

20 October 2017
[29–17]

Call for submissions – Application A1142

Addition of a prescribed method of analysis for resistant starch

FSANZ has assessed an Application made by Ingredion ANZ Pty Limited (Ingredion) to amend the *Australia New Zealand Food Standards Code* (the Code) to add a method of analysis (MoA) for a specifically named fibre i.e. resistant starch, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 4 December 2017

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD1 Assessment of resistant starch as dietary fibre; and suitability of AOAC 2002.02 as a regulatory method of analysis

Executive summary

This Application by Ingredion seeks to amend the *Australia New Zealand Food Standards Code* (the Code) to include AOAC 2002.02 (Resistant starch in Starch and Plant Materials) as a method of analysis (MoA) for resistant starch as a specifically named dietary fibre. Currently, section S11—4 prescribes various methods for analysing total dietary fibre and certain specifically named fibres, but does not include a specific MoA for resistant starch as dietary fibre.

Standard 1.1.2 defines what constitutes ‘dietary fibre’ for the Code’s purposes. FSANZ’s assessment is that resistant starch falls within that definition and is dietary fibre for the purposes of the Code.

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. Including the prescribed MoA, as requested, would mean that food suppliers would be required to use AOAC 2002.02 if they specifically declare the quantity of resistant starch as a sub-group nutrient of dietary fibre in the nutrition information panel on a food label.

Section S12—3 of the Code also prescribes the format for nutrition information panels. If the presence and amount of resistant starch is to be specifically declared in the nutrition information panel as a sub-group nutrient of dietary fibre, that declaration must be indented under the heading ‘Dietary fibre, total’ (resistant starch being a sub-group nutrient of dietary fibre). In addition, it is intended that if the quantity of resistant starch is specifically declared as ‘resistant starch’, that quantity is also included as part of the declaration of the total quantity of dietary fibre. This is to avoid causing confusion for consumers. Section S11—4 currently include specific requirements to avoid double counting of dietary fibre when more than one method of analysis are used.

FSANZ’s assessment also concludes that AOAC 2002.02 is appropriate as a prescribed regulatory method for measuring resistant starch as a component of dietary fibre. It is recognised and widely used internationally, and is the only method for resistant starch in the Codex list of recommended methods. The method is applicable to samples containing between 1–75% resistant starch and method performance parameters including limit of quantification, repeatability, and reproducibility are acceptable for food regulatory purposes.

Therefore, FSANZ is proposing to amend section S11—4 of the Code to include AOAC 2002.02 as a new MoA, specifically for resistant starch. Prescribing this MoA in the Code would provide an internationally recognised, accurate and reliable basis for measuring the amount of resistant starch in foods and for declaring that amount as dietary fibre in the nutrition information panel.

1 Introduction

1.1 The Applicant

The Application was submitted by Ingredion ANZ Pty Ltd (Ingredion).

1.2 The Application

The Application seeks to amend section S11—4 of the *Australia New Zealand Food Standards Code* (the Code) to include in that section's list of prescribed methods of analysis (MoA) a specific MOA for resistant starch as a specifically named dietary fibre. The MoA is AOAC¹ Official Method 2002.02² – Resistant starch in Starch and Plant Materials. Ingredion states that this method is necessary for accurate analysis of resistant starch in food products to enable declaration in the nutrition information panel, as a type of dietary fibre, and to distinguish resistant starch from other forms of dietary fibre present in a food. They note that MoA 2002.02 is specific to resistant starch.

1.3 The current standard

The permitted MoAs in section S11—4 are all established as official methods of AOAC International, which is a globally recognised, independent association that develops consensus standards in the area of analytical chemistry. Section S11—4 prescribes the MoAs that must be used to determine: total dietary fibre; total dietary fibre including all resistant maltodextrins; inulin and fructooligosaccharide; inulin; and polydextrose for declaration in the nutrition information panel. There is no specific method prescribed for resistant starch. The current methods for analysing 'total dietary fibre' in the Code measure some, but not all, resistant starch in a food and the amount measured depends on the food matrix. They do not distinguish resistant starch from other forms of dietary fibre present in the food.

'Dietary fibre' is defined in Standard 1.1.2 of the Code. This definition captures a broad range of dietary fibres and includes resistant starch (see section 2.1).

Determination of the total dietary fibre content or any specifically named dietary fibre content is required for nutrition information labelling purposes under Standard 1.2.8 – Nutrition Information Requirements. These labelling requirements apply if certain nutrition content or health claims are made. That is, a declaration of the presence or absence of dietary fibre must be included in the nutrition information panel if a relevant nutrition content or health claim is made about: dietary fibre; any specifically named dietary fibre (such as resistant starch); sugar; or any other type of carbohydrate (subsection 1.2.8—6(5)). This declaration must be made in accordance with the prescribed format for the nutrition information panel. The format allows for the declaration of any sub-group nutrient of dietary fibre (e.g. resistant starch) indented below the heading 'Dietary fibre, total' (section S12—3). If a relevant nutrition content or health claim is made about resistant starch, then the amount of resistant starch must be declared in this manner.

Conditions for making nutrition content and health claims are in Standard 1.2.7 – Nutrition, health and related claims, and Schedule 4 – Nutrition, health and related claims.

¹ **AOAC** means the *Official Methods of Analysis of AOAC International*, eighteenth edition, 2005, published by AOAC International, Maryland USA.

² This method is equivalent to American Association of Cereal Chemists (AACC) International Method 32-40

Determination of the dietary fibre content 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 (NPSC) (see section S5—6) to make a health claim or to add vitamin D to a breakfast cereal. If fibre points are relied on for a food to meet the NPSC, the dietary fibre must be declared in the nutrition information panel (see section 1.2.7—26 and 1.3.2—7).

1.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

2.1.1 Resistant starch as dietary fibre, as defined in the Code

Resistant starch is described in this report (see SD1) as the fraction of starch that is not digested when it passes through the small intestine; it is also at least partially fermented in the large intestine. Five subtypes (RS1-RS5) are now classified as described in Table 3 in SD1.

In assessing the Application, it is necessary to first determine if resistant starch fulfils the definition of dietary fibre in Standard 1.1.2:

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

- (a) is 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.

FSANZ concludes that the evidence provided by the Applicant, and other scientific literature identified by FSANZ, demonstrates that resistant starch satisfies the definition of dietary fibre as follows:

- Resistant starch is present in the edible parts of plant materials and can be extracted from plant materials.
- Resistant starch is resistant to digestion in the small intestine and is fermented in the large intestine.
- Replacement of digestible starch with resistant starch in a meal promotes modulation of blood glucose by reducing peak postprandial blood glucose concentration.

- Resistant starch promotes laxation.

2.1.2 AOAC 2002.02 as a regulatory method of analysis

Three of the five AOAC methods presented in section S11—4 describe measurement of total dietary fibre. These official methods are AOAC 985.29³ and its derivative AOAC 991.43⁴, and AOAC 2001.03⁵ which is a derivative of AOAC 991.43.

The Codex standard for recommended methods of analysis and sampling (Codex STAN 234-1999) lists AOAC 2002.02 as well as many other methods of analysis of dietary fibre components consistent with the Codex definition of dietary fibre (Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985).

The design of AOAC 2002.02 aims to accurately measure resistant starch to produce results as close as possible to *in vivo* resistant starch results from ileostomy patients, by using enzymes and incubation conditions that simulate physiological conditions. AOAC 2002.02 can reliably measure resistant starch as well as non-resistant starch and total starch, and detect all resistant starch subtypes to some extent.

The extent to which the Code's total dietary fibre methods and AOAC 2002.02 measure resistant starch will be markedly influenced by the distribution of (non-resistant) starch and resistant starch in the food. Many diagrammatic representations in the literature indicate about 75% of resistant starch is measured as dietary fibre by the Code's (older) total dietary fibre methods—AOAC 985.29 and AOAC 991.43. One study of a limited range of foods and ingredients quoted in SD1 indicated about 2–70% of resistant starch was measured. Thus when determining total dietary fibre there is potential for double counting of the resistant starch content, if more than one MoA (including AOAC 2002.02) is used and depending on the composition of the food. However, this issue is addressed by subsection S11—4(3). It provides that, where 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 adding together the results from each method of analysis; and subtracting any portion of dietary fibre which has been included in the results of more than one method of analysis.

FSANZ's assessment concludes AOAC 2002.02 is appropriate as a prescribed regulatory method for measuring resistant starch as a component of dietary fibre. It is internationally recognised, and widely used as a suitable regulatory method; it is accurate and reliable for foods containing a wide range of resistant starch content.

2.2 Risk Management

Based on the assessment outlined above and in SD1, FSANZ considers inclusion of AOAC 2002.02 as a new MoA, specifically for resistant starch in section S11—4 of the Code, is appropriate. Inclusion of the MoA in section S11—4 recognises resistant starch as a specific type of dietary fibre and establishes the MoA as a suitable regulatory method for it.

Inclusion of this new MoA in section S11—4 would mean that, if specifically declared in a nutrition information panel of a food label (as a sub-group nutrient of dietary fibre), the quantity of resistant starch would be required to be measured using the prescribed MoA. In accordance with the prescribed format for nutrition information panels (section S12—3), the entry for resistant starch in the nutrition information panel would be required to be indented below the heading 'Dietary fibre, total' (refer to section 1.3 above).

³ AOAC 985.29 Total Dietary Fiber in Foods

⁴ AOAC 991.43 Total, Soluble and Insoluble Dietary Fiber in Foods

⁵ AOAC 2001.03 Dietary Fiber containing Supplemented Resistant Maltodextrin

When resistant starch is specifically declared in the nutrition information panel (as a sub-group nutrient of dietary fibre), it is intended that the quantity of resistant starch (and any other specifically named dietary fibre(s)) be included in the total quantity of dietary fibre declared⁶. As a result, the value given for 'Dietary fibre, total' would be expected to be equal to, or more than, the total of any specifically named dietary fibres in the nutrition information panel, depending on the types of dietary fibre present. This approach aims to avoid the possibility of the total dietary fibre declared being less than the amount of any one specifically named dietary fibre or less than the sum of the specifically named dietary fibres, as this could create confusion for consumers.

If resistant starch is not specifically declared in the nutrition information panel, the amount of resistant starch measured could still be included in the total quantity of dietary fibre declared. In this case, the Code currently 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. This approach is retained under the draft variation. It provides flexibility for the food supplier to decide how best to determine total dietary fibre (by choosing which prescribed method(s) of analysis to use) according to the food. For example, they may choose not to use the specific resistant starch MoA if they are aware that there is no significant resistant starch present in a food.

Including the specific MoA for resistant starch will potentially enable determination of an increased dietary fibre content (compared to the methods currently in section S11—4). This may increase the number of foods that meet Code requirements, including the NPSC, either for making voluntary nutrition content and health claims or, in the case of breakfast cereals, for being fortified with vitamin D.

As stated above, the current methods for analysing total dietary fibre in paragraphs S11—4(2)(a) and (b) measure some, but not all, resistant starch in a food (see SD1). In this case, resistant starch quantified by AOAC 2002.02 must not be summed with the results of any of the total dietary fibre methods without adjustment for double counting of resistant starch, to obtain a better estimate of dietary fibre. As mentioned above, requirements to ensure that the quantity of the specifically named dietary fibre(s) is not double counted in the quantity of dietary fibre declared, are already included in the Code (subsection S11—4(3)).

Attachment A provides the proposed draft variation to the Code.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The call for submissions for this Application has been notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified via email.

FSANZ acknowledges the time taken by individuals and organisations to make submissions. Every submission on an application is reviewed by FSANZ staff and considered by the FSANZ Board. While not all comments may be adopted, all are valued and contribute to the rigour of our assessment.

⁶ As indicated by the prescribed format for the nutrition information panel in S12—3 and associated notes.

2.3.2 World Trade Organization (WTO)

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

As noted in section 1.3 above, the permitted methods of analysis in section S11—4 are all established as official methods of AOAC International.

Therefore, amending the Code to include the MoA for resistant starch (AOAC 2002.02) is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ is required to consider the impact of regulatory and non-regulatory options on all sectors of the community. In July 2017, the Office of Best Practice Regulation (the OBPR) has advised that, based on the information provided, the proposed changes that would arise from Application A1142 are of a minor nature and no further analysis in the form of a Regulation Impact Statement is required for this Application (OBPR reference ID 22576).

However, FSANZ has undertaken a limited qualitative impact analysis, commensurate to the nature of the Application and significance of the impacts. The declaration of resistant starch on a food label is voluntary. That is, it is required only if a certain type of nutrition content or health claim is made in relation to the resistant starch in a food. However, if resistant starch is specifically declared as a sub-group nutrient of dietary fibre, food suppliers must use the new MoA for resistant starch (AOAC 2002.02) to determine the quantity of the resistant starch in the food.

Industry will use the proposed new method only if it provides them with a benefit. For manufacturers the new method will:

- provide a new reliable, internationally recognised MoA for more accurately measuring the amount of RS in a food
- enable RS to be identified and declared as a specific dietary fibre on a label
- enable the RS content to be included in the total dietary fibre value and therefore increase the amount of dietary fibre declared on a label.

These opportunities would all be of benefit to the food industry. Any additional costs of analysing resistant starch would be at the discretion of the food supplier.

Consumers would potentially benefit from more information about resistant starch as a dietary fibre, and more accurate information about the dietary fibre content of a food containing resistant starch.

For government enforcement agencies, more clarity, accuracy and reliability for labelling compliance purposes would be provided, if resistant starch is specifically declared (as a sub-group nutrient of dietary fibre), based on a listed regulatory MoA.

Therefore, a net benefit will most likely be achieved from the proposed variation to the Code.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

Requiring AOAC 2002.02 as a MoA specifically for resistant starch in the Code would not adversely affect the health and safety of Australian or New Zealand populations.

2.4.2.2 The provision of adequate information to enable consumers to make informed choices

If resistant starch were to be declared as a specific dietary fibre in a nutrition information panel on a food label, the prescribed MoA would be consistently required to be used by food suppliers ensuring that accurate and reliable information is provided to consumers to enable them to make informed choices.

2.4.2.3 The prevention of misleading or deceptive conduct

Approving the addition of the new MoA to the Code means that an internationally recognised, accurate and reliable method is required to be used, if resistant starch is to be declared as a specifically named dietary fibre in a nutrition information panel on a food label. This would help to prevent misleading or deceptive declarations with respect to resistant starch.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has considered both the evidence provided by the Applicant and other scientific literature identified by FSANZ to assess this Application. See SD1.

- **the promotion of consistency between domestic and international food standards**

The AOAC 2002.02 method is widely used internationally, and is the only method for resistant starch in the Codex list of recommended methods.

- **the desirability of an efficient and internationally competitive food industry**

The use of an internationally recognised, accurate and reliable method for measuring the amount of resistant starch in a food would support efficiency and competition.

- **the promotion of fair trading in food**

Prescribing AOAC 2002.02 in the Code would promote fair trading in food. Please see above comments in relation to the protection of public health and safety; provision of information; and prevention of misleading or deceptive conduct.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are no specific policy guidelines that apply to this Application.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1142 – Addition of Prescribed Method of Analysis for Resistant Starch) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1142 – Addition of Prescribed Method of Analysis for Resistant Starch) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 11 is varied by omitting paragraph S11—4(2)(e), substituting

- (e) for polydextrose—section 2000.11;
- (f) for resistant starch—section 2002.02.

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1142 which seeks to amend the Code to include a method of analysis (MoA) for determining the quantity of resistant starch i.e. a specific type of dietary fibre, in food. The Applicant, Ingredient, requests the addition of AOAC⁷ Official Method 2002.02 (Resistant starch in Starch and Plant Materials).

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The draft variation to the Code prescribes the MoA to be used to measure the amount of resistant starch in food for the purposes of subsections 1.2.8—7(7) and S5—6(2) of the Code i.e. AOAC Official Method 2002.02.

Section S11—4 contains the prescribed MoAs for determining the dietary fibre content of a food, including certain specifically named fibres. Declarations of dietary fibre in a nutrition information panel must be determined in accordance with section S11—4 (see subsection 1.2.8—7(7)).

Currently, there is no specific MoA prescribed for resistant starch in section S11—4. The current MoAs for analysing total dietary fibre in the Code measure some but not all resistant starch in a food and the amount measured depends on the food matrix. Those methods do not distinguish resistant starch from other forms of dietary fibre present in the food.

The draft variation requires food suppliers to use AOAC 2002.02 to specifically determine the quantity of resistant starch in a food in accordance with section S11—4 if resistant starch is to be specifically declared as a sub-group nutrient of dietary fibre in a nutrition information panel on a food label.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1142 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

⁷ **AOAC** means the *Official Methods of Analysis of AOAC International*, eighteenth edition, 2005, published by AOAC International, Maryland USA.

The Office of Best Practice Regulation (OBPR) has advised that, based on the information provided, the proposed changes that would arise from this Application are of a minor nature and no further analysis in the form of a Regulation Impact Statement is required (see OBPR reference ID 22576).

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] of the draft variation amends section S11—4 by adding a MoA to be used specifically for measuring the quantity of resistant starch in food i.e. method AOAC 2002.02.