

Application to include Rapid Integrated Total Dietary Fibre method in the Australia New Zealand Food Standards Code

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General Requirements (3.1.1)

B. Applicant details

Applicant: Grains & Legumes Nutrition Council (GLNC)

Contact Person: [REDACTED]

Address: [REDACTED]

Telephone number: [REDACTED]

Email address: [REDACTED]

Nature of business:

GLNC is a not-for-profit company limited by guarantee. GLNC promotes the nutrition and health benefits of grains and legumes to influencers of consumer attitudes with the ultimate aim of reducing chronic disease through good nutrition.

Individuals, companies or organisations associated with the application

The following organisations are Contributors to GLNC:

- Australians Exports Grains Innovation Centre (AEGIC)
- Australian Food & Grocery Council (AFGC)
- Bakers Delight
- Campbell Arnotts
- Cereal Partners Worldwide
- George Weston Foods Limited
- Goodman Fielder
- Kellogg Australia
- Pulse Australia
- Sanitarium Health & Wellbeing
- Simplot Australia
- The Healthy Grain
- Ward McKenzie

C. Purpose of the application

The purpose of this application is to propose a change to Schedule 11 (S11-4) of the Food Standards Code (Code), 'Methods of analysis for dietary fibre and other fibre content', to permit the total dietary fibre content in a food to be determined in accordance with the Rapid Integrated Total Dietary Fibre Method (RITDF) AOAC Method 2017.16¹. It is proposed this method listed in 21st edition (2019, chapter 45.4.18) and is included in addition to the methods currently listed in the Schedule 11. The purpose of the proposed change is to allow more accurate determination of total dietary fibre as defined in the Code in Standard 1.1.2. There is no change to labelling requirements in the Code as a result of this application.

D. Justification for the application

Background

Definition of Total Dietary Fibre

The current definition of fibre is as outlined in Standard 1.1.2 and captures a broad range of dietary fibres as described below².

Dietary fibre means that fraction of the edible part of plants or their extracts, or synthetic analogues that:

- a) are resistant to 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:
- c) polysaccharides or oligosaccharides that have a degree of polymerisation greater than 2; and
- d) lignins.

It is worth noting that no dietary fibre method of analysis is currently approved for quantifying galacto-oligosaccharides (with a degree of polymerisation >2).

Methods of Analysis of Fibre Content

The methods currently included in the Code for determining fibre content are listed in Schedule 11-4 of the Code as shown below.

The total dietary fibre, and amount of any specifically named fibre, in a food must be determined in accordance with any one or more of the methods contained in following sections of the AOAC:

- a) for total dietary fibre—sections 985.29 or 991.43
- b) for total dietary fibre (including all resistant maltodextrins)—section 2001.03;
- c) for inulin and fructo-oligosaccharide—section 997.08;
- d) for inulin—section 999.03;
- e) for polydextrose—section 2000.11.

If the dietary fibre content of a food has been determined by more than one method of analysis, the total dietary fibre content is calculated by:

- a) adding together the results from each method of analysis; and
- b) subtracting any portion of dietary fibre which has been included in the results of more than one method of analysis.

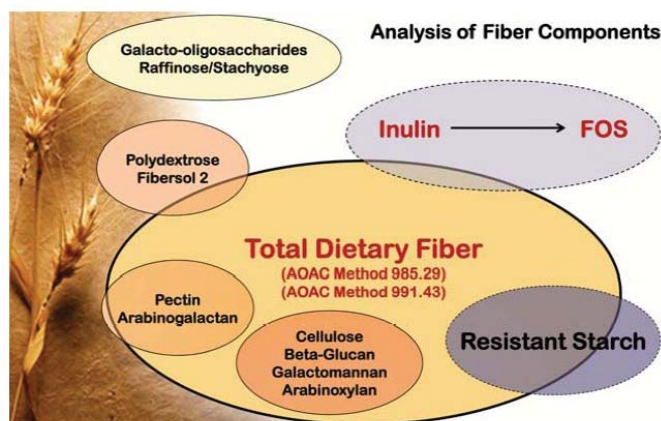
In 2018, the addition of a prescribed method for analysis for resistant starch (AOAC 2002.02) was granted FSANZ approval. However, the RITDF method allows for the measurement of total dietary fibre, including galacto-oligosaccharides, polydextrose, fructans and resistant starch in a single method. The Code allows for any one or more of the prescribed methods of analysis listed in section S11—4 to be used to determine the quantity of dietary fibre in a food for declaration in the nutrition information panel on a food label. The addition of the RITDF may need to be presented as the preferred option, listed first and ahead of the other TDF methods in Schedule 11-4. This is best determined by FSANZ.

Need for the proposed change of methodology

Rapid Integrated Total Dietary Fibre Method

When methods AOAC 985.29 or 991.43 are used to determine total dietary fibre content, and where most of the dietary fibre that is soluble in water and also soluble in 76% aqueous ethanol, the low molecular weight fibres (GOS and FOS) are not measured. On the other hand, and as acknowledged in the Code and indicated in Figure 1, a portion of dietary fibre may be counted twice when using the currently accepted AOAC methods 985.29 and 991.43 together with other methods specifically measuring fructans, polydextrose, and resistant starch.

Figure 1. Schematic representation of dietary fibre components measured and not measured by AOAC methods 985.29 and 991.43 (AACCI Approved Methods 32-05.01 and 32-07.01).



Source: McCleary, B et al. Measurement of Total Dietary Fibre Using AOAC Method 2009.01 (AACC International Approved Method 32-45.01): Evaluation and Updates. Cereal Chemistry. 2013. 90(4):396-414.

The Rapid Integrated Total Dietary Fibre method (RITDF)³ has an AOAC Method number approved and assigned in July, 2018 as AOAC method 2017.16¹ and ICC standard 184. The adoption of this method by AOAC indicates it is an appropriate approach for regulatory purposes. As part of the process an inter-laboratory evaluation was conducted in 2016 to validate the RITDF method¹.

RITDF more accurately measures total dietary fibre as it is defined in Standard 1.1.2 of the Code with a range of benefits including improved accuracy of labelling and without over estimation due to overlap in methodologies. The RITDF method more accurately detects both native and synthetic fibre analogues. The RITDF method offers flexibility for analysis of High Molecular Weight Dietary Fibre (HMWDF) or separated (Insoluble Dietary Fibre + High Molecular Weight Soluble Dietary Fibre), it also allows for determination of the Low Molecular Weight Soluble Dietary Fibre separately.

There are substances (or types of substances) measured as fibre by AOAC 2017.16 but not currently measured as dietary fibre by currently recognized methods in the Code including 1) galacto-oligosaccharides, 2) Raffinose / Stachyose, 3) Fibersol[®]2

- 1) Galacto-oligosaccharides (GOS) do not currently have an approved method of analysis defined in the Code. Since the definition of dietary fibre in the Code refers to *fractions of edible part of plants or their extracts or synthetic analogues*, if GOS were added to the Code, there would need to be a consideration made for GOS derived from animal sources, for example from milk. GOS is a short chain oligosaccharides that is not digestible by humans and promotes a prebiotic effect, assisting with laxation.
- 2) Raffinose / Stachyose are non-digestible short chain carbohydrate or oligosaccharides, and they act as a soluble dietary fibre in the bowel.
- 3) Fibersol[®]2 is a digestion-resistant maltodextrin made from a soluble corn fibre that acts as a low-calorie bulking agent containing 90 percent dietary fibre.

Sugar alcohols are not included in the RITDF method because they fall under carbohydrate. From the list in S11-2(3) only Polydextrose is counted in this method⁴ (pg. 105).

Determination of the dietary fibre in accordance with section S11-4 is also required to calculate fibre points (F points) for the purpose of determining if a food meets the nutrient profiling scoring criterion (NSPC) to make a health claim and for front-of-pack labelling. Hence the importance of accuracy in analysis of fibre in foods.

Support and interest from food industry

Manufacturers within the food industry support the proposed change. This includes:

- Bakers Delight
- Campbell Arnotts
- George Weston Foods Limited
- Goodman Fielder
- Kellogg Australia
- Pulse Australia
- Sanitarium Health & Wellbeing
- Simplot Australia
- The Healthy Grain
- Ward McKenzie

Status of similar applications in other countries

The applicant has not made this application in any other countries.

The advantages of the proposed change over the status quo, taking into account any disadvantages

Advantage for consumers - Provision of adequate information to enable informed choices

Dietary fibre is well recognised for its positive effect on health and quality of life, with higher dietary fibre intakes linked to a reduced risk of cardiometabolic disease, colorectal cancer and type 2 diabetes⁵. The Australian Dietary Guidelines and the New Zealand Eating and Activity Guidelines promote the consumption of high fibre foods, in preference for lower fibre alternatives^{6,7}. The adoption of the RITDF method (AOAC 2017.16) into the Code and use by food industry is unlikely to create confusion amongst consumers. It will instead allow food industry to provide a more accurate measure of total dietary fibre on Nutrition Information Panels and in front-of-pack labelling providing consumers with more accurate information with which to make informed choices.

This new method appears most relevant for fibre fortifiers but also some vegetables, legumes and grain foods which contain fructo-oligosaccharides (FOS), GOS, resistant dextrins and resistant starch, which are only partially captured by the current TDF methods. To determine the effect of using the RITDF method compared with currently approved methods, analysis of representative foods and fibre fortifiers was undertaken (Table 1). Foods were chosen for analysis based on the presence of fibres that are not detected by analytical methods currently approved in the Code.

Consumption of dietary fibre has been shown to have a favourable effect on blood glucose levels in healthy individuals⁸. Within the context of the whole diet, it is also likely that different fibre types have a synergistic effect. In a study by Behall et al., the reduction in glycaemic response was enhanced by combining resistant starch and β -glucan, compared to test foods containing varying amounts of the individual fibres⁹. This highlights the need for an analytical method that measures all dietary fibre types, when assessing the impact of food or diet on health and disease. Furthermore, research also indicates that the composition of colonic gut bacteria and the production of metabolic by-products, is strongly influenced by diet, particularly intake of prebiotics, a type of dietary fibre. Prebiotics, including GOS, FOS, resistant starch, dextrin and inulin, promote the growth and activity of beneficial gut bacteria including Bifidobacterium and Lactobacillus. These gut bacteria produce by-products known as short-chain fatty acids which are thought to influence broader

metabolic processes involved in health and disease^{8,10,11}. As prebiotics vary in their effect on the gut micro biome, it is important that people are able to identify and consume a wide range of high fibre plant foods. Similarly, where fibre is thought to be an issue in relation to gut problems, clarity as to dietary intake may improve accuracy of research outcomes.

There may be a transition period where similar products show differing levels of dietary fibre on the NIP or are making higher fibre claims however this is likely to affect only a few food categories. Manufactured foods (potentially biscuits, crackers, bars and cereal) with added fibre will benefit from the introduction of the RITDF method to the Code. In regards to discretionary foods, a GLNC supermarket product audit in 2014 found that less 1% of sweet plain and flavoured biscuits (non-health food aisle) contained $\geq 2\text{g}$ fibre per serve and were eligible to make a fibre claim. Of the sweet biscuits eligible to make a fibre claim, the majority did not. The most common claims found on sweet biscuits were those about artificial preservatives, colours and flavours.

Advantage for Government - Improved accuracy of population intakes

If adopted, revised nutrient content information will inform the AUSNUT and NUTTAB databases and this would in turn assist with more accurate determination of population dietary fibre intakes from studies such as the National Nutrition Survey. However, it is worth noting that the dietary fibre data within these food data bases do not equate to the FSANZ definition as the analytical methods used (AOAC in Australia and Englyst in New Zealand) measure a different set of components¹². The differences have been assumed to be relatively small, however the impact of this new fibre method was not known at the time of writing the Nutrient Reference Value documents. A recent analysis of dietary fibre from the 2011-12 National Nutrition and Physical Activity Survey shows that intakes are lower than recommended, however high dietary fibre consumers, mostly men, consumer four times as much as low dietary fibre consumers ($32.4 \pm 8.1\text{g}$, vs $9.6 \pm 2.5\text{g}$)¹³. The new method may provide an opportunity to reassess consumption with a greater degree of accuracy in the future.

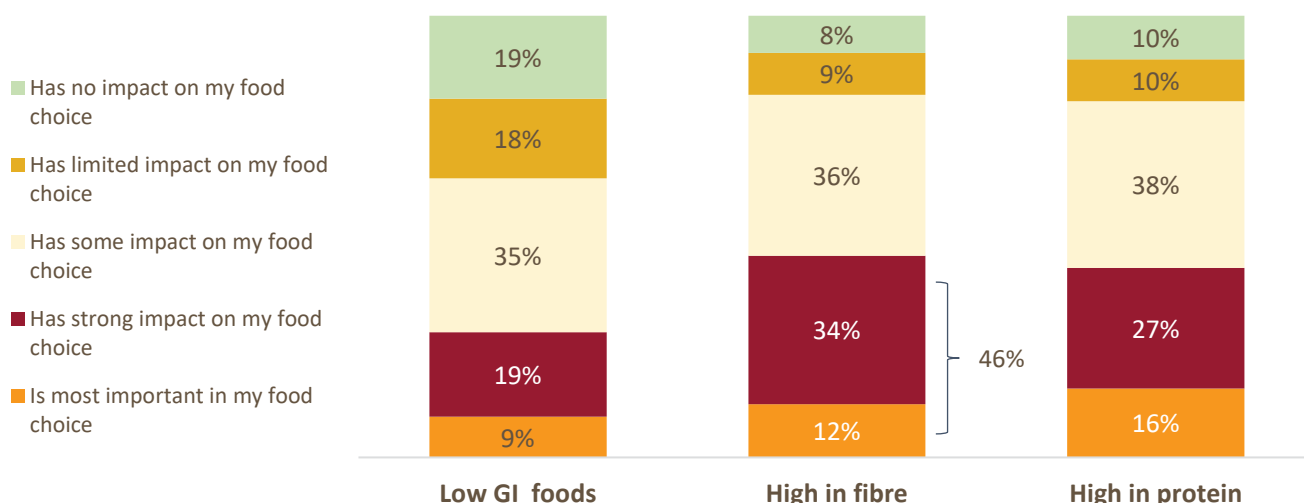
The RITDF method may also improve the accuracy of the public health research that underpins dietary recommendations for dietary fibre intakes. Nutrition research relies on the nutrient information in the AUSNUT and NUTTAB databases. The use of more accurate information for the dietary fibre content of foods in these databases would lead to more accurate understanding of the fibre intake levels linked to improved health outcomes. This is especially important as research increases in the area of the effect of dietary fibre on the gut micro biome, particularly short chain fibres such as oligo-saccharides and resistant starch^{8,10} which are captured by the RITDF methods but not as a single test in the currently approved methods¹⁴.

Advantage for industry

The inclusion of RITDF method in the Code will allow food industry to provide a more accurate measure of total dietary fibre on Nutrition Information Panels. In some cases this may allow a higher level fibre claim. The ability of manufacturers to accurately measure fibre and potentially make higher level fibre claims may provide extra incentive to purchase certain foods.

GLNC Consumer research has indicated a greater purchase intent for high in fibre claims compared to both low Glycaemic Index and high in Protein (Figure 2). With 46% reporting that fibre has at least a strong impact on their food choices with a greater proportion of younger consumers interested in fibre claims (61% of 15-18 year olds)¹⁵.

Figure 2. The impact of high in fibre, high in protein and low Glycaemic Index claims on food choice.



Q. There are also a number of things that attract people to different food groups... Please rate each of the following statements from 1 to 5, where 1 is 'has no impact on my food choice' and 5 is 'is most important in my food choice.'
Total sample: 2017 n=1,121.

An additional benefit to industry is that analysis of fibre using the RITDF method is currently commercially available in Australia including a laboratory involved in the global inter-laboratory validation study. As suggested, the addition of the RITDF method to the Code will be as a voluntary method, and means that food industry is not under any obligation to have the testing performed. However, if demand is created for the RITDF method, other Australian laboratories may introduce RITDF testing.

Effect on labelled total dietary fibre and calculated intakes

The foods most affected by the change from the currently approved methods to the RITDF method includes synthetic fibre analogues, some vegetables, legumes and to a lesser extent grain foods. In many cases the additional fibres captured by the RITDF method are intrinsic to the food, such as oligosaccharides in legumes or resistant starch in green bananas. If a synthetic analogue of fibre is added this would also be captured. The RITDF method does not provide an added incentive for manufacturers to add synthetic fibres to make a higher fibre claim, as it is already possible to measure synthetic fibres using the FSANZ approved methods - AOAC 997.08, AOAC 999.03 and AOAC 2000.01.

Disadvantages

In the short term there will be discrepancies between publically available databases (NUTTAB) and Nutrition Information Panel values. However, the recent allowance for industry to submit data to FSANZ for consideration and inclusion in NUTTAB may assist in reducing this risk. Research data and consumption data may also be affected, however it seems that the greatest impact is on foods containing synthetic fibre analogues rather than from foods that are a native source of fibre.

Safety issues

The applicant is not aware of any safety issues associated with the adoption of the RITDF method.

D.1 Regulatory impact information

D.1.1 Costs and benefits of the application

Costs and Benefits to Industry

The RITDF method will incur a higher cost compared to individual TDF methodologies, however individual tests cannot be added together with accuracy. It is suggested that the RITDF method is added as an option rather than replacing the current approved methods.

The following costs have been provided by the Australian Export Grains Innovation Centre (AEGIC) and are current as of May 2019.

Rapid Integrated: \$635 +GST per sample

Total Dietary Fibre AOAC 985.29: \$230 + GST per sample

Total Dietary Fibre containing supplemented resistant maltodextrin: \$470 + GST per sample.

Transgalactooligosaccharides (TGOS) 2001.02 - There is no price available from AEGIC as although this method is recognised by FSANZ no laboratories (to our knowledge) run this method in Australia or NZ. It requires an Ion Exchange chromatography instrument which labs do not have. TGOS is a part of the fibre that can be measured within the new method 2017.16.

If industry wished to measure specific fibre types in combination with TDF, the cost exceeds the cost of the RITDF method.

β-glucan: \$132

Fructan: \$218

Arabinoxylan: \$130

TDF including Resistant maltodextrin: \$470

Resistant starch: \$328

Food Industry Consumer enquiries regarding fibre:

- a) A cereal manufacturer received five enquiries over two years regarding a change in declared fibre (four requests in 2017 and one request in 2018 relating to three products). These related to a drop in the fibre claim reported in the NIP, predominantly due to a change in the analysis of the fibre content.
- b) A food company received 60 enquiries about fibre in three years since January 2016. In that same time period, they received 517 total contacts about macro nutrients (fat, calories, protein, CHO) so fibre accounted for 12% of contacts (this number does not include contacts about sugar, or vitamins and minerals, so if those were included, fibre queries would make up an even smaller percentage). Sixty seven percent wanted to know “what is the fibre content” or does product X have fibre in it?” Most consumers are wanting to know because they’re wanting a high fibre product, but there are about 10-15% wanting a low fibre product for specific reasons. Twenty two percent of enquiries were in relation to breakfast cereal products however only two contacts were due to recipe changes.

Costs and Benefits to Consumers

There would be no known impact on consumers. Additional cost of the analysis would not cause an increase in the retail RRP of a single product. This is because analytical testing is considered an overhead cost and is not directly related to specific products. Manufacturers have expressed that if the RITDF method was approved, costs would be managed internally and would, for example, be paid for as part of product development or nutrition budgets. This would also apply to small to medium businesses for the same reason.

Costs and Benefits to Government

The key benefit to Government is in the accuracy of measurement of dietary fibre within the food supply and reporting of dietary fibre intakes. There may be costs associated with updating data bases in alignment with new figures as foods are tested however if this is managed as suggested, the cost of this aspect could be minimised.

D.1.2 Impact on international trade

The applicant is not aware of any costs or benefits to international trade. Fibre content is not a quality measure used for international food trade e.g. grains.

E Information to support the application

E.1 Data requirements

Table 1. Total dietary fibre of commonly consumed foods containing fibre using currently approved analytical method 985.29¹⁶, 2009.01 and the RITDF method 2017.16³ with NUTTAB data for comparison using 985.29.

Food Category	AOAC Method 985.29 HMWDF (% w/w)	AOAC Method 2009.01 + AMG incubation step)			RITDF AOAC Method 2017.16			NUTTAB 2010 * Fibre g (Dry matter basis) on a 100g Moisture free basis	Moisture g/100g edible portion (average of samples)
		HMWDF (% w/w)	SDFS (% w/w)	TDF (HMWDF + SDFS (% w/w)	HMWDF (% w/w)	SDFS (% w/w)	TDF (HMWDF + SDFS (% w/w)		
Wholemeal bread	9.95	12.4	1.8	14.2	12.0	1.5	13.5	10.4	37.4
White bread	4.33	4.8	0.5	5.3	4.6	1.4	6.0	4.6	36.9
Oat bran	18.22	18.9	0.5	19.4	19.9	1.4	21.3	14.7	5.5
WeetaBix	9.21	9.8	2.3	12.1	10.1	1.4	11.6	11.7	5.9
Kellogg All Bran	25.52	26.6	2.5	29.1	28.1	3.6	31.7	31.1	3.4
Whole wheat pasta	9.28	9.9	1.9	11.8	10.1	2.2	12.3	10.8	9.6
Chickpeas (tinned)	19.35	18.0	1.3	19.3	17.6	2.1	19.7	14.5	67.6
Semi-ripe banana	NA	30.2	0.9	31.1	30.2	1.4	31.6	13.4	77.3
Butter beans	17.85	20.2	2.2	22.4	19.9	3.0	22.9	43.8	85.4
Sweet corn (tinned)	13.66	12.7	0.1	12.8	12.4	0.5	12.9	11.6	73.2
Garden peas (petit pois)	25.12	29.1	1.3	30.4	29.1	2.2	31.3	31.0	77.4
Cabbage	25.99	28.9	1.1	30.0	26.5	1.3	27.8	31.3	92.4
Broccoli	27.70	28.1	0.4	28.5	29.7	0.6	30.3	34.0	89.4
Carrots	22.00	21.8	0.5	22.3	22.2	1.2	23.4	34.2	88.6
(i) Fibresym® (RS4)	NA	28.6	1.1	29.7	59.2	1.0	60.2	NA	NA
(ii) Fiber Rite®	NA	8.7	1.2	9.9	8.0	1.1	9.1	NA	NA
(iii) Hylon VI® (high amylose maize starch)	NA	49.3	0.0	49.8	58.8	0.0	58.8	NA	NA
(iv) Polydextrose®	NA	1.5	83.3	84.8	1.1	83.3	84.4	NA	NA

(i) Resistant Starch available in Australia; (ii) Resistant starch – fat replacer; (iii) Not available in Australia at time of writing; (iv) Synthetic polymer of glucose

Table 2 Inter-laboratory studyⁱ results for total dietary fibre in foods using the rapid integrated total dietary fibre (RITDF) method. For complete table see reference Table 4 ¹. NUTTAB 2010 data added for comparison where appropriate.

Food Category	Number of samples	Mean Dietary Fibre content (g/100g)	NUTTAB 2010 * Fibre g per 100g (number of samples)	Moisture g/100g edible portion (average of samples)
Fibresym®	10	60.37		
Kidney beans (canned, washed and lyophilized)	11	23.80	6.45 (2)	70.3
Bran cereal	11	29.22	23.4 (5)	6.6
Defatted cookies containing fructo-oligosaccharides	10	6.90		
Oat Bran	11	16.15	13.9 (2)	5.5
Defatted cookies containing polydextrose and RS2	11	19.43		
Dark rye crispbread	11	21.02	14.4 (Ryvita)	5
Wholemeal bread	11	10.82	6.5 (3)	37.4

i) Study involved 13 laboratories, however the result presented here are from 11 laboratories due to issues in analysis (see comments on p10); samples were analysed as 8 blind duplicates.

E.1.1 Data related to safety studies

The applicant does not believe this data is relevant to the application

E.1.2 Data related to surveys on chemicals or other substances in food

The applicant does not believe this data is relevant to the application

E.1.3 Data related to epidemiological/intervention studies in humans

The applicant does not believe this data is relevant to the application.

F Assessment Procedure

The applicant considers a General Assessment Procedure to be appropriate when assessing the application. The application relates to a minor change to a labelling requirement, and so could be classified as level 1 (maximum of 350 hours). If the application requires additional analytical, nutrition and food composition assessment, it may be classified as a general procedure level 2.

G Confidential Commercial Information

NIL

H Other Confidential Information

The applicant does not identify any other information provided to be confidential information.

I Exclusive Capturable Commercial Benefit

The applicant does not expect the application to confer an exclusive capturable commercial benefit. The approval of this application would have a broad reach, benefiting industry, consumers and government by improving the accuracy of dietary fibre information of food products. No one party would benefit exclusively from the acceptance of this application.

As outlined previously, industry would benefit from being able to make higher fibre claims on vegetable and legume-based products as well as some grain foods. Other public health benefits include improved accuracy of population intake monitoring, as well as more accurate nutrition research on the health effects of fibre.

If approved, permission would not be required for industry to amend packaging to include fibre claims. There is no intellectual property connected to this application. The method for the RITDF is now published and has an AOAC number applied.

J International and Other National Standards

J.1. International Standards

The definition of dietary fibre introduced by CODEX Alimentarius (CODEX) in 2009 includes resistant starch and the option to include non-digestible oligosaccharides¹⁷. This definition aligns with the current definition of dietary fibre in the Code.

However, when the definition for dietary fibre was introduced by CODEX in 2009 it did not align with the CODEX-approved methods of determining total dietary fibre. The fibre methods that were approved by CODEX (AOAC 985.29^{18,19} and 991.43²⁰) underestimated the total fibre content as most resistant starch and all non-digestible oligosaccharides are not captured by these methods (as per table 3 below²¹).

Table 3 Methods of analysis for dietary fibre: Adapted from Codex Standard CXS 234-1999 (p28)²¹

CXS 234-1999					28				
Methods of analysis for dietary fibre: Guidelines for Use of Nutrition and Health Claims: Table of Conditions for Claims									
Standard	Provisions	Method	Principle	Type					
General methods that do not measure the lower molecular weight fraction (i.e. monomeric units <=9) ⁽²⁾									
All foods (1)	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction. (4)	AOAC 985.29 AACC Intl 32-05.01	Enzymatic gravimetry	Type I					
All foods (1)	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction and also includes determination for soluble and insoluble dietary fibres (4)	AOAC 991.43 AACC Intl 32-07.01 NMKL 129	Enzymatic gravimetry	Type I					

To assist implementation of the new CODEX definition of dietary fibre a new methodology was developed, the integrated total dietary fibre method, which has since been modified to the RITDF method.

The applicant has been informed that the RITDF method will be discussed at the AOAC Board meeting in Washington DC on 13th December and presented to the FDA. The method will be put forward at the next relevant CODEX meeting with support expected from AOAC, ICC, FDA, ILSI and the Japanese Fibre Society (personal communication B. McCleary via email 3/12/18).

J.2. Other National Standards

Adopting the RITDF method would potentially ensure alignment with jurisdictions around the world. Countries that have adopted the integrated TDF methods AOAC 2009.01 and 2011.25 (as per table 4 below²¹) include the USDA²², EFSA²³, and Health Canada²⁴. It is the applicant's understanding that the following jurisdictions have adopted the method as well as the definition: China, Brazil, Chile, Mexico, Thailand, Korea, Malaysia and Indonesia. Given these countries have previously adopted the integrated TDF method it is reasonable to expect they will adopt the RITDF method.

Table 4 Methods of analysis for dietary fibre: Adapted from Codex Standard CXS 234-1999 (p28)²¹

General methods that measure both the higher (monomeric units > 9) and the lower molecular weight fraction (monomeric units <=9) ⁽²⁾				
All foods (1)	Method applicable for determining the content of dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AOAC 2009.01 AACC Intl 32-45.01	Enzymatic-Gravimetry High Pressure Liquid Chromatography	Type I
All foods (1)	Method applicable for determining the content of insoluble and soluble dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant	AACC Intl 32-50.01 AOAC 2011.25	Enzymatic-Gravimetry High Pressure Liquid Chromatography	Type I

General Food Labelling (3.2.1)

This application is not proposing a change to food labelling and so this section of the application is not required.

Warning and Advisory Statements (3.2.2)

This application does not require the introduction or change to warning and advisory statements listed in Standard 1.2.3.

Declaration of Allergens (3.2.3)

This application does not introduce or change the requirements for the mandatory declaration of allergens.

Labelling for Consumer Information and Choice (3.2.4)

This information is provided in Section D – Justification.

Nutrition Information Labelling (3.2.5)

This application is not proposing a change to nutrition information labelling and so this section of the application is not required.

Nutrition and Health Claims (3.2.6)

This application is not proposing a change to Standard 1.2.7, Schedule 4 or Schedule 6 of the Food Standards Code, and so this section of the application is not required.

Food Additives (3.3.1)

This application does not relate to food additives and so this section of the application is not required.

Processing Aids (3.3.2)

This application does not relate to processing aids and so this section of the application is not required.

Substances Used for a Nutritive Purpose (3.3.3)

This application does not relate to the use of substances for nutritive purpose and so this section of the application is not required.

References

1. McCleary BV. Total Dietary Fiber (CODEX Definition) in Foods and Food Ingredients by a Rapid Enzymatic-Gravimetric Method and Liquid Chromatography: Collaborative Study, First Action 2017.16. *Journal Of AOAC International*. 2018.
2. FSANZ. Standard 1.1.2 Definitions used throughout the Code. 2016;
<http://www.foodstandards.gov.au/code/Documents/1.1.2%20Definitions%20v159.pdf>. Available at: <http://www.foodstandards.gov.au/code/Pages/default.aspx>.
3. McCleary BV, Sloane N, Draga A. Determination of total dietary fibre and available carbohydrates: A rapid integrated procedure that simulates in vivo digestion. *Starch - Stärke*. 2015;67(9-10):860-883 DOI 10.1002/star.201500017.
4. McCleary B.V. C, J., Ivory R., Delaney E.,. Definition and Analysis of Dietary Fiber in Grain Products. In: *Food Chemistry, Function and Analysis No. 6 Cereal Grain-based Functional Foods: Carbohydrate and Phytochemical Components*. The Royal Society of Chemistry 2019; 2018.
5. SACN. Carbohydrates and Health Report. In: Scientific Advisory Committee on Nutrition Recommendations on Carbohydrates
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/445503/SACN_Carbohydrates_and_Health.pdf; 2015.
6. National Health and Medical Research Council, 2013. Australian Dietary Guidelines: Providing the scientific evidence for healthier Australian diets. 2013;
https://www.nhmrc.gov.au/files/nhmrc/file/publications/n55_australian_dietary_guidelines1.pdf. Accessed July 2018.
7. New Zealand Ministry of Health. *Eating and Activity Guidelines for New Zealand Adults*.
http://www.health.govt.nz/system/files/documents/publications/eating-activity-guidelines-for-new-zealand-adults-oct15_0.pdf2015.
8. Fuller S, Beck E, Salman H, Tapsell L. New Horizons for the Study of Dietary Fiber and Health: A Review. *Plant foods for human nutrition*. 2016;71(1):1-12 DOI 10.1007/s11130-11016-10529-11136.
9. Behall KM, Scholfield DJ, Hallfrisch JG, Liljeberg-Elmstahl HG. Consumption of both resistant starch and beta-glucan improves postprandial plasma glucose and insulin in women. *Diabetes care*. 2006;29(5):976-981 DOI 10.2337/dc2305-2012.
10. Lockyer S, Nugent AP. Health effects of resistant starch. *Nutrition Bulletin*. 2017(42):10-41 DOI 10.1111/nbu.12244.
11. Lockyer S, Spiro A, Stanner S. Dietary fibre and the prevention of chronic disease – should health professionals be doing more to raise awareness? *Nutrition Bulletin*. 2016;41(3):214-231 DOI 10.1111/nbu.12212.
12. NHMRC. Nutrient Reference Values for Australia and New Zealand - Dietary Fibre. In: Australian Government <https://www.nrv.gov.au/nutrients/dietary-fibre>; 2014.
13. Fayet-Moore F, Cassettari T, Tuck K, McConnell A, Petocz P. Dietary Fibre Intake in Australia. Paper II: Comparative Examination of Food Sources of Fibre among High and Low Fibre Consumers. *Nutrients*. 2018;10(9):1223 DOI 10.3390/nu10091223.
14. Slavin J. Fiber and Prebiotics: Mechanisms and Health Benefits. *Nutrients*. 2013;5(4):1417-1435 DOI 10.3390/nu5041417.
15. GLNC. 2017 Australian Grains and Legumes Consumption and Attitudinal Report. In: <https://www.glnc.org.au/wp-content/uploads/2018/09/GLNC-Consumption-Study-Summary-5.pdf>, ed. Unpublished: Grains & Legumes Nutrition Council; 2017.
16. McCleary BV, Sloane N, Draga A, Lazewska I. Measurement of Total Dietary Fiber Using AOAC Method 2009.01 (AACC International Approved Method 32-45.01): Evaluation and Updates. *Cereal Chemistry Journal*. 2013;90(4):396-414.
17. CODEX. Guidelines on Nutrition Labeling In: CODEX Alimentarius http://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BGL%2B2-1985%252FCXG_002e.pdf; 2017.

18. Prosky L, Asp NG, Furda I, DeVries JW, Schweizer TF, Harland BF. Determination of total dietary fiber in foods and food products: collaborative study. *J AOAC*. 1985;68(4):677-679 <https://europepmc.org/abstract/med/2993226>.
19. Prosky L, Asp NG, Schweizer TF, DeVries JW, Furda I, Lee SC. Determination of soluble dietary fiber in foods and food products: collaborative study. *Journal of AOAC International*. 1994;77(3):690-694 <https://europepmc.org/abstract/med/8012222>.
20. Lee SC, Prosky L, DeVries JW. Determination of total, soluble and insoluble dietary fiber in foods-enzymatic-gravimetric method, MES-tris buffer: Collaborative study. *J AOAC*. 1992;75:395-416.
21. Codex. RECOMMENDED METHODS OF ANALYSIS AND SAMPLING CXS 234-1999. In:1999.
22. FDA. *Food Labeling: Revision of the Nutrition and Supplement Fact Labels*. USA: U.S. Food & Drug Administration;2016.
23. EFSA, Panel on Dietetic Products, Nutrition, Allergies. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. *EFSA Journal*. 2010;8(3):1462 DOI 1410.2903/j.efsa.2010.1462.
24. Canada H. *Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products*. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/legislation/pol/fibre-label-etiquetage-eng.pdf;2012.

Appendix 1- Attached references

1, 4, 16, 20, 21, 22

Appendix 2 – Statutory Declaration

Statutory Declaration – Australia

STATUTORY DECLARATION

*Statutory Declarations Act 1959*¹

I, [REDACTED]

[REDACTED] *Grains and Legumes Nutrition Council* make the

following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

[REDACTED]

[REDACTED]

¹ <http://www.comlaw.gov.au/Series/C1959A00052>.

² A statutory declaration must be made before a prescribed person under the *Statutory Declarations Act 1959*. The list of prescribed persons is available in the *Statutory Declarations Regulations 1993* at <http://www.comlaw.gov.au/Series/F1996B00198>.

Appendix 3 - Checklist

General requirements (3.1.1)		
Check	Page No.	Mandatory requirements
	Y	A Form of application ☐ <i>Application in English</i> ☐ <i>Executive Summary (separated from main application electronically)</i> ☐ <i>Relevant sections of Part 3 clearly identified</i> ☐ <i>Pages sequentially numbered</i> ☐ <i>Electronic copy (searchable)</i> ☐ <i>All references provided</i>
	2	B Applicant details
	2	C Purpose of the application
	2	D Justification for the application ☐ <i>Regulatory impact information</i> ☐ <i>Impact on international trade</i>
	8	E Information to support the application ☐ <i>Data requirements</i>
	10	F Assessment procedure ☐ <i>General</i> ☐ <i>Major</i> ☐ <i>Minor</i> ☐ <i>High level health claim variation</i>
	10	G Confidential commercial information ☐ <i>CCI material separated from other application material</i> ☐ <i>Formal request including reasons</i> ☐ <i>Non-confidential summary provided</i>
	10	H Other confidential information ☐ <i>Confidential material separated from other application material</i> ☐ <i>Formal request including reasons</i>
	10	I Exclusive Capturable Commercial Benefit ☐ <i>Justification provided</i>
	11	J International and other national standards ☐ <i>International standards</i> ☐ <i>Other national standards</i>
	16	K Statutory Declaration
	17	L Checklist/s provided with application ☐ <i>3.1.1 Checklist</i> ☐ <i>All page number references from application included</i> ☐ <i>Any other relevant checklists for Chapters 3.2–3.7</i>