test species:	DDY male mice (SPF, 5 weeks old) divided into 3 groups with 10 mice per group. Dosed by oral administration of solution/suspension at volume of 0.5 ml/10 g body weight by gavage.
Dose:	10, 20, 40 g/kg body weight
Guidelines:	Not stated

Test material

Fibersol-2B was suspended in purified water at the maximum concentration physically possible of 80 % w/v and then diluted to prepare 40 and 20% w/v solutions.

Study conduct

After 1 week pre-feeding, the mice were divided into 3 groups (10, 20 and 40 g/kg body weight). They were fasted for 18 hours before the test and administered the solution or suspension of Fibersol-2B at a volume of 0.5 ml/10 g body weight with stomach sonde. After the administration, the mice were observed generally for 5 hours to check for any unusual symptoms and were observed continuously once a day in the morning for the following seven days.

Body weight was checked before the test and one, four and seven days after the administration. After the 7-day observation period, all mice were dissected and the major thoracoabdominal organs were examined.

Results

After 1 week pre-feeding, the mice were divided into 3 groups (10, 20 and 40 g/kg body weight). They were fasted for 18 hours before the test and administered the solution or suspension of Fibersol-2B at a volume of 0.5 ml/10 g body weight with stomach sonde. After the administration, the mice were observed generally for 5 hours to check for any unusual symptoms and were observed continuously once a day in the morning for the following seven days. Body weight was checked before the test and one, four and seven days after the administration. After the 7-day observation period, all mice were dissected and the major thoracoabdominal organs were examined.

Acute toxicity of Fibersol-2 (Wakabayashi et al., 1992)

Test material:	Fibersol-2
Test species:	Male mice (Slc: ICR, SLC)
Dose:	5, 10, 20g/kg body weight administered as a single oral dose
Guidelines:	Not stated

Study conduct

Acute toxicity was determined after a 7-day observation period of 3 groups of 10 male mice that received single oral administration of Fibersol-2 at 5, 10 and 20g/kg body weight. After the 7-day observation period, all mice were dissected and the major thoracoabdominal organs were examined.

Results

The maximum administration in this study did not cause death during the observation period. From these results, the LD_{50} for Fibersol-2 was estimated at more than 20 g/kg body weight. In all groups, spontaneous movement was slightly suppressed over a period of 10 minutes following administration. In the high dose group (20 g/kg body weight), all animals presented with diarrhoea at 2-3 hours following administration and excretion of soft faeces after one day. In the moderate dose group (10 g/kg body weight) most animals presented with diarrhoea at 2-3 hours following administration and excretion of soft faeces at one day. In the low dose group (5g/kg body weight), excretion of soft faeces was noticed in a few animals. There were no other noticeable changes in general health conditions in all groups. All animals were subjected to autopsy on the last day of observation and no changes were present in any major organ in the chest or abdomen.

Conclusion

The results of acute toxicity studies are summarised in Table 2. The LD_{50} values of greater than 20g/kg bw for Fibersol-2 and 40 g/kg bw for Fibersol-2B are quite high and it is highly unlikely that people would physically be able to consume this amount from food.

While these values cannot be directly compared with LD_{50} values for other water-soluble fibres because of the different test animals used, the LD_{50} values for Fibersol-2 and Fibersol-2B are higher than for arabic gum, guar gum and sorbitol (Food Additives Handbook) as stated in the report by Matsutani *et al*. (1990), indicating that both Fibersol-2 and Fibersol-2B are safe substances.

Table 2: Acute toxicity (LD_{50} g/kg body weight)

Administration path	Animal	Gender	Result
P.O.	DDY mouse	Male	>40 g/kg body weight, no death was observed
Oral gavage	Mouse (Slc: ICR, SLC)	Male	>20g/kg body weight, no death was observed

2.2.3 Sub-chronic studies

One sub-chronic animal study in rats is available which measured blood biochemical and physical parameters.

Fibersol-2 and Fibersol-2B 5-week dietary study in rats (Wakabayashi et al., 1991)

Test material: Fibersol-2
Test species: SD male rats (5 weeks old)
Dose: Groups 1-5 fed for 5 weeks on stock diet and tap water, 20% Fibersol-2B, 5% Fibersol-2, 10% Fibersol-2 and 20% Fibersol-2 solution respectively.
Guidelines: Not stated

Study conduct

Five-week old SD male rats (CE-s, Nippon Crea) were divided into 5 groups (8 rats per group) after pre-feeding with stock feed for 1 week. For the test period, Group 1 was fed with stock diet and tap water, Group 2 was fed with stock diet and 20% Fibersol-2B solution, Group 3 was fed with stock diet and 5% Fibersol-2 solution, Group 4 was fed with stock diet and 10% Fibersol-2 solution, and Group 5 was fed with stock diet and 20% Fibersol-2 solution. Each week body weight was checked and at the end of the 5-week observation period, blood was drawn from the heart and the weights of internal organs were recorded. Blood biochemical measurements taken were: total cholesterol, HDL-cholesterol, triglycerides, protein, calcium, GOT and GPT.

Results

General observation over the 5-week period showed no abnormal changes. There were no differences in body weight, feed intake and feed efficacy among the groups. Total cholesterol levels in all test groups (Groups 2-5) were significantly lower compared with the control group. Other blood biochemical measures did not differ significantly across the groups. No abnormalities were observed in any major internal organ and there were no differences in organ weights among the groups.

Conclusion

No significant changes in blood biochemical measures such as liver function, HDL-cholesterol, triglycerides, protein or calcium levels were recorded. Reductions in total cholesterol were recorded. There were no significant changes in body weight or major internal organ weight and there were no abnormalities noted in the internal organs upon dissection. The results of this study do not indicate any safety problems where Fibersol-2 and Fibersol-2B are included in the diet at 20%.

2.3 Human studies

2.3.1 Acute studies

2.3.1.1 Determination of ED_{50} for diarrhoea

Fibersol-2 and Fibersol-2B are not digested or absorbed in the upper gastrointestinal tract, but when they reaches the large intestine, it is partly fermented by bacteria, producing short-chain fatty acids. Fibersol-2 affects the absorption rate of carbohydrates in humans and this moderates postprandial blood glucose levels. The products of Fibersol-2 and Fibersol-2B in the large intestine, short-chain fatty acids, are expected to improve the intestinal microflora, intestinal regularity and immune function. The following study has estimated the ED_{50} for Fibersol-2B, that is, the single administration dose that results in diarrhoea in 50% of subjects.

Human toleration single-administration study with Fibersol-2B in water (Satouchi et al., 1993)

Purpose

The purpose of this study was to investigate the effect of a single-administration of Fibersol-2B on the gastrointestinal function and defecation conditions in healthy adult volunteers.

Study conduct

Subjects were 74 healthy adults, aged 20-60 years old, 53 males (age 38.3±11.3 years, height 169.0±5.5 cm, body weight 64.0±7.1 kg) and 21 females (age 31.7±9.9 years, height 156.9±4.9 cm, body weight 50.3±5.7 kg). Subjects were orally administered Fibersol-2B at doses of 10, 20 or 40 g dissolved in 100 ml of water after a breakfast meal at 9am. Each subject received each dose with at least one-week interval between administration and the order of dosage was randomly selected. 9 male subjects participated in a further stage of the experiment by ingesting 60g. Subjects were instructed to maintain their ordinary lifestyle including dietary habits. Usage of medication was discouraged, however, when medication was necessary, the name and dosage were recorded. Stool conditions and gastrointestinal conditions were observed in subjects for 48 hours following ingestion. Subjects completed a questionnaire by referring to a table with pictures of different types of stool conditions and recorded the time of defecation.

Results

Stools conditions tended to soften at all doses (10-60g) after intake of Fibersol-2B in comparison with conditions before oral administration in both males and females. Most of the stools were healthy in being banana shape or past-like and no clinical problems observed. No serious gastrointestinal conditions were observed, with mostly normal conditions: partially 'rumbling', 'flatulence' or 'flatus'. Muddy faeces were found following intake of 40 g of Fibersol-2B, which was not seen after intake of 10 or 20g, however, this symptom disappeared within 48 hours after intake. Occurrence of diarrhoea following intake of 40 g Fibersol-2B was 2.5% (male) and 5.3% (female). None of the 9 male subjects who took 60g Fibersol-2B experienced diarrhoea, no female subjects experienced diarrhoea at 10 g or 20g Fibersol-2B intake and no male subjects experienced diarrhoea at 60g intake. T

These results, such as 2.5% males experiencing diarrhoea after intake of 40 g Fibersol-2 while no males experienced diarrhoea at the higher 60 g dose, highlight the range of individual responses. The single administration volume for 50% occurrence of diarrhoea (ED_{50}, the effective dose for 50% diarrhoea) was estimated from a graph with intake volume on the horizontal axis (10 and 20g for male, and 20 and 40 g for female) and diarrhoea occurrence on the vertical axis. The ED_{50} was estimated as 156g for male and 118g for female. The average body weight was 64.0±7.1 kg for males and 50.3±5.7 kg for females, giving an ED_{50} value of 2.4g/kg body weight for both males and females.

Conclusion

The reported ED_{50} values for fructooligosaccharides (indigestible oligosaccharide) is 0.8g/kg body weight while the reported ED_{50} for sorbitol (a sugar alcohol) is 0.5g/kg body weight, both of which are much lower than the ED_{50} for Fibersol-2B. It is postulated that the higher ED_{50} for Fibersol-2B compared with other indigestible saccharides is due to its higher molecular weight and lower osmotic pressure. The estimate of ED_{50} is likely to be an overestimate since it was calculated for both males and females from the dose that produced highest occurrence of diarrhoea. The dose, which produced the highest occurrence of diarrhoea, was not the highest dose administered for males. For females, the ED_{50} was calculated from the proportion of diarrhoea at 2 doses, 10 g and 20g, however, at 10 g no diarrhoea occurred. An estimate of the ED_{50} for Fibersol-2 was calculated based on the results of the Fibersol-2B study (Satouchi *et al*., 1993) using an adjustment factor for the increased fibre content of Fibersol-2 as compared with Fibersol-2B. The ED_{50} for Fibersol-2 estimated in this way is 1.4g/kg body weight. The assumptions and methodology applied in this calculation of an estimated ED_{50} for Fibersol-2 were not supplied. Fibersol-2B is considered safe for human consumption at dose levels of 60g in a single administration, which was the highest dose administered in this study and this equates from the graph, to approximately ED_{10} to ED_{20} for both male and females (that is, occurrence of diarrhoea in 10 to 20% of subjects).

2.3.1.2 Glucose tolerance studies

The following single-administration studies of Fibersol-2 in humans were conducted to investigate the effect of Fibersol-2 on glucose tolerance. Water-soluble dietary fibres such as pectin and guar gum help to lower plasma glucose levels and reduce insulin secretion following glucose loading.

The mechanism described is that insulin secretion decreases because these water-soluble fibres with high viscosities cause the digestive tract to delay the absorption of nutrients, leading to a gradual increase in blood glucose levels. Fibersol-2 and Fibersol-2B are water-soluble fibres with low viscosity. It was hypothesized that Fibersol-2 ingested with or following a meal (or glucose, sucrose or maltodextrin loading) would also improve glucose tolerance and the following single-administration studies were performed in order to confirm this hypothesis. However, the possibility of Fibersol-2 ingestion being associated with gastrointestinal symptoms or hypoglycaemia was also raised. Therefore, a review of any adverse effects observed in these studies can assist in determining the safety of Fibersol-2.

Human toleration single administration study with Fibersol-2 contained in tea (Tokunga & Matsuoka, 1999)

Study conduct

The test beverage contained 5.12g Fibersol-2 in a 340 g canned tea beverage mix (roasted tea, oolong tea, black tea and Vitamin C). A total of 40 subjects undertook the single administration test, 32 males aged 25-49 years and 8 females aged 25-28 years. The following physical measurements were obtained: height; body weight; waist and hip circumference; and Body Mass Index (BMI) and waist/hip ratio (WHR) were calculated. The subjects were starved after breakfast at 7am until 12pm when fasting blood glucose was determined by a self-monitoring glucose analyser (Taito-Bayer-Sankyo Co. Ltd.). Subjects were then given either green tea (control) or the 340 g tea beverage containing Fibersol-2 within 15 min after a meal (Japanese noodles and rice with topping containing 16 g protein, 9 g fat, 105 g carbohydrates, with a total energy of 580 kcal). Blood glucose levels were measured at 30, 60 and 120 minutes after the beverage consumption. Subjects were blind to beverage loading and performance of the random loading was crossed over at intervals of 3-7 days. Increases in blood glucose levels between the two loading periods were compared and changes in blood glucose were monitored for 6 male subjects administered the Fibersol-2 containing beverage alone.

Results

Physical measurements of the group of 40 subjects are as follows for male: height 169±1.1 cm, body weight 68.6±2.1 kg, BMI 23.8±0.6, WHR 0.87±0.01, body fat 22.7±1.1%; and for females: height 158±1.6 cm, body weight 50.5±1.5 kg, BMI 20.1±0.7, WHR 0.7±0.03, and body fat 21.7±1.1%. The peak blood glucose level with Fibersol-2 loading following the meal declined compared with the control in 33 of the 40 subjects (83%). The area under the mean blood glucose curve was significantly lower with Fibersol-2 loading (74.2±4.8 mg min/dl) compared with the control (105.4±6.5 mg min/dl). Of 18 subjects with exceedingly high peak blood glucose values, the peak blood glucose levels was lower with Fibersol-2 compared with the control and a decrease in the area under the mean blood glucose curve with Fibersol-2 occurred for all 18 of these subjects. Ingestion of Fibersol-2 did not result in any adverse effects such hypoglycaemia, diarrhoea or gastrointestinal disorders.

Human toleration single administration study with Fibersol-2 contained in tea (Sinohara et al., 1999)

Study conduct

Test beverage contained 5g of Fibersol-2 with 1g of powdered natural green leaf tea dissolved in 100 ml hot water. The control beverage comprised 6g of powdered green tea dissolved in 100 ml hot water. Subjects were 39 healthy adult volunteers, 26 men and 13 women (age 33.2±8.0 years, BMI 22.4±3.2). A single-blind crossover study was conducted in which the subjects took either the control or test beverage and after at least one-day interval took the other beverage. The subjects fasted from 9pm the day prior to the study until the beverage was ingested at 9am on the day of the test. The subjects then ate a meal consisting of noodles and rice cake (14.g protein, 3.9g fat, 130.4g carbohydrates and 615 kcal energy). Blood glucose levels were determined before ingestion and at 30, 60 and 120 minutes after ingestion. Subjects were observed during the course of the study for any gastrointestinal symptoms.

Results

Four subjects were excluded from the statistical calculations because their fasting blood glucose levels were 120 mg/dl or above or their postprandial blood glucose level was 200 mg/dl or above after ingestion of the control beverage, which classifies them as diabetic. The remaining 35 subjects were divided into 2 groups on the basis of their blood glucose level 30 minutes following ingestion of the control beverage. Those subjects whose blood glucose level was 155 mg/dl or above (mean peak in postprandial blood glucose) at 30 minutes were allocated to Group A and those subjects whose blood glucose level was below 155 mg/dl were allocated to Group B. 22 subjects (19 men and 3 women) were allocated to Group A and 13 subjects (4 men and 9 women) were allocated to Group B. Fibersol-2 significantly suppressed postprandial blood glucose level 30 minutes after the meal compared with the control beverage in Group A, which showed higher initial blood glucose levels. Fibersol-2 did not have any effect on Group B which had lower initial blood glucose levels, however, Fibersol-2 did not induce hypoglycaemia in any of the subjects nor did it induce any gastrointestinal symptoms such as diarrhoea or abdominal bloating.

Human toleration single administration study with Fibersol-2 contained in soft drink (Mizushima et al., 1999)

Study conduct

The soft drink (100 ml) contained 9.8g of Fibersol-2, as well as minor ingredients (flavours, preservatives, acidifier, caramel, sodium metaphosphate and sweetener) while the control drink (100 ml) contained only minor ingredients. Subjects were 25 healthy adult males (37.6±6.1 years, BMI 23.5±2.6) divided into 2 groups: Group A (10 subjects), which readily showed a rise in blood glucose; and Group B (12 subjects), which did not readily show a rise in blood glucose. Subjects fasted from 9pm on the day ingestion till 9am on the day of ingestion. Subjects then ingested either the test soft drink containing Fibersol-2 or a placebo drink with a starchy meal of noodles and boiled rice which contained 14.1g of protein, 2.8g of fat, 138.6g of carbohydrate and 636 kcal of total energy within 15 minutes. Blood samples were taken before ingestion, and then 30, 60 and 120 minutes after ingestion.

Subjects were blind to beverage loading and performance of the random loading was crossed over after 7 days. Gastrointestinal symptoms experienced during the study such as diarrhoea and abdominal bloating were recorded.

Results

Of the 25 male subjects that participated in the study, three had fasting blood glucose levels of 126 mg/dl or above or a postprandial blood glucose level after ingestion of the control drink of 200 mg/dl or above and their data were excluded because they could be classified as diabetic according to the diagnostic criteria of diabetes mellitus of the Japan Diabetes Society. The peak in blood glucose 30 minutes after the meal was inhibited significantly with Fibersol-2 for Group A, but not inhibited significantly for Group B. There were no gastrointestinal symptoms such as diarrhoea or abdominal bloating, nor was hypoglycaemia induced in any of the subjects including the three that were considered diabetic.

Human toleration single administration study with Fibersol-2 contained in tofu (Uno et al., 1999)

Study conduct

Subjects were 34 healthy adults, 17 males (age 40.6±11.9 years, body fat 20.7±4.8 %, BMI 21.9±2.8, WHR 0.86±0.06) and 17 females (age 38.4±11.2 years, body fat 27.9±5.4, BMI 21.9±2.9, WHR 0.77±0.05). The test meal consisted of 150 g tofu containing 5g indigestible dextrin (form not specified) and carbohydrate rich foods (noodles and rice with 639 calories, 3g fat, 140 g carbohydrate, and 13g protein), while the control meal was identical except the tofu did not contain any indigestible dextrin. Subjects were starved from 9pm the day prior to the test and fasting blood glucose levels were measured at 8.30am on the day of the test. Subjects were then given the test or control meal and blood glucose was measured at intervals of 30, 60 and 120 minutes following ingestion. Groups were crossed over after a 1-week interval.

Results

The test results of 2 subjects were omitted from the statistical analysis because their peak postprandial blood glucose levels were higher than 200 mg/dl and they would be classified as diabetics. Another 2 subjects were omitted from the analysis because their peak postprandial blood glucose levels were lower than their starving blood glucose levels. Subjects were then divided into 2 groups according to the average blood glucose level at 30 minutes after the meal: Group A had a postprandial blood glucose level at 30 minutes of 138 mg/dl or more; and Group B had a postprandial blood glucose level at 30 minutes of less than 138 mg/dl. The blood glucose levels at 30 minutes after the meal were significantly lowered by the intake of indigestible dextrin containing tofu for Group A, but indigestible dextrin had no effect on Group B. None of the subjects showed any signs of hypoglycaemia and no adverse gastrointestinal symptoms were observed.

Human toleration single administration study with Fibersol-2 contained in miso-soup (Kishimoto et al., 2000)

Study conduct

Subjects were 27 healthy adult males. Three types of freeze-dried instant miso-soups (awase, akadashi and shiromiso) containing the same ingredients (spinach, fried bean curd, wakame and welsh onion) were supplemented with either Fibersol-2 (test) or maltodextrin (control). The miso-soups were given to subjects after reconstitution with 160 ml of hot water. The composition of these soups is summarised in table 3.

Table 3: Contents of test miso-soups ingested

Miso soup	Protein	Fat	Carbohydrate	Sodium	Dietary Fibre
Awase	2.0	1.0	4.8	443	4.4
Akadashi	2.0	0.8	4.7	448	4.7
Shiromiso	2.3	1.0	4.5	464	4.8

Subjects fasted for 4 hours from 8am after having breakfast. Blood glucose levels were measured at 12pm and the trial subjects then ingested either awase miso-soup containing Fibersol-2 or the control within 15 minutes. Blood glucose was measured at 30, 60 and 120 minutes following ingestion. Subjects were double blind to the test/control meals, which were randomly assigned and ingested at intervals of 2-3 days. On the basis of mean peak glucose level after ingestion of the control meal, the trial subjects were categorized into 2 groups: Group H who tended to have higher blood glucose levels after the meal; and Group L who tended to have lower blood glucose levels after the meal. In addition, 8 subjects received all three types of miso-soups to compare the blood glucose moderating effects of the three soups. Any adverse gastrointestinal symptoms observed during the trial were recorded.

Results

Awase miso-soup containing Fibersol-2 significantly reduced the postprandial rise in blood glucose levels with a more marked reduction in subjects who tended to have higher blood glucose levels. No difference was noted in the blood glucose moderating effects of the three miso-soups. No adverse gastrointestinal symptoms or hypoglycaemia was observed during the study.

Human toleration single administration study with Fibersol-2 (Wakabayashi et al., 1999)

Study conduct

- Oral sugar loading test

  Subjects were 5 healthy adult males (age 30.2±1.6 years, height 173.4±2.4 cm, body weight 61.6±1.8 kg, BMI 20.5±0.9). Subjects were starved from 9pm the day prior to the study, while on the day of the study both food and drink were restricted.

On the day of the study, subjects received: (1) 150 ml carbonated water with 50 g glucose; (2) 300 ml of carbonated water with 100 g sucrose; (3) 150 ml of carbonated water with 50 g maltodextrin (2.5% glucose, 7% maltose, 9% maltotriose, and 81.3% oligosaccharides/dextrin); (1) – (3) were either with or without 10 g Fibersol-2; or (4) 150 ml of carbonated water with 10 g Fibersol-2. These tests were conducted at one-week intervals. Blood samples were collected before loading, 30 min, 60 min and 120 min after loading (except for the sucrose loading study for which blood samples were only collected to 60 min).

- Meal loading test

  Subjects were 10 healthy males (age 36.2±3.1 years, height 165.1±5.0 cm, body weight 58.5±2.9 kg, BMI 21.4±0.8). Subjects were starved after breakfast at 7am on the day of the study and blood glucose levels were determined at 12pm. A meal was consumed immediately after that comprising Kitsune Udon and rice (protein 16g, fat 9g, carbohydrate 105g and total calories 565) with green tea either with or without 5g Fibersol-2. Blood glucose levels were measured at 120 minutes following the meal. Cross-over was performed after 1 week interval.

  Using a similar procedure, healthy subjects (10 males and 14 females) were administered sweet rolls with sweet bean jam (protein 13g, fat 5g, carbohydrate 114g, total calories 553) with 100 ml of coffee containing 7g of Fibersol-2 within 15 minutes and then blood glucose levels measured at 120 minutes after the meal.

Results

- Oral sugar loading test

  Fibersol-2 did not affect the blood glucose response following glucose loading, however, the insulin secretion was decreased significantly. Following sucrose loading, Fibersol-2 decreased both the blood glucose and insulin secretion. Following maltodextrin loading, Fibersol-2 decreased insulin secretion but not blood glucose. Following Fibersol-2 loading alone, blood glucose and insulin secretion showed a very small rise, which was not statistically significant in comparison with the baseline measurements. No gastrointestinal symptoms, e.g. diarrhoea, were observed.

- Test meal loading

  Fibersol-2 decreased the peak in post meal blood glucose level to 87% of the peak in the post control meal blood glucose level at 30 min with Udon noodles and rice. Fibersol-2 decreased the peak in post meal blood glucose level to 84% of the peak in the post control meal blood glucose level at 30 min with the sweet rolls meal. Again, no gastrointestinal symptoms were observed.

Conclusions

The single-administration studies indicate that resistant maltodextrin causes a reduction in postprandial blood glucose levels following a meal, more markedly in subjects who tended towards higher blood glucose levels.

Relevant to the safety is the fact that ingestion of resistant maltodextrin did not induce hypoglycaemia in any subjects, even those with lower blood glucose levels. In addition, no adverse gastrointestinal symptoms were observed in any of the studies at dose levels up to 10 g in a single dose.

2.3.2 Sub-chronic studies

A number of sub-chronic human studies investigating the effects of Fibersol-2 or Fibersol-2B on blood biochemical, urine and physical parameters are available for a range of food products. Studies have been conducted with healthy, diabetic, hyperlipidemic and hyperglycaemic subjects.

Human toleration 13-week study with Fibersol-2 contained in tea (Kajimoto et al., 2001)

Study conduct

- Sample: sample beverage was a tea blend (green tea, barley tea, oolong tea, roasted tea, Job's tear tea) containing 6.1g of Fibersol-2 (equivalent to 5.5g of soluble dietary fibre) and also vitamin C.

- Subjects: subjects were 16 healthy adults (8 male, 8 female), aged 23-48 years old (29.2±6.2). Study was conducted in accordance with the Helsinki declaration of 1964.

- Schedule: for 3 months (13 weeks), from 25 July 2000 to 24 October 2000, subjects ingested 250 ml of the tea blend 3 times daily at meal times. During the study, subjects were instructed to avoid consuming dietary supplements and not to change their ordinary lifestyle.

- Examination of blood: blood was obtained 4 times in total: before the study; at 1 month, 2 months and 3 months. The blood was examined for haematological counts (white blood cells, red blood cells, haemoglobin (Hb), hematocrit (Ht), platelets, aspartate aminotransferase (AST, GOT), glutamate pyruvate transaminase (GPT), alkaline phosphatase (ALP), gamma-glutamyltranspeptidase (γ-GTP), lactic dehydrogenase (LDH), leukocyte alkaline phosphatase (LAP), total proteins, albumin, triglycerides, total cholesterol, blood glucose, glycosylated haemoglobin (Hb_{A1c}), fructosamine, blood urea nitrogen (BUN), creatine, uric acid, creatine kinase, sodium (Na), chloride (Cl), potassium (K), calcium (Ca), magnesium (Mg), iron (Fe) and ferritin. Blood examination was conducted at Sagamino Hospital (Sagamihara, Kanagawa, Japan) by collecting fasting blood samples (fasting period was 10pm on day prior to collection to 11am on day of collection). Blood samples were collected in the sitting position after at least 5 minutes rest. The collected blood samples were analysed on the same day.

- Urine Examination: urine samples were collected within 24 hours of blood collection and analysed for specific gravity, pH, urinary glucose, urinary protein, urinary ketone bodies and urinary blood.

- Blood pressure and physical examination: the following measurements were made at the time of blood and urinary analyses: blood pressure, height, body weight, waist, hip, and body fat (Omron HBF-303, personal body fat metre). BMI and WHR were calculated from those measurements.

- Interview: at the same time as the blood/urine sample collection and measurements were made, the subjects were asked about sickness, nausea, vomiting, faecal characteristics and other subjective symptoms.

- Daily report: the subjects recorded the following details twice a week (dates uniformly predetermined): meals, snacks and alcohol consumed; body weight; body fat ratio; exercise including pedometer counts (Seiko WZ100A); physical condition and medication taken.

- Statistical analyses: paired one-way analysis of variance was used to analyze the measurements and in the case where main effects in subjects were found and multiple comparisons were applicable, multiple comparison analysis by Dunnet test was applied. All statistical analyses employed two-side test with significant levels less than or equal to 5% using SPSS® Advanced model.

Results

- Subjects: two subjects (1 male and 1 female) were omitted from this study because they required medication during the study period. The required medication was unrelated to the study, the male suffered persistent fever from infection at the root of a tooth while the female suffered from a systemic rash caused by systemic lupus erythematosus. The results for the remaining 14 subjects (7 male and 7 female) were used in the calculation.

- Blood examination: some significant changes from baseline by gender were observed for at particular months for: LDH; albumin; total cholesterol levels; fructosamine; BUN; uric acid and ferritin. However these were changes within normal ranges. Changes in measurements outside the limits of normal ranges were observed for some individuals for GPT (2 males at 1 month) and total cholesterol (1 male at 1 month and 1 female at 1, 2 and 3 months). The GPT changes were assessed as not clinically significant because the total alcohol consumed in the month for both of the males was large and the changes were transient. The abnormal changes in total cholesterol for the male were assessed to be not clinically significant since the pretest value was on the border of the normal range and his total cholesterol values were in the normal range at 2 and 3 months). The abnormal changes in total cholesterol for the female were assessed to be not clinically significant since the pretest value was on the border of the normal range.

- Urine examination: The average values for specific gravity were significantly different at 2 and 3 months in males and 3 months in females, however, the changes were within the normal range and not clinically significant. No other significant changes were observed.

- Blood pressure and physical examination: there were significant changes in body fat for males at 1 and 2 months. The changes were within the normal range and without associated problems, and there were no significant changes in other measurements.

- Interview: no serious symptoms or adverse events were reported during the study.

- No clinical abnormalities were observed in haematological examination, hepatic function, renal function, glucose metabolism, fat metabolism, electrolyte metabolism, blood pressure nor through physical examination.

Human toleration 12-week study in diabetic subjects with Fibersol-2 containing diet (Nomura et al., 1992)

Study conduct

Five non-insulin dependent diabetes mellitus (NIDDM) patients with hyperlipidemia (56±5 years) received a diet therapy (25-30 kcal/kg ideal body weight). Following the treatment, their hyperlipidemic conditions were rechecked and 60g/day of Fibersol-2 (20g/meal) was administered for 12 weeks. The dose to NIDDM patients was 1g/kg body weight on average. The dose of Fibersol-2 was determined based on the LD_{50} for Fibersol-2B of more than 40 g/kg body weight (no death occurred).

Blood samples were collected under fasting conditions before the administration period, then at 2, 4, 8 and 12 weeks. The following measurements were taken: fasting plasma glucose (FPG); cholesterol; high density lipoprotein (HDL)-cholesterol; triglycerides; Ca; Mg; phosphorus (P); Fe; red blood cell count (RBC); GOT; GPT; γ-GTP; and LDH. Subjects were also asked about any symptoms.

Results

Blood cholesterol levels were significantly reduced at weeks 4, 8 and 12 weeks during the administration period, while serum cholesterol levels were significantly reduced at weeks 4 and 8 weeks of the administration period (but the result was not significant at 12 weeks due to the scatter of individual's values). Fasting blood glucose levels were significantly reduced after 12 weeks of administration. No significant changes in other serological values were noted, e.g. Fe, Ca, RBC or hepatic indicators. No adverse reactions such as diarrhoea or intestinal pains were observed in this study.

Human toleration 1-month study in healthy and hyperlipidemic patients with Fibersol-2 contained in canned tea beverage (Tokunaga & Matsuoka, 1999)

Study conduct

The beverage was a 340 g canned tea (roasted tea, oolong tea and black tea) beverage with 5.12g of Fibersol-2 and Vitamin C. A total of 40 subjects underwent a single-intake test, which was discussed previously in this assessment, while 10 volunteers (32-59 years, mean 48.3±3.4 years) were further tested with continual administration for a period of 1 month with 1 can per meal. Subjects were instructed not to alter their usual physical activities, dietary habits or any other aspect of their lifestyle.

Physical parameters were obtained including height, body weight, and waist and hip circumference. BMI and WHR were derived from the measurements. Body fat was determined using a body-composition analyzer-attached scale (TBF-501, Tanita Co. Ltd.).

Fasting blood samples were collected and the following analyzed: serum lipids; serum total cholesterol, HDL-cholesterol and triacylglycerol; fasting blood glucose; Hb_{A1c}; total protein; total bilirubin; uric acid; nitrogen in urea; creatinine; GOT (AST); GPT (ALT); γ-GTP, LDH; LAP; creatine phosphokinase (CPK); Na; Cl; K; Ca; RCB; Hb, Ht, white blood cell count (WBC) and platelet counts.

Results

Based on the WHO criteria for hyperlipidemia, of the 10 volunteers (height: 164.1±1.1 cm; body weight: 68.1±2 kg; BMI: 25.3±0.6; WHR: 0.89±0.01), 3 were categorized as type IIb hyperlipidemic, 4 were categorized as type IV hyperlipidemic and 3 indicated normal readings.

All subjects except for one normal subject had lower blood glucose levels after administration period. The 3 subjects with hyperlipidemia type IIb showed decreases in serum total cholesterol levels, although the mean serum total cholesterol for all 10 subjects after administration period was not significantly different compared with pre-administration values. Although increases in HDL-cholesterol levels in 8 of the 10 subjects were noted, the mean post-administration value did not differ significantly from the mean pre-administration value. Triacylglycerol levels decreased in all subjects after the administration period and this difference was significant.

There were no other significant changes in biochemical or haematological parameters between pre- and post-administration and no clinical problems were observed. No adverse effects such as hypoglycaemia, diarrhoea or gastrointestinal upset were observed.

Human toleration 3-month study in hyperglycaemic patients with Fibersol-2 contained in miso-soup (Kishimoto et al., 2000)

Study conduct

10 subjects who were classified as hyperglycaemic (i.e. showed a tendency for a rise in blood glucose following a meal) took part in this study. Three types of freeze-dried instant miso-soups (awase, akadashi and shiromiso) containing the same ingredients (spinach, fried bean curd, wakame and welsh onion) were supplemented with either Fibersol-2 (test) or maltodextrin (control). The miso-soups were given to subjects after reconstitution with 160 ml of hot water. The composition of these soups was summarised in section 2.3.2.

Subjects consumed the miso-soups three times daily for 3 months. Subjects were instructed to maintain their normal lifestyle including exercise and dietary habits. The following measurements were obtained immediately prior to the study and at 1, 2 and 3 months into the test period: body weight; waist circumference; hip size; body fat content; blood pressure; pulse; blood biochemical parameters such as total protein, albumin content and actin to gelsolin ration (A/G); liver functional parameters such as GOT, GPT, ALP, LDH, cholinesterase (ChE), LAP, γ-GTP and CPK; kidney functional parameters such as uric acid, urea nitrogen content and creatinine; electrolyte values such as Na, Cl, Ca, P and Fe; lipid metabolic parameters such as total cholesterol, HDL-cholesterol and triglycerides; sugar metabolic parameters such as glucose, fructosamine and Hb_{A1c}; haematological parameters such as leukocyte count, red blood cell count, Hb, Ht, mean corpuscular volume (MCV, MCH), mean corpuscular haemoglobin concentration (MCHC), platelet count and specific gravity; and urinary analysis such as specific gravity, pH, urobilinogen, bilirubin, ketone body, protein, glucose and occult blood.

Results

There was no significant difference in any of the physical parameters. After one month, serum triglyceride level was significantly reduced and total cholesterol levels declined (though not significantly). The Cl level had significantly decreased after 3 months but was still within the normal range. Other measurements were not changed after the three-month period. No other adverse effects were observed throughout the test period.

Human toleration 1-month study with Fibersol-2 contained in soft drink (Mizushima et al., 1999)

Study conduct

The soft drink (100 ml) contained 9.8g of Fibersol-2, as well as minor ingredients (flavours, preservatives, acidifier, caramel, sodium metaphosphate and sweetener) while the control drink (100 ml) contained only minor ingredients. 25 healthy adult males were recruited to undertake a single-administration study (reported in this assessment) and of these, 3 subjects (age 35.0±3.6 years; BMI 24.1±2.1) were recruited to continue taking Fibersol-2 for a repetitive administration study. Subjects ingested the test drink three times a day at each meal for 1 month. Blood and urine samples were collected at 4pm on the day prior to start of the test period and after 1 month. The following parameters were measured: red cell count; haemoglobin; hematocrit; platelet count; white cell count; liver function (GOT, GPT, ALP, zinc turbidity test (ZTT), γ-GTP, bilirubin and total protein); renal function (BUN, serum creatinine, uric acid); urine analysis (protein, sugar, urobilinogen, bilirubin, ketones, occult blood and pH); total cholesterol; HDL-cholesterol; triglyceride; whole blood specific gravity; serum amylase; Hb_{A1c}; fasting blood glucose; and blood pressure.

Results

There were no significant changes in any of the major parameters measured. However, there were non-significant favourable changes in triglyceride and HDL-cholesterol. No gastrointestinal symptoms or hypoglycaemia were observed or reported in any of the subjects during the 1 month period.

Human toleration 12-week study in hyperglycaemic patients with Fibersol-2 contained in soft drink (Mizushima et al., 2000)

Study conduct

100 ml bottles of soft drink were ingested, containing 9.8g of Fibersol-2. The nutritional composition was: energy 4 kcal; carbohydrate 1.1g; sodium 11.6 mg; and protein and lipid 0 g. Subjects were adult males with hyperglycaemia or borderline hyperglycaemia (blood glucose of 100 to 130 mg/dl) at a regular health check (age 44.4±6.9 years; body fat 25.7±5.9%; BMI 25.4±3.3; and fasting blood glucose level of 113.7±13.5 mg/dl).

Subjects fasted from 9pm on the day before the start of the trial. At 9am on the day of the trial blood samples and urine were collected for analyses, height, weight and body fat were measured and BMI was calculated. Subjects then received the test drinks daily at breakfast, lunch and supper for 12 weeks.

Subjects were observed regularly and instructed not to modify their normal lifestyle. Subjects underwent blood tests, urinalysis and health checks at weeks 4, 8 and 12 and again 8 weeks after the trial.

The following measurements were taken:

- Physical examination: body weight, body fat percentage, blood pressure, and pulse rate. Blood pressure and pulse rate were measured at the start of the trial, at week 12 and at 8 weeks post ingestion.

- Haematological examination: RBC, WBC, Hb, Ht, platelet count, MCV, MCH, MCHC, and whole blood specific gravity.

- Blood biochemical examination: Fasting blood glucose, Hb_{A1c}, fructosamine, Na, K, Cl, Ca, total protein, urea nitrogen, uric acid, creatinine, LAP, serum amylase, γ-GTP, CK, ZTT, GOT, GLP, ALP, LDH, total bilirubin, total cholesterol, HDL-cholesterol, triglycerides, and free fatty acids.

- Urinalysis: pH, urobilinogen, glucose, protein, occult blood, ketone bodies and bilirubin.

Results

- Physical examination: no significant changes were found in body weight at weeks 4, 8, 12, or 8 weeks post-ingestion. Body fat decreased at weeks 8 ($p<0.01$) and 12 weeks ($p<0.05$) and 8 weeks post-ingestion ($p<0.01$).

- Haematological examination: no significant changes were found in any haematological parameters at weeks 4, 8, 12 or 8 weeks post-ingestion compared with pre-test values.

- Blood biochemical examination: fasting blood glucose and fructosamine levels in the ingestion and post-ingestion periods were significantly lower than their pre-test values ($p<0.01$) indicating an improvement in glucose metabolism. Triglycerides decreased significantly at week 4 ($p<0.05$) and tended to decrease at weeks 8 and 12 (though not significantly) compared to the pre-test value. Changes in other parameters such as electrolytes, protein metabolism, renal function, pancreatic function and hepatic function were within normal ranges and not significant.

- Urinalysis: there were no significant changes in any parameter compared with the pre-test value.

At the start of ingestion, 3 of the 10 subjects had soft stools and an increase in defecation frequency, 2 subjects had slightly soft stools and an increase in defecation frequency and a sensation of flatulence, while 1 subject had a sensation of flatulence only. All of these symptoms were found in the initial ingestion period only and disappeared within one month without treatment. Otherwise, there were no adverse effects of clinical problems observed.

Human toleration 4-12 week study with indigestible dextrin containing diet (Matsuoka et al., 1992)

Study conduct

Subjects were 10 healthy male volunteers; aged 33-59 years (mean 50.3 years), height 158-173 cm tall (mean 164.8 cm) and body weight 52 to 82 kg (mean 68.8 kg). Indigestible dextrin was dissolved in water at a concentration of 10 g/100 ml and administered orally 3 times daily (30g indigestible dextrin/day) before each meal for 4 weeks. Two subjects then continued the administration regime at the same dose (30g/day) for an additional 4 weeks (8 weeks in total) while the remaining 8 subjects continued the administration regime on half the dose (15g/day) for an additional 4 weeks.

The following measurements were taken prior to administration regime and 4 weeks after the start of administration:

- Physical examination: Body weight, blood pressure, and pulse rate.
- Haematological examination: RBC, WBC, Hb, Ht, MCV, MCH, MCHC, platelet count, reticulocyte count, differential leukocyte count, and fibrinogen.
- Blood biochemical examination: Fasting blood glucose, Hb_{A1c}, Na, K, Cl, P, Mg, Fe, Ca, protein, protein fraction, albumin, A/G, urea nitrogen, uric acid, creatinine, total bile acid, LAP, serum amylase, γ-GTP, CK, ChE, ZTT, thymol turbidity test (TTT), GOT, GPT, ALP, LDH, bilirubin, total cholesterol, HDL-cholesterol, triglycerides, free fatty acids, and lipoprotein fraction.
- Urinalysis: Specific gravity, pH, urobilinogen, sediments, glucose, protein, occult blood, nitrite, ketone bodies and bilirubin.

Results

- Physical examination: there were no significant changes in body weight, blood pressure or pulse rate at 4 weeks in comparison with pre-test values.
- Haematological examination: the change in reticulocyte count from pre-test to 4 weeks was statistically significant, but within the normal range.
- Blood biochemical examination: there were no significant changes in the following blood biochemical parameters: glucose tolerance; electrolytes; protein metabolism; renal function; pancreatic function; and liver function. Total cholesterol level had decreased (not significantly) in all subjects except one at week 4 and had further decreased (not significantly) in all subjects including those whose dose was reduced by half from week 4 to week 8. HDL-cholesterol showed a change within normal range but the ratio of HDL-cholesterol to total cholesterol increased in 8 subjects at week 4 and 9 subjects at week 8 as compared with the pre-test value. Similar results were obtained for lipoprotein fraction. Triglyceride levels decreased during the study but not significantly. Free fatty acids decreased significantly throughout the study to be within the normal range.

- Urinalysis: the results of urinalysis were not discussed in the English translation of this paper.

No other adverse effects such as gastrointestinal upset were observed.

Human toleration 16-week study in diabetic subjects with indigestible dextrin containing diet (Fujiwara and Matsuoka, 1993)

Study conduct

Subjects were 5 outpatients (3 males and 2 females) within NIDDM (age 55±6 years; height 162±2 cm; body weight 69.2±5.8 kg; and BMI 26.6±2.9). For the treatment of diabetes, four patients received diet therapy and an oral hypoglycaemic drug (Glibenclamide), while the other patient received diet therapy alone. The following complications were present, not for all subjects: hypertension; hyperlipidemia; and fatty liver. Four patients had good blood glucose control, while the other had poor blood glucose control as judged by Hb_{A1c} levels.

Indigestible dextrin was dissolved in water at a concentration of 10 g/100 ml and given orally 3 times daily (30 g/day before each meal) as outlined in the previous study (Matsuoka *et al*., 1992) and administered for 16 weeks. Physical measurements, blood and urine samples were obtained before the start of administration, at weeks 4, 8, 12 and 16. The diet therapy and/or drug treatment on patients were continued for the entire study period unless significant changes were found.

The following measurements were taken:

- Physical examination: body weight and blood pressure.

- Haematological examination: RBC, WBC, Hb, Ht and platelet count.

- Blood biochemical examination: fasting blood glucose, fructosamine, Hb_{A1c}, Hb_{A1}, 1,5-anhydroglucitol, ketone body fraction (acetoacetic acid, β-hydroxybutyric acid), total cholesterol, HDL-cholesterol, triglyceride, β-lipoprotein, free fatty acids, phospholipids, lipoprotein fraction, apoprotein fraction, Ca, P, Mg, Fe, total protein, TTT, total bile acid, GOT, GPT, ALP, LDH, CK, LAP, lipase, urea nitrogen, uric acid and creatinine.

- Urinalysis: albumin, α_1-microalbumin, β_2-microalbumin and N-acetyl-β-D-glucosaminase (NAG).

Results

- Physical examination: there was no significant change in body weight during the administration period compared with pre-test value. Both systolic and diastolic blood pressure showed a tendency to decrease gradually following the start of administration without a significant difference.

- Haematological examination: no significant changes were found in any parameter.

- Blood biochemical examination: fructosamine, Hb_{A1} and Hb_{A1c}, which are indices of blood glucose, control showed no significant changes after administration. 1,5-anhydroglucitol showed a tendency to decrease gradually although the change was not statistically significant. Ketone body fraction tended to decrease for both acetoacetic acid and β-hydroxybutyric acid although the ratio of these fractions did not change very much. There were significant beneficial decreases in triglyceride and β-lipoprotein levels. Total cholesterol and HDL-cholesterol tended to decrease and increase respectively within normal ranges and the changes corresponded with an increase in α-lipoprotein fraction and a decrease in β-lipoprotein fraction. Free fatty acids showed an abnormally higher mean value at the start of administration and had decreased to within normal range by week 16, though this change was not significant. Apoprotein B showed a significant decrease at weeks 4 and 8. ALP, LDH and CK showed significant changes during the administration period, but the values were within normal ranges and were assessed to be of no clinical significance. There were no effects on Ca, P, Mg, Fe, liver or kidney function.

- Urinalysis: microalbumin decreased after administration with a significant difference at week 4 but no other parameters showed significant changes.

Subjects reported that the feeling of hunger between meals was lessened. No adverse effects such as digestive symptoms like diarrhoea were reported.

Conclusion

The human toleration studies of Fibersol-2/indigestible dextrin (form not specified in some studies) in various food products indicate a tendency toward favourable changes in the parameters measured and no adverse effects. There was a tendency for: reductions in total cholesterol levels, fasting blood glucose levels, triglyceride levels and β-lipoprotein levels; and increases in HDL-cholesterol and the ratio of HDL-cholesterol: total cholesterol. These changes were statistically significant in some studies. There were some statistically significant changes in some other blood biochemical and haematological parameters in some studies such as reticulocyte count (Matsuoka *et al*., 1992), LDH, albumin, fructosamine, BUN, uric acid and ferritin and GPT (Kajimoto *et al*., 2001), however, these changes were either within normal ranges or not clinically significant because of other factors external to the study (e.g. excess consumption of alcohol related to changes in GPT). There were no changes in any physical measurements such as body fat and no changes in urinalysis. In addition, no adverse effects such as gastrointestinal symptoms or hypoglycaemic responses were noted in any subjects.

Therefore, Fibersol-2/indigestible dextrin (form not specified in some studies) did not produce any adverse effects at: dose levels up to 60g/day in diabetic subjects for 12 weeks; or dose levels up to 30g/day in diabetic subjects for 16 weeks; or 30g/day for 12 weeks in healthy subjects (healthy subjects were not subjected to a dosage regime of 60g/day).

2.4 Mutagenicity studies

Mutagenicity studies have been performed for both Fibersol-2 and Fibersol-2B.

Reverse mutation assay on Fibersol-2 in bacteria
(Matsutani Chemical Industry Co. Ltd. ed.: Review: Safety of Pinefibre, 1990)

Purpose

To investigate the mutagenicity of Fibersol-2 by gene mutagenicity test using bacteria (Ames Test).

Study conduct

E. coli WP2uvrA, S. typhimurium TA98, TA100, TA1535, and TA1537 were used as indicative bacteria. In the metabolic inactivation method, Na-Pi buffer solution of S9 Mix, a fractionated SD male rat liver microsome prepared after intraperitoneal administration of Phenobarbital and 5,6-benzoflavone. Fibersol-2 was added at the amount of 40-5000 μg/plate in the form of purified water solution.

After incubating the plate containing 0.1 ml of bacteria suspension, 0.1 ml of the solution and 0.5 ml of the Na-Pi buffer and 2.0 ml of soft agar solution (Bacto-agar, Difco Lab) (2.7 ml in total) at 37oC for 48 hours, the reverse colonies per plate were counted. Na-Pi buffer solution of S9 Mix was used instead of Na-Pi buffer in the metabolic activation method.

Results

Fibersol-2 did not increase the number of reverse mutate colonies in comparison with the reference buffer solution in any strain of the tested bacteria at the amount of 40-5000 μg/plate, not withstanding whether metabolically activated or not. The positive references AF-2, NaN_3 and 9-AA increased the number of reverse mutate colonies without S9 Mix, and 2-AA also increased the number of reverse mutate colonies with S9 Mix. The reverse mutagenesis on bacteria of Fibersol-2 was determined to be negative.

Reverse mutation assay on Fibersol-2B in bacteria (Wakabayashi et al., 1992)

Purpose

To investigate the mutagenicity of Fibersol-2B by gene mutagenicity test using bacteria (Ames Test).

Study conduct

E. coli WP2uvrA, S. typhimurium TA98, TA100, TA1535, and TA1537 were used as indicative bacteria. Positive references used were: AF-2 (2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide); NaN3 (sodium azide); 9-AA (9-aminoacridine); 2-AA (2-aminoanthracene). Saline buffer was used as a reference solution. No further details provided.

Results

No mutagenicity was observed in S. typhimurium TA98, TA100, TA1535, TA1537 or *E. coli* WP2uvrA$^-$ in comparison with saline buffer. The positive references AF-2, NaN_3 and 9-AA increased the number of reverse mutate colonies without S9 Mix, and 2-AA also increased the number of reverse mutate colonies with S9 Mix.

Conclusion

No mutagenicity was observed for either Fibersol-2 or Fibersol-2B in S. typhimurium TA98, TA100, TA1535, TA1537 or *E .coli* WP2uvrA$^-$ in comparison with reference buffer.

2.5 Studies on mineral absorption

In-vitro study on mineral absorption
(Matsutani Chemical Industry Co. Ltd. ed.: Review: Safety of Pinefibre, 1990)

Purpose

The purpose of this study was to evaluate the effect of Fibersol-2B on mineral absorption.

Methods

Cellulose membranes filled with metal ions in solution were used as a model system of the digestive tract. Each metal ion (3000 ppm of Na^+, K^+, Ca^{2+}, Cu^{2+}, Zn^{2+} and 1000 ppm of Fe^{3+}) were separately added to 10 ml of Deionised water with 1% Fibersol-2B, and were filled into a cellulose dialysis membrane (Cellotube VT351, <3500 Mwpass, Nakarai Tesque) and then sealed. The tube was soaked in 500 ml Deionised water at 37oC. The diffused ion in the outer solution was measured for 180 min. In addition, apple pectin (Wako Pure Chemical), guar gum (Organo) and polydextrose (Pfizer) were examined. A solution containing no dietary fibre was used as a reference.

Results

No inhibition of any metal ion diffusion was observed in the presence of 1% Fibersol-2B in solution. In contrast, pectin and guar gum inhibited the diffusion of metal ions, particularly for Ca^{2+} and Cu^{2+}.

In-vivo study on mineral absorption
(Matsutani Chemical Industry Co. Ltd. ed.: Review: Safety of Pinefibre, 1990)

Purpose

Examine serum calcium levels following administration of Fibersol-2 and Fibersol-2B.

Methods

Five-week old SD male rats were divided into 5 groups (8 rats per group) after pre-feeding with stock feed (CE-s, Nippon Crea) for 1 week. Groups 1-5 were fed the following diets for 5 weeks: Group 1 – stock diet with tap water; Group 2: 20% Fibersol-2B solution; Group 3 – 5% Fibersol-2 solution; Group 4: 10% Fibersol-2 solution; Group 5: 20% Fibersol-2 solution. At the end of the 5 week period, blood was drawn to determine calcium content.

Results

Blood levels of calcium were not significantly different among the control and 4 test groups.

Conclusion

Some soluble dietary fibres such as pectin or guar gum are constituted from plant non-structural polysaccharides and their solutions are highly viscous or form gels and have been shown to reduce the absorption of some nutrients. The studies available did not indicate any effect of Fibersol-2 or Fibersol-2B on mineral absorption. The low viscosity of Fibersol-2 and Fibersol-2B is likely to have contributed to the lack of inhibition of mineral absorption.

3. Overall conclusion

Fibersol-2, and to a lesser extent, Fibersol-2B are resistant to digestion and are poorly absorbed in the upper gastrointestinal tract. In the lower gastrointestinal tract, they are partially fermented by intestinal bacteria producing short-chain fatty acids, primarily acetate, propionate and butyrate. The remainder of Fibersol-2 and Fibersol-2B is excreted. Fibersol-2 and Fibersol-2B are considered safe for human consumption at all levels studied in humans (up to 60g in a single administration and 60g per day over three months). This conclusion is based on the following:

- Acute toxicity studies in animals indicate that the LD_{50} is more than 20 g/kg bw and 40 g/kg bw for Fibersol-2 and Fibersol-2B.

- Sub-chronic studies in rats showed no significant changes in blood biochemical measures, body weight, internal organ weight and no abnormalities in internal organs upon dissection when Fibersol-2 and Fibersol-2B are included in the diet at up to 20%.

- The single administration dose that produces diarrhoea in 50% of subjects was estimated to be greater than 100 g.

- Single-administration human studies show a reduction in postprandial blood glucose following a meal and no indication of hypoglycaemia or any adverse gastrointestinal symptoms at dose levels up to 10 g.

- Human toleration studies of up to four months on healthy subjects and diabetic subjects showed favourable changes in some blood and blood biochemical parameters such as reductions in total cholesterol, β-lipoprotein, fasting blood glucose and triglycerides and increases in HDL-cholesterol. No other changes that were outside of normal ranges or clinically significant were detected in blood biochemical parameters, haematological parameters or urinalysis.

There were no changes in physical parameters and no adverse gastrointestinal symptoms at dose levels up to 60g/day in diabetic subjects and 30g/day in healthy subjects (healthy subjects were not subjected to a regime of 60g/day in any of the studies).

- No mutagenicity was observed for either Fibersol-2 or Fibersol-2B in *S. typhimurium* TA98, TA100, TA1535, TA1537 or *E .coli* WP2uvrA$^-$ in comparison with reference buffer.

- Neither Fibersol-2 nor Fibersol-2B inhibit mineral absorption in *in-vitro* or *in-vivo* studies and this is attributed to their low viscosity.

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ATTACHMENT 7

A491 – Resistant Maltodextrin as Dietary Fibre
Dietary Exposure Assessment Report – Conducted at Draft Assessment

Summary

An application was received by FSANZ seeking to amend Standard 1.2.8 – Nutrition Information Requirements of the *Australian New Zealand Food Standards Code* (the Code) to recognise resistant maltodextrins (RMD) as a dietary fibre and to include a specific method of analysis for dietary fibre in foods containing RMD.

If RMD is recognised as a dietary fibre, it may be used in a variety of foods including canned goods, snack foods, sweeteners and various other products.

A dietary exposure assessment was undertaken to determine the potential dietary impact resulting from the addition of RMD to a variety of foods in Australia and New Zealand. The dietary exposure assessment was conducted assuming that consumers do not change the amounts and general types of foods that they eat. Food consumption data from the most recent Australian and New Zealand National Nutrition Surveys (NNSs) were used; the 1995 Australian NNS of those aged 2 years and above, and the 1997 New Zealand NNS of those aged 15 years and above. Dietary exposure was estimated for the total populations of Australia (2+ years) and New Zealand (15+ years).

Estimated mean and 95th percentile dietary exposures for consumers of RMD for Australia (2+ years) were 59.2 grams per day (g/day) and 152.6g/day respectively. Estimated mean and 95th percentile exposures for New Zealand (15+ years) consumers of RMD were 38.5g/day and 129.9g/day respectively. Both the Australian and New Zealand mean results are below 60g RMD/day, the highest dose tested; however the results for the 95th percentile exceed this level for both countries.

Bolus doses of RMD based on high consumers of individual foods do not exceed 16 grams for any food for either the Australian or New Zealand populations. This is less than the maximum bolus dose identified in the safety assessment (Attachment 4) of 60 g.

Background

RMD has been categorised by the Applicant as starch hydrolysates (e.g. dextrin and maltodextrin) that contain indigestible components. RMD can be used in a variety of foods, at varying concentrations that are currently formulated with maltodextrin.

The Applicant has requested an amendment to Standard 1.2.8- Nutrition Information Requirements. Standard 1.2.8 defines dietary fibre and prescribes methods of analysis to determine both the total dietary fibre and specifically named fibre content of food.

The Applicant has provided a list of possible foods in which RMD may be used, including general processed foods, beverages, cultured dairy products, cereals, frozen dairy desserts, confectionery, snack foods, baked goods, processed meats, dry mixes, high intensity sweeteners, nutritional/functional foods and dietary supplements (both food and therapeutic). Potential use levels of RMD in these foods were provided as ranges.

To estimate a worst-case scenario, dietary modelling was conducted with RMD present in all of the proposed foods at the maximum level of use.

Dietary Exposure Assessment Provided by the Applicant

As the Applicant has not provided a dietary exposure assessment, FSANZ conducted its own dietary exposure assessment to estimate potential exposure to RMD if it was added to all the proposed foods.

Dietary Modelling

The dietary exposure assessment was conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data to estimate the exposure to the food chemical from the diet. The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary exposure = food chemical concentration x food consumption

The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with proposed levels of use of RMD in foods.

Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

The dietary exposure assessment was conducted for both Australian and New Zealand populations. An assessment was conducted for the whole population of Australia (2+ years) and the whole of the New Zealand population (15+ years).

Additional Food Consumption Data or Other Relevant Data

No further information was required or identified for the purpose of refining the dietary exposure estimates for this application

Resistant Maltodextrin Concentration Levels

The levels of RMD in foods that were used in the dietary modelling were the maximum levels from those provided by the Applicant. The foods and proposed levels of use provided by the applicant and the levels of RMD used in the dietary exposure assessment are shown below in Table 1. A detailed list of the foods consumed in the NNS that were assigned to each of the food groups in Table 1 is provided in Appendix 1, Table A1.1, A1.2 for Australia and New Zealand respectively.

Estimating Risk

Estimated dietary exposures are usually compared to a reference health standard in order to determine the potential risk to health of a population or its sub groups. However, RMD does not have an established reference health standard such as an Acceptable Daily Intake (ADI). Therefore, estimated exposures based on all proposed foods were simply reported in gram amounts per day.

Bolus doses of RMD (doses of RMD consumed in one meal) of 60 grams or more can produce gastrointestinal upset including diarrhoea, cramping and bloating in some individuals (see toxicology report). Estimated exposures to RMD from high consumers of single food groups are compared to this level.

How the Estimated Dietary Exposures were Calculated

The DIAMOND program allows RMD concentrations to be assigned to specific food groups. All foods contained in this group are assigned the concentration of RMD shown in Table 1.

Each individual's exposure to the RMD was calculated using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of RMD by the amount of food that an individual consumed from that group in order to estimate the exposure to each food. Once this has been completed for all of the foods specified to contain RMD, the total amount of RMD consumed from all foods is summed for each individual. Population statistics (mean and high percentile exposures) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individual's total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived.

Percentage contributions of each food group to total estimated exposures are calculated by dividing the sum of consumers' exposures from a food group by the sum of all consumers' exposures from all foods, and multiplying the result by 100.

Food consumption amounts for each individual take in to account where each food in a classification code is consumed alone and as an ingredient in mixed foods (for example, RMD used in bread).

Assumptions in the Dietary Modelling

Assumptions made in the dietary modelling include:

- where a permission is assigned to a food group, all foods in that group contain RMD;
- all the foods within the group contain RMD at the proposed levels;
- consumption of foods as recorded in the NNS represent current food consumption patterns;
- consumers always selected the products containing RMD; and
- the total amount of fibre in the fortified foods was RMD (i.e. habitudinal fibre content was not added to the proposed RMD).

These assumptions are likely to lead to a conservative estimate of RMD dietary exposure.

Table 1: Proposed levels of use of RMD

Food group	Food name	Proposed level of use from application (grams per 100 grams)	Level used in exposure assessment (grams per 100 grams)
General Processed Foods	Canned fruit	0-5	5
	Soup – ready to eat	0-5	5
	Soup mix	0-32	32
Beverages	Fruit and vegetable drinks	0-10	10
	Water based drinks	0.10	10
	Tea and coffee dry mixes	0-75	75
	Modified and flavoured milks	0-10	10
	Soy beverages	0-10	10
Cultured Dairy Products	Cup yoghurts Sweetened	0-5	5
	Yoghurt beverages	0-2.5	2.5
	Sour cream and sour cream based dips	0-5	5
Cereals	Hot Cereal	0-5	5
	Ready-to-eat (RTE), Flaked, Extruded	0-5	5
Frozen Dairy Desserts	Ice-creams, Sorbets, Frozen yoghurts, Novelties, Other frozen dairy	0-5	5
	Frozen novelties – water, soy and dairy based	0-5	5
Confectionary Products	Chocolate	0-2.5	2.5
	Other confectionary	0-6	6
	High Fibre Jelly Mix	0-38	38
	Prepared Jelly Desserts	8-9	9
	Low joule confectionary	0-18	18
Snack Foods	Extruded (hot and cold), baked and fried	1-5	5
Baked Goods	Bread	0-6	6
	Sweet yeast-leavened baked goods	0-6	6
	Sweet biscuits	0-12.5	12.5
	Crackers	0-12.5	12.5
	Rice Crackers	0-6	6
Processed Meats	Processed meat	0-10	10
	Sausages	0-5	5
Special Purpose Foods	Formulated meal replacement drinks prepared	0-10	10
	Formulated meal replacement mixes	0-30	30
	Formulated meal replacement biscuits and bars	0-15	15
	Formulated supplementary drinks prepared	0-10	10
	Formulated supplementary food mixes	0-30	30
	Formulated supplementary food	0-15	15
Special Fibre Supplements	Fibre drink	3-40	40
	Fibre drink mix	0-100	100
High Intensity Sweetener	Tabletop sweeteners (intense sweetener and maltodextrin only)	99	99

Limitations of the Dietary Modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data is available, and this data tends to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

Results

Estimated Dietary Exposures to RMD

The estimated dietary exposures for RMD are shown in Table 2. Estimated mean dietary exposures for Australian and New Zealand consumers of RMD were 59.2g/day and 38.5g/day respectively. Estimated 95th percentile dietary exposures for consumers of RMD are 152.6g/day for Australia and 129.9g/day for New Zealand.

Table 2: Estimated Dietary Intake of RMD for Australian and New Zealand

Population group	Exposure	Actual fibre intake from NNS		Estimated intake from proposed RMD use	
		Mean	95 %ile	Mean	95 %ile
Australia#					
All (2+ years)	g/day	22.0	42.9	59.2	152.6
	g/kg bw/day	0.4	0.8	1.1	3.2
New Zealand#	g/day	20.3	48.4	38.5	129.9
All (15+ years)	g/kg bw/day	0.3	0.7	0.5	1.8

*95th percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.
Total number of respondents for Australia: = 13 858, New Zealand: = 4 636.

Major contributing foods to total estimated dietary exposures

The major foods (>5%) that contributed to the total estimated dietary exposures to RMD for Australia and New Zealand are displayed in Table 3. The major contributors to dietary exposure to RMD were soft drinks (23-27%), cordials (8-10%) and breads (5-6%). The proposed concentrations of RMD in soft drinks and cordials was not relatively high (10%), however, the consumption amounts of these foods are large therefore resulting in these foods being a major contributor. Bread also had a low proposed level of use (6%), however its use as a staple food in Australian and New Zealand diets resulted in its level of overall contribution.

Table 3: Major contributors to total estimated RMD dietary exposures for Australia and New Zealand

Country	Age group	Major contributing foods and percent of total RMD exposures
Australia	Whole population (2+ years)	Soft drinks, cola (13%) Soft drinks, non-cola (9%) Cordials (8%) Breads (5%) Fruit Drinks (5%) Soft drinks, diet cola (5%)
New Zealand	Whole population (15+ years)	Regular soft drinks (23%) Cordials (10%) Breads (6%)

Estimated dietary exposures to RMD for single food groups

The dietary exposures to RMD from individual foods were calculated in order to determine whether a consumer could exceed the 'bolus dose', or safe level of consumption from a single food or single eating occasion, based on the safety assessment. They were calculated by multiplying the 95th percentile food consumption amount for a food group by the specified concentration of RMD as outlined in Table 1. Due to the way DIAMOND is programmed, single eating occasion data cannot be derived.

The estimated exposures are shown in Tables 4 and 5 for Australia and New Zealand respectively. These dietary exposures differ from the estimated 95th percentile dietary exposures to RMD referred to earlier in the report, in that the results in this section are for 95th percentile consumption amounts for single foods whereas the results earlier in the report refer to 95th percentile dietary exposure to RMD from consumption of a range of foods proposed to contain RMD.

Where there are less than 21 consumers of a food group, no bolus dose exposures have been calculated since there are insufficient consumers to derive a statistically robust 95th percentile. Therefore, only foods or food groups for which there were more than 21 consumers were included.

All estimated short-term exposures from a bolus dose are less than 16g for any population group and for any food. This exposure is less than the level of 60g, which was the maximum level tested in humans and as such, the maximum level considered safe for human consumption, based on the safety assessment. This is likely to lead to an overestimate of the bolus dose of RMD.

Table 4: Estimated dietary exposure to individual foods groups at the 95th percentile (P95) level of consumption for Australia

Food code	Food description	Level of use (g/100 g)	P95 food intake per day (g)	Grams RMD / day
20	Soup	3.5	928.84	3.25
202	Dry soup mix	32	35.44	1.13
16413801	Peach, Canned in Light Syrup	5	481.8	2.41
16522601	Pineapple, Canned, NS as to type of packing liquid	5	187.8	0.94
16711901	Fruit Salad, Tropical, Canned in Light Syrup	5	588.33	2.94
	Fruit, canned (<21 consumers)*	5	392	1.96
1127	Coffee based mixes, beverage	10	1581.69	15.82
301	Beverage flavourings	75	20.40	1.53
198	Flavoured milk	10	1056.94	10.57
1133	Fruit drinks	10	935.4	9.35
1135	Fruit-flavoured drink base and cordial	10	253.18	2.53
1144	Electrolyte drinks	10	1270	12.70
114	Soft drinks, flavoured mineral waters	10	1393.7	13.94
116	Water with other additions	10	573.19	5.73
1971	Soy-based beverage	10	530	2.65
1923	Yoghurt, flavoured full fat	5	400	2.00
1924	Yoghurt, flavoured, reduced fat	5	259	1.30
1925	Yoghurt, flavoured, low fat, skim	5	332.45	1.66
1926	Yoghurt, flavoured, low fat, skim	5	380.47	1.90
19270601	Yoghurt beverage, reduced fat, fruit	2.5	207	0.52
19270701	Fermented milk drink	2.5	65	0.16
1932	Cream, sour and sour cream-based dip	5	97.2	0.49
1935	Cream, sour, reduced fat, light, extra light	5	131.5	0.66
1937	Cream, sour, unspecified fat level	5	121.5	0.61
128	Breakfast Cereal, Hot Porridge Type	5	650	3.25
127	Breakfast Cereals, Mixed Source	5	180	0.90
195	Frozen milk products	5	312.25	1.56
1972	Soy based ice confection	5	259	1.55
2632	Water ice confection, gelato	5	300	1.30
2711	Chocolate	2.5	100	1.50
273	Other confectionery	6	100	0.25
	Jelly (crystals anf made up)*	9	420	3.78
25	Snack Foods	5	100	0.50
122	Regular Breads, and Rolls	6	242	1.45
1244	Fancy Breads (e.g. Focaccia with cheese, vegetables, or fruit)	6	179.5	1.08
131	Sweet biscuits	12.5	83.33	1.04
132	Savoury biscuits	12.5	71.6	0.90
12620101	Rice crackers	6	41.2	0.25
186	Processed meat	10	135.72	1.36
185	Sausages, frankfurts and saveloys	5	234.66	1.17
3031	Artificial sweetening spoon for spoon	99	4	0.40
3011	Fortified dry beverage flavourings	30	17.25	0.52
	Biscuit and liquid supplements*	10	822.16	8.22
2913	Milk based powder meal replacements	30	151.5	4.55

Total number of respondents for Australia: = 13 858.

* Food groups that did not have >21 consumers, and therefore combined to more accurately estimate P95

Table 5: Estimated dietary exposure to individual foods groups at the 95th percentile (P95) level of consumption for New Zealand

Food code	Food description	Level of use (g/100 g)	P95 food intake per day (g)	Grams RMD / day
281	Soups	3.5	647.45	2.27
25310033	Peach, canned, in heavy syrup, not drained	5	257.4	0.86
25310039	Peach, canned, in light syrup, not drained	5	425	0.69
25810006	Salad, fruit, fresh with canned base	5	474	1.29
25810010	Fruit, salad, from canned	5	404.34	0.396
25810011	Fruit, salad, fresh, with canned bas	5	474	2.02
	Canned fruit (<21 consumers)*	5	380	1.90
3031	Hot beverages including Milo, hot chocolate	75	31.08	2.33
306	Cordials	10	1234.702	12.34
307	Soft drinks	10	1564.5	15.65
309	Soft drinks	10	1309.834	13.10
085	Flavoured milks	10	1084.65	10.85
094	Yoghurt	5	300	1.50
00092	Sour cream	5	129.013	0.65
0923	Sour cream dips	5	250	1.25
032	Porridge and cooked cereals	5	650	3.25
031	Muesli	5	156.25	0.78
033	Processed bran cereals	5	80	0.40
035	Single cereal; puffed, flakes or extruded	5	75	0.38
036	Wheat based biscuits and shredded wheat	5	75	0.38
	Frozen Dairy*	5	248	1.24
273	Lollies	6	120	0.72
274	Chocolate and chocolate-based confectionary	2.5	127.75	0.32
	Jelly (crystals and made up)*	9	562.24	5.06
24	Snack Foods	5	152	0.76
021	Regular bread and rolls	6	292	1.75
023	Speciality breads	6	293.36	1.76
041	Biscuit, sweet	12.5	92	1.15
042	Biscuit, savoury	12.5	69.6	0.87
19	Sausages and processed meats	10	255.6	2.56
191	Sausages	5	243.27	1.22
3031	Hot drinks includes Milo, hot chocolate	75	31.08	0.93
27110011	Artificial sweetener, powder (spoon for spoon)	99	3.3	0.33
	Biscuit and liquid supplements*	21	230.153	2.30

Total number of respondents for New Zealand: = 4 636.

* Food groups that did not have >21 consumers, and therefore combined to more accurately estimate P95

Table A1.1: Proposed levels of use of RMD in foods for Australia

Food group in Application	Food name as per Application	NNS Code and name used for exposure assessment	Proposed level of use from application (grams)	Level used in exposure assessment (grams)
General Processed Foods	Sauces/Dressings/Soups (retorted, dry)/Gravies	201 Soup	0-3.5	3.5
		202 Dry soup mix	32	32
	Canned goods (fruit, vegetables, meats, pasts)	16122801 Pear, Canned in Light Syrup	0-5	5
		16123001 Pear, Canned, NS as to type of packing liquid	0-5	5
		16212401 Boysenberry, Canned in Light Syrup	0-5	5
		16214901 Raspberry, Canned in Syrup	0-5	5
		16215901 Strawberry, Canned in Syrup	0-5	5
		16410651 Apricot, Canned in Light Syrup	0-5	5
		16410751 Apricot, Canned, NS as to type packing liquid	0-5	5
		16411301 Cherry, Canned in Light Syrup	0-5	5
		16413801 Peach, Canned in Light Syrup	0-5	5
		16413901 Peach, Canned, NS as to type of packing liquid	0-5	5
		16414501 Plum, Canned in Light Syrup	0-5	5
		16414601 Plum, Canned in Heavy Syrup	0-5	5
		16522201 Pineapple, Canned in Light Syrup	0-5	5
		16522401 Pineapple, Canned in Heavy Syrup	0-5	5
		16522601 Pineapple, Canned, NS as to type of packing liquid	0-5	5
		16532601 Mango, Canned in Light Syrup	0-5	5
		16612801 Lychee, Canned in Light Syrup	0-5	5
		16614701 Rhubarb, Canned in Light Syrup	0-5	5
		16711301 Fruit Salad, Canned in Light Syrup	0-5	5
		16711501 Fruit Salad, Tropical, Canned in Heavy Syrup	0-5	5

Food group in Application	Food name as per Application	NNS Code and name used for exposure assessment	Proposed level of use from application (grams)	Level used in exposure assessment (grams)
		16711901 Fruit Salad, Tropical, Canned in Light Syrup	0-5	5
		16712101 Fruit Salad, Canned, NS as to type & packing liquid	0-5	5
		16714401 Two Fruits, Canned in Light Syrup	0-5	5
		16714501 Two Fruits, Canned, NS as to type of packing liquid	0-5	5
Beverages	Tea & Coffee	1127 Coffee based mixes, beverage	0-75	75
		301 Beverage flavourings	0-75	75
	Dairy	198 Flavoured milk	0.10	10
	Fruit Drinks	1133 Fruit drinks	0-10	10
		1135 Fruit-flavoured drink base and cordial	0-10	10
	Water Based Drinks	1144 Electrolyte drinks	0-10	10
		114 Soft drinks, flavoured mineral waters	0-10	10
		116 Water with other additions	0-10	10
	Soy formulated smoothies	1971 Soy-based beverage	0-10	10
Cultured Dairy Products	Cup yoghurts Sweetened	1923 Yoghurt, flavoured full fat	0-5	5
		1924 Yoghurt, flavoured, reduced fat	0-5	5
		1925 Yoghurt, flavoured, low fat, skim	0-5	5
		1926 Yoghurt, flavoured, low fat, skim	0-5	5
	Yoghurt drinks, Cultured dairy beverages	19270601 Yoghurt beverage, reduced fat, fruit	0-2.5	2.5
		19270701 Fermented milk drink	0-2.5	2.5
	Pro-biotic products, sour cream	1932 Cream, sour and sour cream-based dip	0-5	5
		1935 Cream, sour, reduced fat, light, extra light	0-5	5
		1937 Cream, sour, unspecified fat level	0-5	5
Cereals	Hot Cereal	128 Breakfast Cereal, Hot Porridge Type	0-5	5
	Ready-to-eat (RTE), Flaked, Extruded	127 Breakfast Cereals, Mixed Source	0-5	5
Frozen Dairy Desserts	Ice-creams, Sorbets, Frozen yoghurts, Novelties, Other frozen dairy	195 Frozen milk products	0-5	5

Food group in Application	Food name as per Application	NNS Code and name used for exposure assessment	Proposed level of use from application (grams)	Level used in exposure assessment (grams)
	Frozen Soy Products	1972 Soy based ice confection	0-5	5
	Frozen Water Products	2632 Water ice confection, gelato	0-5	5
Confectionary Products	Chocolate	2711 Chocolate	0-2.5	2.5
	Hard and soft candies	273 Other confectionery	0-6	6
	High Fibre Jelly Mix	26310101 Jelly crystals, all flavours	0-38	38
		26310201 Jelly crystals, all flavours, artificially sweetened	0-38	38
	Prepared Jelly Desserts	26310301 Jelly, made up, regular, all flavours	8-9	9
		26310401 Jelly, made up, artificially sweetened	8-9	9
Snack Foods	Extruded (hot and cold), baked and fried	25 Snack Foods	1-5	5
Baked Goods	Yeast and chemically leavened bread	122 Regular Breads, and Rolls	0-6	6
		1244 Fancy Breads (e.g. Focaccia with cheese, vegetables, or fruit)	0-6	6
	Sweet biscuits	131 Sweet biscuits	0-12.5	12.5
	Crackers	132 Savoury biscuits	0-12.5	12.5
	Rice Crackers	12620101 Rice crackers	0-6	6
Processed Meats	Ground meats, Coarse ground products	186 Processed meat	0-10	10
	Emulsion type products, injected or recombined whole muscle foods	185 Sausages, frankfurts and saveloys	0-5	5
High Intensity Sweetener	Tabletop sweeteners (intense sweetener and maltodextrin only)	3031 Artificial sweetening spoon for spoon	99	99
Dietary Supplements (both food and therapeutic types)	Dry Mixes	3011 Fortified dry beverage flavourings	1-30	30
	Prepared meals, bars, Snacks, Tablets, Capsules	2911 Biscuit and bar meal replacement	0-15	15
	Fluid beverages	2912 Milk-based liquid meal replacements	0-10	10
		2913 Milk based powder meal replacements	0-30	30
		2914 Oral supplement liquids	0-10	10
		19121001 Supplemented milk drink, fluid, whole fat	0-10	10
		19140501 Supplemented milk drink, fluid, low fat	0-10	10

Table A1.2: Proposed levels of use of RMD in foods for New Zealand

Food group in application	Food name as per application	NNS Code and name used for exposure assessment	Proposed level of use from application (grams)	Level used in exposure assessment (grams)
General Processed Foods	Sauces/Dressings/Soups (retorted, dry)/Gravies	281 Soups	0-3.5	3.5
	Canned goods (fruit, vegetables, meats, pasts)	25110014 Apple, canned, ns as to packing liquid	0-5	5
		25120015 Pear, canned, in light syrup, drained	0-5	5
		25120017 Pear, canned, ns as to packing liquid	0-5	5
		25120018 Pear, canned, ns as to packing liquid	0-5	5
		25210008 Boysenberry, canned, ns as to drained	0-5	5
		25210012 Raspberry, canned, not drained	0-5	5
		25310007 Apricot, canned, in light syrup, not drained	0-5	5
		25310009 Apricot, canned, in heavy syrup, not drained	0-5	5
		25310011 Apricot, canned, ns as to packing liquid	0-5	5
		25310018 Apricot, canned, ns as to packing liquid	0-5	5
		25310033 Peach, canned, in heavy syrup, not drained	0-5	5
		25310036 Peach, canned, ns as to packing liquid	0-5	5
		25310037 Peach, canned, ns as to packing liquid	0-5	5
		25310039 Peach, canned, in light syrup, not drained	0-5	5
		25310048 Plum, canned, ns as to packing liquid	0-5	5
		25310060 Peach, canned, in light syrup, ns as	0-5	5
		25520008 Pineapple, canned, in light syrup	0-5	5
		25520010 Pineapple, canned, in heavy syrup	0-5	5
		25520012 Pineapple, canned, ns as to packing liquid	0-5	5
		25520013 Pineapple, canned, ns as to packing liquid	0-5	5
		25530004 Lychee, canned, not drained	0-5	5
		25530007 Mango, canned, in syrup, not drained	0-5	5
		25530023 Guava, canned, syrup, not drained	0-5	5

Food group in application	Food name as per application	NNS Code and name used for exposure assessment	Proposed level of use from application (grams)	Level used in exposure assessment (grams)
		25710009 Prune, canned, ns as to drained	0-5	5
		25810002 Fruit, canned, nfs	0-5	5
		25810006 Salad, fruit, fresh with canned base	0-5	5
		25810007 Salad, fruit, ns as to fresh or canned	0-5	5
		25810010 Fruit, salad, from canned	0-5	5
		25810011 Fruit, salad, fresh, with canned bas	0-5	5
Beverages	Juice, Fortified water, Sports drinks, Other beverages	3031 Hot beverages including Milo, hot chocolate	0-75	75
		306 Cordials	0-10	10
		307 Soft drinks	0-10	10
		309 Soft drinks	0-10	10
	Dairy	085 Flavoured milks	0-10	10
Cultured Dairy Products	Cup yoghurts, Yoghurt drinks, Cultured dairy beverages	094 Yoghurt	0-5	5
	Pro-biotic products, sour cream	092 Sour cream	0-5	5
		0923 Sour cream dips	0-5	5
Cereals	Hot Cereal	032 Porridge and cooked cereals	0-5	5
	Ready-to-eat (RTE), Flaked, Extruded	031 Muesli	0-5	5
		033 Processed bran cereals	0-5	5
		035 Single cereal; puffed, flakes or extruded	0-5	5
		036 Wheat based biscuits and shredded wheat	0-5	5
Frozen Dairy Desserts	Ice-creams, Sorbets, Frozen yoghurts, Novelties, Other frozen dairy	093 Ice cream	0-5	5
	Frozen yoghurts	0934 Frozen yoghurts, all types	0-5	5
		095 Other dairy products, frozen	0-5	5
Confectionary Products	Hard and soft candies	273 Lollies	0-6	6
	Chocolate, Coatings, Compounded flavourings	274 Chocolate and chocolate-based confectionary	0-2.5	2.5
		27810001 Jelly, crystals, regular	0-38	38

Food group in application	Food name as per application	NNS Code and name used for exposure assessment	Proposed level of use from application (grams)	Level used in exposure assessment (grams)
		27810002 Jelly, crystals, artificially sweetened	0-38	38
		27810003 Jelly, made up, regular, plain	0-9	9
		27810004 Jelly, made up, regular, fruit added	0-9	9
		27810005 Jelly, made up, artificial sweet, plain	0-9	9
		27811007 Jelly, made up, ns to sweetener, plain	0-9	9
Snack Foods	Extruded (hot and cold), baked and fried	24 Snack Foods	0-5	5
Baked Goods	Yeast and chemically leavened bread	021 Regular bread and rolls	0-6	6
		023 Speciality breads	0-6	6
	Sweet biscuits	041 Biscuit, sweet	0-12.5	12.5
	Crackers	042 Biscuit, savoury	0-12.5	12.5
Processed Meats	Ground meats, Coarse ground products,	19 Sausages and processed meats	0-10	10
	emulsion type products, injected or recombined whole muscle foods	191 Sausages	0-5	5
Dry Mixes	Beverages, Baked goods	3031 Hot drinks includes Milo, hot chocolate	1-30	30
High Intensity Sweetener	Tabletop sweeteners (intense sweetener and maltodextrin only)	27110011 Artificial sweetener, powder (spoon for spoon)	99	99
Dietary Supplements (both food and therapeutic types)	Bars	3221 Meal replacement bars	0-15	15
	Drinks	3222 Meal replacement drinks	0-10	10