Ingredion

APPLICATION

JANUARY 2017

TO:
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:
APPLICATION FOR ADDITION OF A PRESCRIBED METHOD OF ANALYSIS FOR THE DETERMINATION OF RESISTANT STARCH

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ADMINISTRATIVE INFORMATION

Applicant Details

(As per section 3.1.1 B of the Application Handbook as at 1 March 2016)

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Nature of Business

(As per section 3.1.1 B of the Application Handbook as at 1 March 2016)

Ingredion is a global ingredient solutions company manufacturing sweeteners, starches and unique ingredients from plant sources such as corn, tapioca, rice, sago and potato. The business is focused on providing critical ingredients to the food, beverage, industrial, pharmaceutical and personal care industries.

Ingredion has a global network of manufacturing facilities, Ingredion Idea Labs™ innovation centers and sales offices with over 11,000 employees. The business is headquartered in Westchester, Illinois USA.

Details of Other Parties Associated with the Application

(As per section 3.1.1 B of the Application Handbook as at 1 March 2016)

The following Scientific and Regulatory Consultant is involved in the preparation, submission and stewardship of this application:

Fiona Fleming, Director, FJ Fleming Food Consulting Pty Ltd

1. APPLICATION INFORMATION

Status of Similar Applications

(As per Section 3.1.1 D of the Application Handbook as at 1 March 2016)

Ingredion is not aware of any similar current applications.

Assessment Procedure

(As per section 3.1.1 F of the Application Handbook as at 1 March 2016)

Ingredion seeks to proceed with an **unpaid** application for consideration as a General Procedure (maximum of 350 hours).

Confidential commercial information

(As per section 3.1.1 G of the Application Handbook as at 1 March 2016)

This application **does contain** information that is confidential commercial information.

Ingredion requests that FSANZ treat the following information, which forms part of the Application, as confidential commercial information:

Appendix	Title
1	Letter of support for the application
4	Executive Summary – Systematic Review Report – Food-Health Relationship – Resistant Starch and Digestive Health
Table	**Title**
3	Levels of use of HI-MAIZE®

The CCI information is not publicly available and disclosure of the information would cause Ingredion to suffer a detriment.

Exclusive capturable commercial benefit

(As per section 3.1.1 I of the Application Handbook as at 1 March 2016)

This application will **not** confer an exclusive capturable commercial benefit for Ingredion or any other individual company.

2. PURPOSE OF THE APPLICATION

(As per section 3.1.1 C of the Application Handbook as at 1 March 2016)

Ingredion is making this application to amend the *Australia New Zealand Food Standards Code* (hereafter, the Code) to add a method for specifically named fibre content of food (resistant starch) to Schedule 11 – Calculation of values for nutrition information panel, clause S11-4 Methods of analysis for dietary fibre and other fibre content.

Ingredion requests the addition of AOAC Official Method 2002.02/AACC Approved Method 32-40 for resistant starch to S11-4.

3. JUSTIFICATION FOR THE APPLICATION

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

Resistant Starch

Dietary fibre is defined in the Code[1] as:

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:

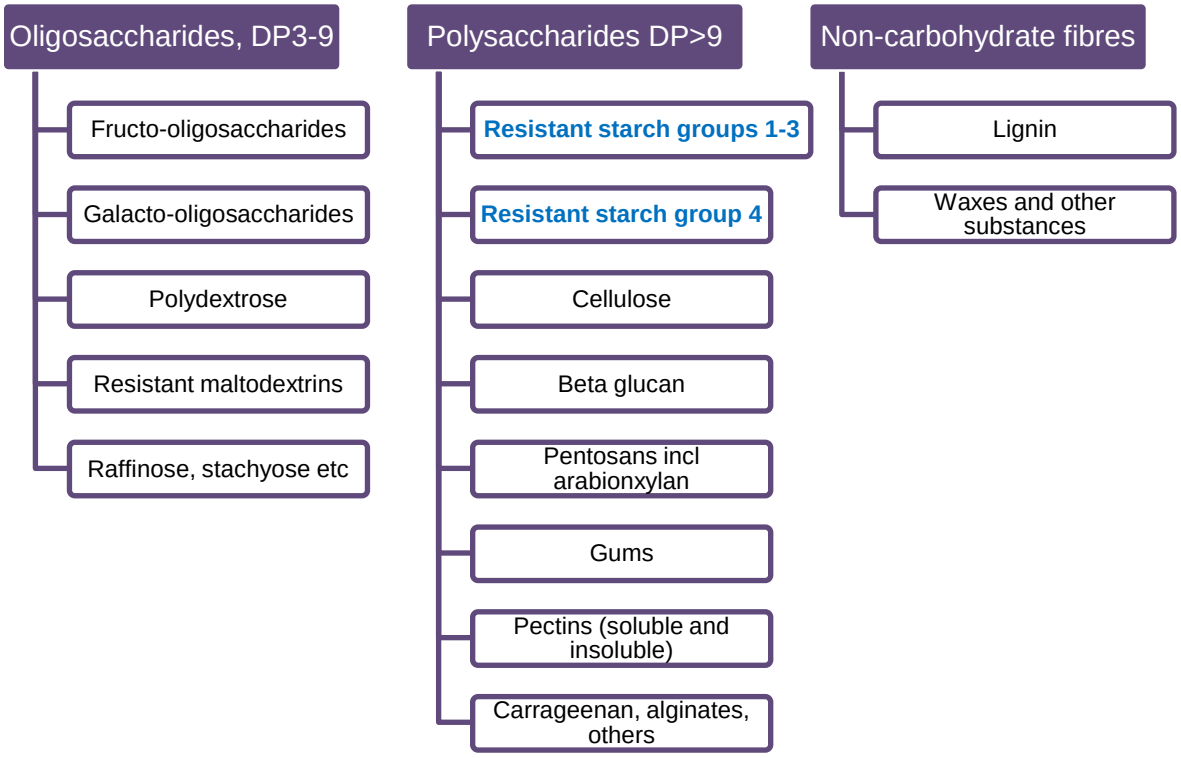
(c) polysaccharides or oligosaccharides that have a degree of polymerisation greater than 2; and

(d) lignins.

A wide range of substances are encompassed by this definition. Typically, these substances are carbohydrates but some other substances, such as lignin and waxes also meet the definition. **Figure 1** provides a schematic of the major types of substances that meet the Code definition of dietary fibre (FSANZ, 2014).

1 ANZ Food Standards Code - 1.1.2-2 Definitions – general; https://www.legislation.gov.au/Details/F2016C00158

Figure 1: Major types of dietary fibres, by composition and size (based on Westenbrink et al 2013) (FSANZ, 2014).



Resistant starch (RS) is a component naturally present in starchy foods consumed throughout the world, including cereals, corn, legumes, fruits and vegetables. When consumed, a portion of the starch (termed resistant starch) resists enzymatic digestion in the small intestine and enters the large intestine where it is partially or wholly fermented (McCleary et al 2002; McCleary and Rossiter 2004).

Resistant starch has been officially defined as:

"starch and the derivatives of starch that are not digested in the small intestines of healthy people". (Brown 2004).

Resistant starches are starches that are wholly or partly indigestible in the small intestine because of their natural physical structure (such as in raw bananas, some maize starches) or changes to their structure as a result of cooking, cooling, storage or processing (DeVries and Rader, 2005). Plant breeding techniques have enabled the production of cereal flours with a higher than usual resistant starch content, such as HI-MAIZE™ starch from a maize flour that was bred to contain more resistant starch than usual (Morita et al, 2007, Lunn & Buttriss, 2007).

Resistant starches are classified as RS1, RS2, RS3, or RS4 types, according to their physical and chemical attributes. RS1, RS2 and RS3 resistant starches are naturally present in foods. RS4 is not naturally present in foods and resists digestion due to bonds introduced through chemical modifications.

The types of resistant starch are summarised in **Table 1** below.

Table 1: Types of Resistant Starch (RS)

Type	Description of Resistant Starch	Food Sources
RS1	Physically inaccessible	Whole grains, coarsely milled grains, seeds
RS2	Resistant starch granules	Raw potato, green banana, some legumes, high amylose maize starch (HAMS): e.g. HI-MAIZE®
RS3	Retrograded or crystalline non-granular starch	Cooked and cooled starchy foods ie. potato, bread and cornflakes
RS4	Chemically modified starch	Commercially modified starches due to cross-bonding with chemical reagents (XL starches)

Reference: Englyst et al 1992 in McCleary and Monaghan (2002).

Resistant Starch and Dietary Fibre

The following table shows a substantiation of resistant starch against the definition of dietary fibre in the Code.

Table 2: Substantiation of Resistant Starch against the definition of dietary fibre in the Code

Definition	Resistant Starch 2	Reference
(a) are resistant to digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine;	Y	McCleary et al 2002; McCleary and Rossiter 2004
(b) promote one or more of the following beneficial physiological effects: (i) laxation; (ii) reduction in blood cholesterol; (iii) modulation of blood glucose;	Y Modulation of blood glucose	EFSA NDA Panel (2011)
and includes: (c) polysaccharides or oligosaccharides that have a degree of polymerisation greater than 2; and (d) lignins	Y DP > 9	Sajilata et al, 2006; Leszczynski, 2004

Resistant Starch 2 levels in foods

The resistant starch content of a range of foods is provided in **Appendix 2.**

HI-MAIZE® Resistant Starch 2

The Applicant markets an RS2 product under the brand HI-MAIZE® derived from high amylose corn - a high amylose maize starch (HAMS). A Product Data Sheet for the Applicant's RS2 product is provided in **Appendix 3.**

While numerous factors contribute to the resistance of naturally occurring RS, high amylose corn has particular processing advantages due to its composition. As the amylose content of grains increase, the resistance of starch granules to digestion also increases. In particular, high amylose corn starches have high gelatinization temperatures relative to other starches, which mean that the resistant starch can be preserved when high amylose corn starches are used in prepared foods (Brown et al 1995).

HI-MAIZE® resistant starch (RS2) is used in a range of food products at concentrations ranging from 0.5 – 10%. The types of food products and levels of use are set out in **Table 3** which is provided under CCI.

3.1 Need for the Proposed Change

(As per section 3.1.1 D(a) of the Application Handbook as at 1 March 2016)

S11-4 - Methods of analysis for dietary fibre and other fibre content contains the prescribed methods for the determination of total dietary fibre and any specifically named fibre content for the purposes of nutrition information labelling in Standard 1.2.8.

The permitted methods of analysis in S11-4 are all methods established as official methods of AOAC International, which is a globally recognised, independent association that develops consensus standards in the area of analytical chemistry (FSANZ, 2014).

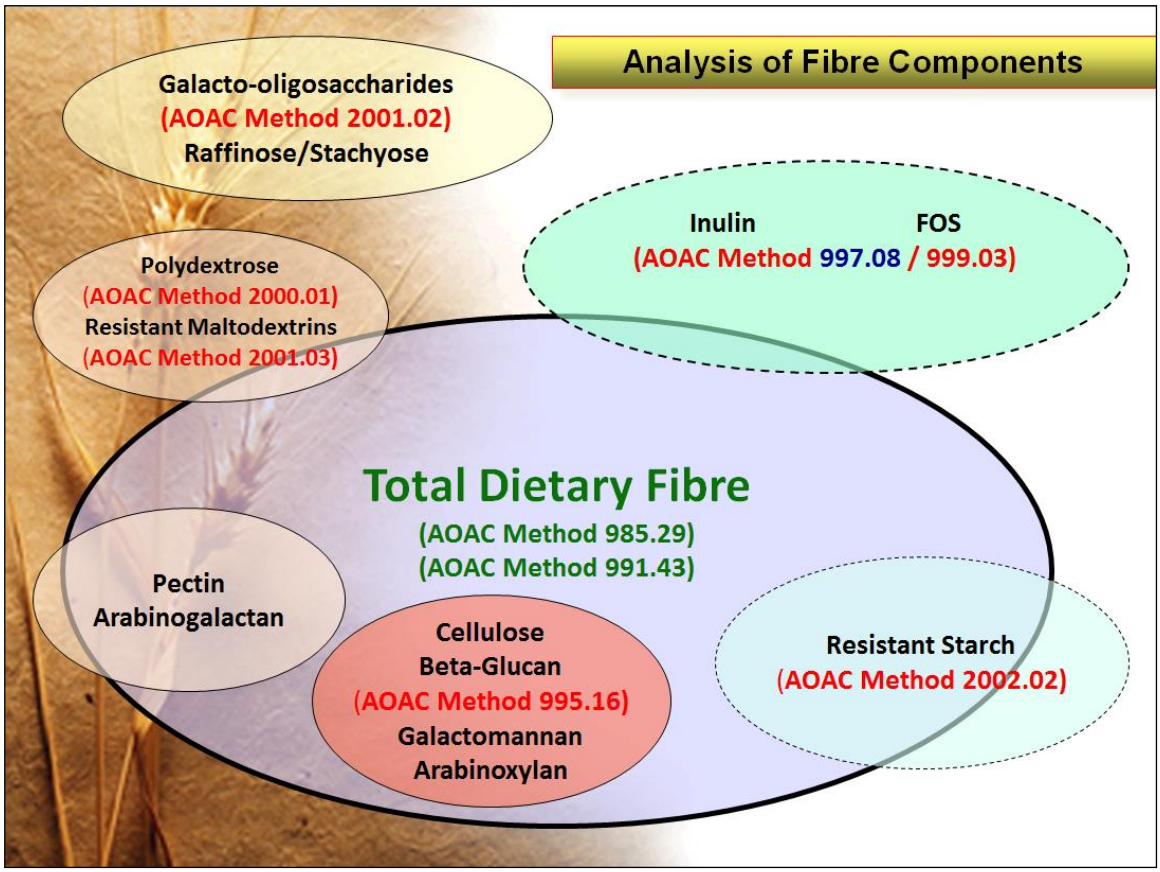
There are methods prescribed for total dietary fibre, total dietary fibre (including all resistant maltodextrins); inulin and fructooligosaccharide; and inulin and polydextrose.

Figure 2 shows the types of dietary fibre and the methods of analysis available.

S11-4 currently does not include a prescribed method of analysis for resistant starch for the purpose of nutrition labelling.

Detail on the method requested for inclusion in S11-4 is provided in **Section 7.**

Figure 2: Analysis of Fibre



The Applicant considers that the AOAC Official Method 2002.02/AACC Approved Method 32-40 for resistant starch is appropriate for the reasons outlined in this section and **Section 7.**

3.1.1 Current Prescribe Methods for Dietary Fibre

Inclusion of this method is necessary for accurate analysis of resistant starch in food products to enable declaration in the nutrition information panel. The Applicant acknowledges that declaration is not mandatory, however where a nutrition content or general level claim is made about RS then a declaration is required in the nutrition information panel. A method is required that distinguishes resistant starch from other forms of dietary fibre present.

Table 4 (below) provides a comparison of current methods of analysis and their suitability for analysis and declaration of RS2. These methods do distinguish resistant starch from other forms of dietary fibre which may be present in the product.

Table 4: Comparison of Methods of Analysis for TDF and RS2

METHOD	INCLUDED IN THE CODE	TESTS FOR	COMMENT
AOAC 985.29	Y	Total (high molar) dietary fibre	Resistant starch is not distinguished from other forms of dietary fibre present. Resistant starch is underestimated in foods where it is the main dietary fibre component. Excludes resistant starch categories RS1, RS2, and RS4; only RS3 will be incorporated in the test result Eurofins (2012).
AOAC 991.43	Y	Total dietary fibre	Resistant starch is not distinguished from other forms of dietary fibre present. Resistant starch is underestimated in foods where it is the main dietary fibre component. This method excludes most types of the resistant starch dietary fibre (Eurofins 2012).
2001.03	Y	Total dietary fibre (including all resistant maltodextrins)	Resistant starch is not distinguished from other forms of dietary fibre present.
AOAC 2009.01	N	Total dietary fibre including high molar and low molar weight.	Resistant starch is not distinguished from other forms of dietary fibre present.
AOAC 2011.25	N	Total dietary fibre including soluble and insoluble high and low molar weight	Resistant starch is not distinguished from other forms of dietary fibre present.
AOAC/2002.02/AACC Approved method 32-40	N	Resistant starch	Specific to resistant starch.

FSANZ noted that:

The Code contains a definition of dietary fibre and also lists several AOAC International methods of analysis that can be used for analysis of dietary fibre content of foods for the purposes of label declaration. These methods also underpin the existing Daily Intake value and [draft] criteria for dietary fibre content claims in Proposal P293 – Review of Health and Related Claims. Some of the listed methods partially measure resistant starch although no method is listed that measures resistant starch only (FSANZ, 2011).

Further, it was noted by the Codex Working group under the Codex Committee on Nutrition and Foods for Special Dietary Uses (Codex 2009) that:

No one AOAC validated method can measure all non-digestible carbohydrates in foods. AOAC 991.43 is one of the most widely used 'total' dietary fibre methods. Both this method and AOAC 985.29 will measure insoluble polysaccharides and soluble high molecular weight components i.e. those that are precipitated by alcohol. However, neither measures fully the resistant starch fraction, nor do they recover the non-digestible oligosaccharide components included in the definition of dietary fibre.

They quantify only part of the total resistant starch, inulin, polydextrose, fructo-oligosaccharides and resistant maltodextrin, all of which have relevant physiological functions. Furthermore, some oligosaccharides are not measured at all.

Therefore, Ingredion requests the addition of AOAC Official Method 2002.02/AACC Approved Method 32-40 for resistant starch to S11-4 which is specific to resistant starch RS2 and RS3.

3.1.2 Dietary Fibre and Resistant Starch content claims

The Applicant acknowledges that mandatory declaration of total dietary fibre in the NIP is not required (although voluntary declarations are permitted), unless nutrition content or health claims are made about dietary fibre, any specifically named fibre, sugars or any other types of carbohydrate.

Resistant Starch is becoming a more recognised and important fibre component that food manufacturers are looking to incorporate in their products and to communicate to consumers about. With the health effects of resistant starch becoming increasingly known, it is beneficial to have resistant starch measured as a fibre and labelled on pack. It is expected that the interest in resistant starch will increasingly become more important and manufacturers will look to add ingredients with resistant starch into new products.

Where a nutrition content claim is being made about products for resistant starch (or any other nutrient) it is important that a consistent method of analysis is used to ensure consumers are comparing "like with like" when making purchase decisions.

3.1.2.1 Nutrition, Health and Related Claims – Nutrition Content Claims

Standard 1.2.7 – Nutrition, Health and Related Claims sets out the requirements and conditions for these types of claims on food products and in advertising in Australia and New Zealand.

Under Standard 1.2.7 claims in relation to resistant starch are only permitted to be made as nutrition content claims as per 1.2.7-13 - Nutrition content claims about properties of food not in section S4—3

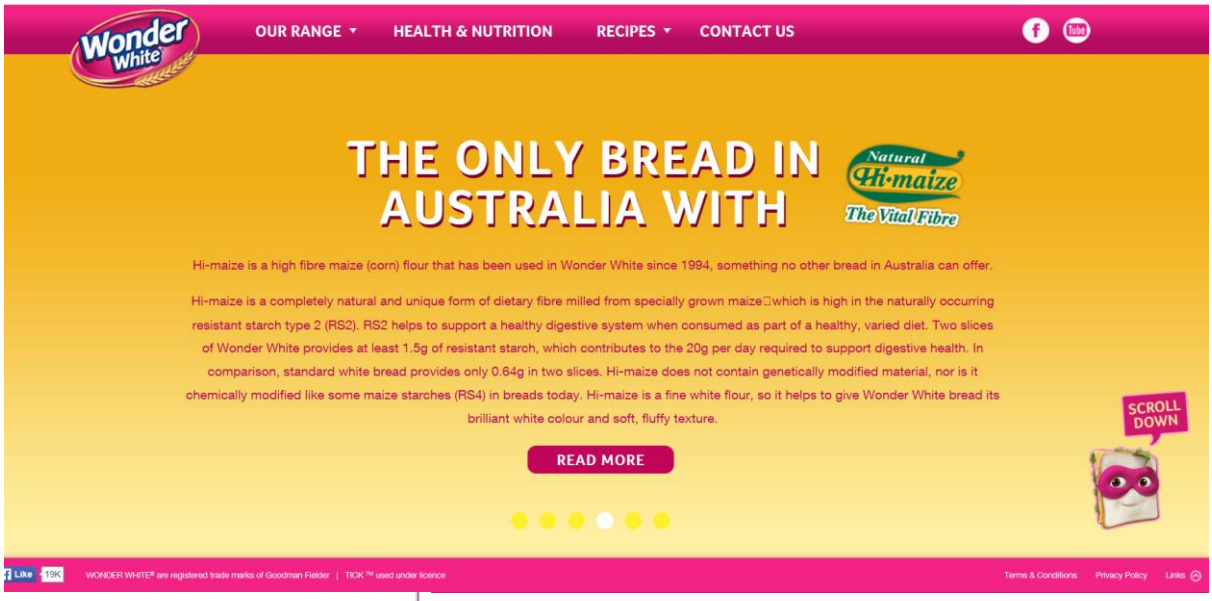
*(1) A nutrition content claim about a *property of food that is not mentioned in the table to section S4—3 may state only:*

> *(a) that the food contains or does not contain the property of food; or*
>
> *(b) that the food contains a specified amount of the property of food in a specified amount of that food; or*
>
> *(c) a combination of paragraph (a) and (b).*

(2) A statement made for the purposes of paragraph (1)(a) must not use a descriptor listed in Column 3 of the nutrition content claims table, or any other descriptor, except a descriptor that indicates that the food does not contain the property of food.

An example of a product currently in the market that makes nutrition content claims which comply with these requirements is Wonder White bread as shown in **Figure 3.**

Figure 3: Wonder White brand products – Resistant Starch Nutrition Content and Self-Substantiated General Level Health Claims



To: Food Standards Australia New Zealand
In relation to: Application for addition of a prescribed method of analysis for the determination of resistant starch

3.1.2.2 Nutrition, Health and Related Claims – General Level Health Claims

This Application seeks **only** the addition of AOAC Official Method 2002.02/AACC Approved Method 32-40 for resistant starch to S11-4.

The Applicant understands that for a general level or high level health claim about resistant starch to be made the food-health effect relationship would first need to be established in accordance with Standard 1.2.7. It is noted that if a manufacturer chooses to explore using RS and making a general level health claim then they will need to make a separate application to FSANZ or prepare a Scientific Literature Review (SLR) to meet the requirements of Schedule 6.

Health Effects of Resistant Starch

In "The Resistant Starch Report", Landon et al (2012) summarise the health effects of resistant starch, noting that:

A significant body of research has been developed demonstrating digestive and colonic health benefits of high amylose maize starch (HAMS) resistant starch as well as showing metabolic advantages (Nugent 2005).

The benefits summarised by Landon et al (2012) include:

- Digestive health;
- Glycemic control; and
- Satiety.

Digestive Health

The Applicant has notified a food-health relationship for resistant starch and digestive health based on a systematic review as described in Schedule 6 of the Code.

The potential wording of a general level health claim supported by the systematic review is:

Resistant starch 2 (RS2) helps to maintain/support a healthy digestive system when consumed as part of a healthy diet made up of a variety of foods

OR

The dietary inclusion of ##g/day or (## serves/day) of resistant starch 2 (RS2) helps support/maintain digestive health in a generally healthy population representative of the Australian and New Zealand populations.

The Executive Summary from the Systematic Review report is provided under **CCI** as **Appendix 4.**

Glycemic Control

The European Food Safety Authority (EFSA) substantiated a health claim in relation to the ability of resistant starch to reduce post prandial blood glucose response when replacing digestible starch in high carbohydrate foods (EFSA 2011).

The Applicant understands that FSANZ has identified the food-health relationship between resistant starch and reduction of blood glucose rise after a meal as an EU approved claim that will be further considered during the transition period for Standard 1.2.7 (FSANZ, 2012).

Satiety

Numerous published studies (but not all) show positive effects of HI-MAIZE® resistant starch on satiety and recent data from animal studies have identified potential mechanisms underlying these effects.

Short-term satiety benefits:

HI-MAIZE® enhances short-term satiety because its slow glycemic carbohydrates are digested lower in the small intestine compared to rapidly digested carbohydrates like traditional starches and glucose, which are digested high within the small intestine.

Long-term satiety benefits:

HI-MAIZE® also offers longer-term satiety — which is an unexpected timing for satiety benefits. The mechanism is believed to be related to fermentation in the large intestine (Witwer, 2012).

Resistant starch is present in and added to, a variety of foods and is acknowledged for a range of health effects as outlined in this section. The formal recognition of a method of analysis in the Code will ensure that levels of RS listed in the nutrition information panel on food products and in advertising materials are based on a consistent method. This will enable consumers to make informed choices when choosing foods containing resistant starch.

3.1.3 International Alignment

The method proposed is recognised in other countries as set out under **Section 6.**

3.2 Advantages of the Proposed Change

(As per section 3.1.1 D(b) of the Application Handbook as at 1 March 2016)

The advantages of the proposed change include:

- More accurate representation of the amount of resistant starch present in products;
- Confidence that claims for resistant starch will be made using a consistent analytical method;
- Potential for industry innovation if the true levels of resistant starch are stated consistently on food products;
- The ability to market resistant starch and the health benefits of resistant starch as consumers will be able to look for products containing RS; and
- Research – support method alignment for future research and systematic reviews.

3.3 Disadvantages of the Proposed Change

(As per section 3.1.1 D(b) of the Application Handbook as at 1 March 2016)

Where companies wish to label for resistant starch there will be the cost of an additional test as they will still need to analyse for total dietary fibre as well as resistant starch if they wish to declare on the nutrition information panel.

The total cost for both tests (991.43 and 2002.02) will be approximately $550 (AUD) compared to the cost of TDF (991.43) alone $230 (AUD).

4 REGULATORY IMPACT INFORMATION

(As per section 3.1.1 D.1 of the Application Handbook as at 1 March 2016)

4.1 Costs and Benefits – Consumer

(As per section 3.1.1 D.1.1 of the Application Handbook as at 1 March 2016)

The proposed amendment places no additional economic cost on consumers.

A prescribed method of analysis for resistant starch will be a potential benefit for both industry and consumers by providing a level of consistency in the estimation – and thus labelling – of the resistant starch content in foods.

Consumers may benefit from the minimal changes in nutrition education messages and nutrition content claims about resistant starch that may occur from a consistent method of analysis.

Consumers may also have access to a wider choice of products containing resistant starch and will have access to more accurate nutrition information on the resistant starch content of foods.

4.2 Costs and Benefits - Industry and Business

Approval of this application will benefit manufactures of resistant starch and those who add resistant starch to their products as the content will be more accurately reflected than with current prescribed methods of analysis.

Use of resistant starch products will be at the discretion of business, therefore there are no direct costs imposed on industry.

Where companies wish to label for resistant starch there will be the cost of an additional test as they will still need to analyse for total dietary fibre as well as resistant starch.

The total cost for both tests (991.43 and 2002.02) will be approximately $550 (AUD) compared to the cost of TDF (991.43) alone $230 (AUD).

4.3 Costs and Benefits – Government

The proposed amendment places no additional regulatory costs on government beyond the initial regulatory cost of amending the Code and for enforcement agency laboratories in developing analytical capability for the method.

Enforcement agencies may benefit from the inclusion of the proposed prescribed method of analysis for resistant starch, through improved clarity and straightforward regulation on resistant starch nutrition content claims.

4.4 Impact on International Trade

(As per section 3.1.1 D.1.2 of the Application Handbook as at 1 March 2016)

The Applicant notes that, in developing food standards, FSANZ must have regard to its WTO obligations; the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. These matters encompass consideration of international standards and trade issues.

This method is recognised in other markets as set out in **Section 6.**

5 INFORMATION TO SUPPORT THE APPLICATION

(As per section 3.1.1 E of the Application Handbook as at 1 March 2016)

5.1 Data Requirements

Not relevant for this Application.

5.2 FSANZ Act Objectives

Information is provided in this application to enable the objectives specified in Section 18 of the FSANZ Act to be addressed as follows:

(a) The protection of public health and safety: information to support objective - the Applicant is not aware of any public health and safety issues.

(b) The provision of adequate information relating to food to enable consumers to make informed choices: data to support objective (b) are provided in Section 8.

(c) The prevention of misleading or deceptive conduct: information supporting objective (c) is provided in Section 8.

5.3 Public Health and Safety Issues

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

The Applicant is not aware of any public health and safety issues.

5.4 Consumer Choice

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

Resistant starch will be labelled in the ingredient list (where added rather than naturally occurring) and nutrition information panel (NIP) so consumers will have the information required to make an informed choice at the point of purchase.

5.5 Support for the Proposed Change

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

A letter from a company who has an interest in this Application is provided in **Appendix 1** and is considered CCI.

6 INTERNATIONAL AND OTHER NATIONAL STANDARDS

(As per section 3.1.1 J of the Application Handbook as at 1 March 2016)

6.1 International Standards

(As per section 3.1.1 J.1 of the Application Handbook as at 1 March 2016)

Codex has approved the use of an enzymic method (AOAC 2002.02) specifically for RS2 and RS3.

6.2 Other National Standards or Regulations

(As per section 3.1.1 J.2 of the Application Handbook as at 1 March 2016)

6.2.1 United States of America

AOAC 2002.02 is an approved method for resistant starch in the USA as follows:

Following is a summary for the labeling of dietary fiber, including the approved methods from the new Nutrition Facts Labeling regulation.

Recording Fiber on the Label:

FDA proposes to amend § 101.9(c)(6)(i) to indicate that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber (in proposed § 101.9(c)(6)(i)) from the value obtained using AOAC 2009.01, AOAC 2011.25 or an equivalent AOAC method of analysis as given in the “Official Methods of Analysis of the AOAC International” 19th Edition. (pg. 477)

FDA agrees that AOAC 2009.01 and 2011.25 do not measure all forms of RS4, such as cross-linked wheat starch (Ref. 143). In these cases, when submitting a citizen petition or a health claim petition, a more appropriate method can be identified that can measure all of the RS4.

Following is paragraph (g)(2) of the new Nutrition Labeling regulation, which indicates that appropriate methods as provided in AOAC, or other reliable and appropriate method if no AOAC method is available. This isn't much different from the previous paragraph (g)(2), except that the old regulation listed AOAC 15th edition.

21CFR 101.9
(g) Compliance with this section shall be determined as follows:
* * * * *
(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by

appropriate methods as given in the "Official Methods of Analysis of the AOAC International," or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

6.2.2 Canada

Health Canada (in consultation with the Canadian Food Inspection Agency) lists a number of analytical methods for dietary fibre under general methods and specific methods.

AOAC 2002.02 is listed under methods for quantifying specific dietary fibre components – resistant starch 2 and 3 (RS2 and RS3).

6.2.3 United Kingdom/Europe

In Europe, it is also accepted by EFSA.

The following table provides evidence of approval of AOAC method 2002.02 in each of the countries listed above.

Table 5: International approval/acceptance of AOAC method 2002.02

JURISDICTION/COUNTRY	STANDARD/REGULATION	LINK/Reference
CODEX	Report of the thirty-second session of the Codex Committee on methods of analysis and sampling, March 2011	Appendix 5, p 35
CANADA	Health Canada Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products 8. Methods of Analysis Table 2 – Methods for quantifying specific dietary fibre components	http://www.hc-sc.gc.ca/fn-an/legislation/pol/fibre-label-etiquetage-eng.php#a8
UK/EUROPE	Statement of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to dietary fibre, July 2007. European Commission, Guidance document for competent authorities for the control of compliance with EU legislation, Dec 2012	Appendix 6

7 RESISTANT STARCH METHOD OF ANALYSIS

7.1 Technical Information

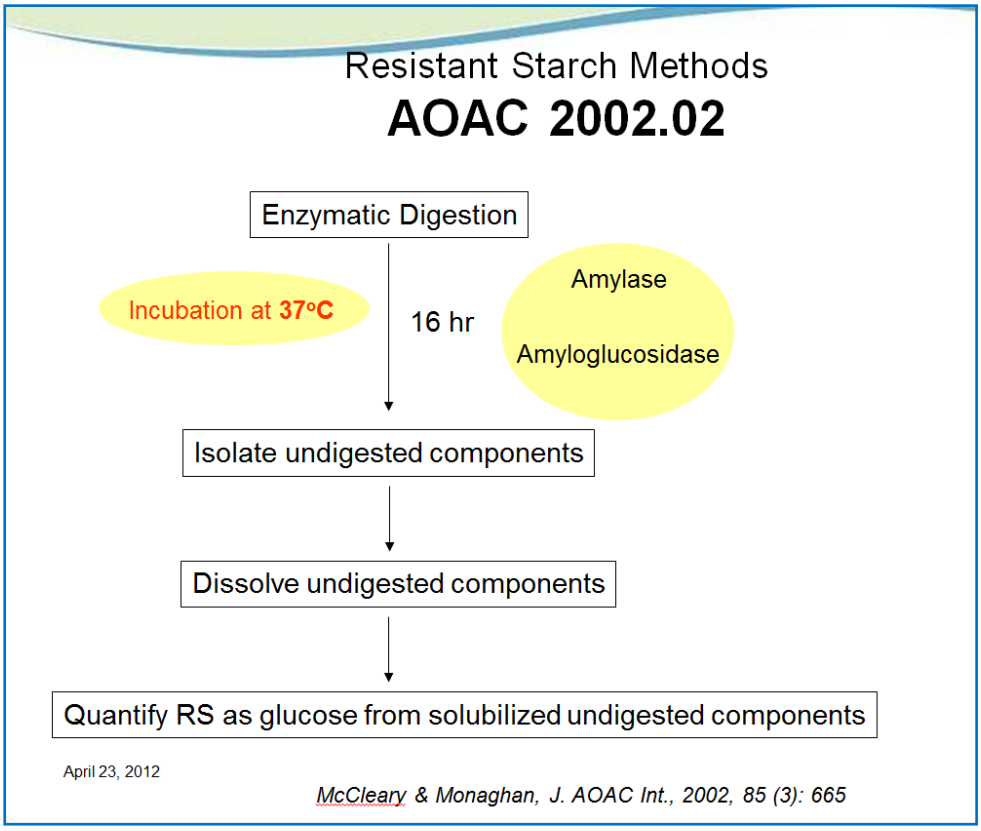
7.1.1 Description of Proposed Method of Analysis

The AOAC Official Method 2002.02 and AACC Method 32-40 has been described as a robust and reliable method that reflected in vivo conditions and yielded values that were physiologically significant (Landon et al 2012). This method is applicable to plant and starch materials with resistant starch content greater than 2% w/w.

The method is provided as **Appendix 7.**

The principle of the method as described by Landon et al (2012) involves hydrolysing the starch by incubation with alpha amylase and amyloglucosidase, extracting the hydrolysed product with 50% ethanol and discarding it. The resistant starch is then solubilised with 2N potassium hydroxide and hydrolysed with amyloglucosidase. The glucose is measured with a glucose oxidase/peroxidase (GOPOD) analysis kit.

Figure 4: Method of Analysis – AOAC 2002.02



7.1.2 Information to Support the Selection of the Method

The following laboratory can perform the AOAC Official Method 2002.02/AACC Approved Method 32-40 for resistant starch in Australia:

- Australian Export Grains Innovation Centre (AEGIC) – Analytical Services, North Ryde, NSW 2113 (http://aegic.org.au/)

The method is suitable across a range of food matrices but less accurate at RS contents less than 2% w/w.

In 2013 Ingredion and Goodman Fielder provided new composite data for resistant starch (and other fibres – total dietary fibre, soluble fibre, insoluble fibre) in a range of foods. The foods tested included the following:

- Breads and baked goods;
- Biscuits, cereal bars and savory snacks;
- Grains;
- Vegetables;
- Other – potato dishes; banana and chick peas.

The analysis results are reported by Landon et al (2012) in the Resistant Starch Report (Table 2) which is provided as **Appendix 8.** The results are also published on the FSANZ website[2] and provided in Appendix 8.

These results show that the method is applicable across a range of food categories and product types.

8 GENERAL FOOD LABELLING

(As per section 3.2.1 of the Application Handbook as at 1 March 2016)

8.1 General Information to support the proposed labelling change

(As per section 3.2.1 A of the Application Handbook as at 1 March 2016)

The Applicant is **not** proposing a change to food labelling and therefore does not intend to respond to this section of the Application Handbook.

2 http://www.foodstandards.gov.au/science/monitoringnutrients/nutrientables/Pages/Data-provided-by-food-companies-and-organisations.aspx, accessed 03/01/2017

9 NUTRITION INFORMATION LABELLING

(As per section 3.2.5 of the Application Handbook as at 1 March 2016)

The Applicant is **not** proposing a change to nutrition information labelling.

Standard 1.2.8 – Nutrition information requirements specify that a nutrition information panel must contain the following information:

(5) If a *claim requiring nutrition information is made in respect of:

(a) fibre or any specifically named fibre; or

(b) sugars or any other type of *carbohydrate;

a nutrition information panel must include a declaration of the presence or absence of *dietary fibre in accordance with section S12—3.

A nutrition content or health claim in relation to resistant starch 2 would therefore trigger this requirement.

S12-3 – format for nutrition information panels – subsections1.2.8-6(3) and 1.2.8-6(5) require the format for a nutrition information panel is set out as shown below in **Figure 5.** It is noted that a sub-group nutrient is required to be “nested” under the nutrient heading. **Figure 6** shows an example of how resistant starch is currently declared in compliance with this requirement.

The Applicant is not proposing to request a change to this format.

Figure 5: Format for nutrition information panel – fibre or any specifically named fibre

NUTRITION INFORMATION Servings per package: (insert number of servings) Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100 g (or 100 mL)
Energy	kJ (Cal)	kJ (Cal)
Protein, total	g	g
—*	g	g
Fat, total	g	g
—saturated	g	g
—**	g	g
—trans	g	g
—**	g	g
—polyunsaturated	g	g
—**	g	g
—monounsaturated	g	g
—**	g	g
Cholesterol	mg	mg
Carbohydrate	g	g
—sugars	g	g
—**	g	g
— **	g	g
—**	g	g
Dietary fibre, total	g	g
—*	g	g
Sodium	mg (mmol)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, µg (or other units as appropriate)	g, mg, µg (or other units as appropriate)

Figure 6: Example Nutrition Information Panel (NIP) with Resistant Starch

NUTRITION INFORMATION

SERVINGS PER PACKAGE: 8.5 (15 SLICES AND 2 CRUSTS)
SERVING SIZE: 82g (2 SLICES)

	AVERAGE QUANTITY PER SERVING	% DAILY INTAKE* (PER SERVING)	AVERAGE QUANTITY PER 100g
ENERGY	780kJ	9%	955kJ
PROTEIN	6.4g	13%	7.8g
FAT, TOTAL	1.7g	2%	2.1g
- saturated	<1.0g	<4%	<1.0g
CARBOHYDRATE	33.0g	11%	40.2g
- sugars	2.3g	3%	2.8g
DIETARY FIBRE, TOTAL	6.4g	21%	7.8g
- soluble fibre	1.5g		1.8g
- insoluble fibre	4.9g		6.0g
- resistant starch	1.6g		2.0g
SODIUM	330mg	14%	400mg

* Percentage Daily Intakes are based on an average adult diet of 8700kJ. Your daily intakes may be higher or lower depending on your energy needs.
< Means less than.

9.1 Additional Information to Support a Change

(As per section 3.2.5 A of the Application Handbook as at 1 March 2016)

9.1.1 Description of how the proposed labelling will change the nutrition information labelling of the food

(As per section 3.2.5 A.1 of the Application Handbook as at 1 March 2016)

As noted, the Applicant is **not** proposing a change to food or nutrition information labelling however wishes to acknowledge the potential for "double counting" of dietary fibre in the nutrition information panel.

Although the different methods stipulated in the Code or available from AOAC appear to measure different types of dietary fibre, and specific components of fibre, in practice there is some overlap between methods so that the same fibre type may be captured more than once leading, potentially, to an incorrect estimate of dietary fibre content (Englyst et al, 2007 in FSANZ, 2014).

The following diagram illustrates the potential for "double counting" of dietary fibre by showing the overlap in captured substances with each method of analysis.

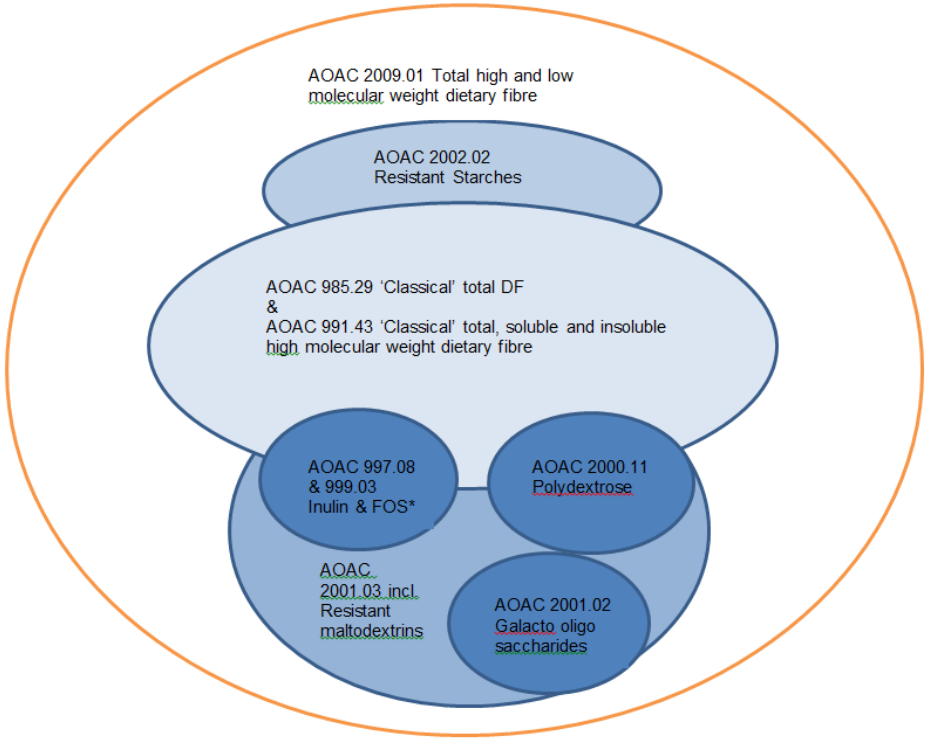


Figure 7: Summary of the types of fibre measured using different methods of analysis (adapted from Westenbrink et al, 2013) (FSANZ, 2014)

Further, it was noted by the Codex Working group under the Codex Committee on Nutrition and Foods for Special Dietary Uses (Codex 2009) that there is potential for double accounting:

> *The definition encompasses a range of different types of carbohydrate polymers which are recovered to varying extents by different analytical methods. This creates potential problems of double accounting when a carbohydrate fraction is partially or completely measured by more than one method. Examples of this are high molecular weight inulin, which in addition to being measured specifically by enzymatic-chemical fructan methods are also partially recovered in the residue of enzymatic-gravimetric methods. The enzymatic-gravimetric methods AOAC 991.43 and 985.29 also recover some but not all resistant starch, which can create a double accounting problem if this data is then combined with that obtained by a separate specific determination of resistant starch. There is also the potential for obtaining a lower than expected value if there is under recovery of a specific fraction by particular methods.*

The same document notes that AOAC 2002.02 is a good method to measure all resistant starch; if used in combination with AOAC 991.43 it can lead to overestimation of RS.

This poses a challenge for food science analysts and those in food companies responsible for developing products NIPs because if, for example, resistant starch is measured using AOAC 2002.02 and the value obtained is added to the value for TDF measured using AOAC 985.29, this results in a quantity of resistant starch being 'double counted' leading to an artificially high value for dietary fibre.

The Applicant understands that the NIP in **Figure 6** does not double count the various fibre components and can confirm that the NIP is prepared by analysis as follows:

- Total dietary fibre: AOAC 985.29
- Insoluble fibre: AOAC 991.42
- Soluble fibre: by difference SDF = TDF - IDF
- Resistant Starch: by AOAC 2002.02

A review of consumer enquires to the Goodman Fiedler call centre indicates no calls received from consumers wanting to understand why all three fibres do not tally up to the total fibre value. Record were reviewed for the past two years (Pers. Comm, GF, 2016).

The Applicant recommends that where RS2 is analysed and reported in the NIP that it is NOT added to the total of TDF to avoid double counting.

9.1.2 Data to demonstrate that the proposed labelling change will assist consumers to make an informed choice and will not mislead them

(As per section 3.2.5 A.2 of the Application Handbook as at 1 March 2016)

The Applicant is **not** proposing a change to food or nutrition information labelling

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