

20 March 2018 [41-18]

Approval report – Application A1142

Addition of a prescribed method of analysis for resistant starch

FSANZ 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 resistant starch, and prepared a draft food regulatory measure.

On 20 October 2017, FSANZ sought submissions on the draft variation and published an associated report. FSANZ received seven submissions, and one late comment.

FSANZ approved the draft variation on 8 March 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 14 March 2018.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

| EXECUTIVE SUMMARY | | | | | | | |
|-------------------|--------------------------------------|--|---|--|--|--|--|
| | 1.1 | THE APPLICANT | 3 | | | | |
| | 1.2 | THE APPLICATION | 3 | | | | |
| | 1.3 | THE CURRENT STANDARD | 3 | | | | |
| | 1.4 | REASONS FOR ACCEPTING THE APPLICATION | 4 | | | | |
| | 1.5 | PROCEDURE FOR ASSESSMENT | 4 | | | | |
| - | 1.6 | DECISION | 4 | | | | |
| 2 | SUM | MARY OF THE FINDINGS | 4 | | | | |
| | 2.1 | SUMMARY OF ISSUES RAISED IN SUBMISSIONS | 4 | | | | |
| | 2.2 | RISK ASSESSMENT | 7 | | | | |
| | 2.2.1 | Resistant starch as dietary fibre, as defined in the Code | 7 | | | | |
| | 2.2.2 | AOAC 2002.02 as a regulatory method of analysis | 7 | | | | |
| | 2.3 | RISK MANAGEMENT | 8 | | | | |
| | 2.4 | RISK COMMUNICATION | 9 | | | | |
| | 2.4.1 | Consultation | 9 | | | | |
| | 2.3.2 | World Trade Organization (WTO) | 9 | | | | |
| | 2.5 | FSANZ ACT ASSESSMENT REQUIREMENTS | 0 | | | | |
| | 2.5.1 | Section 29 1 | 0 | | | | |
| | 2.5.2 | 2. Subsection 18(1) 1 | 1 | | | | |
| 3 | VARI | ATION TO THE CODE1 | 2 | | | | |
| | Аттасни | MENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE | 3 | | | | |
| 1 | ATTACHMENT B – EXPLANATORY STATEMENT | | | | | | |

Supporting document

The <u>following document</u> 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 sought 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 of the Code 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 'dietary fibre'. FSANZ's assessment concluded 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 on a food label. Including the prescribed MoA, as requested, means that food suppliers will 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.

Section S12—3 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'. Moreover, if the quantity of resistant starch is specifically declared, that quantity should be included as part of the total quantity of dietary fibre declared. This is to avoid causing confusion for consumers. Section S11—4 currently includes requirements to avoid double counting of dietary fibre when more than one method of analysis are used.

FSANZ's assessment concluded 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 specifically measuring resistant starch in the Codex list of recommended methods. The method applies 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 approved a draft variation to amend section S11—4 to include AOAC 2002.02 as a new MoA, specifically for resistant starch. Prescribing this MoA provides 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.

Introduction

1.1 The Applicant

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

1.2 The Application

The Application sought to amend section S11—4 of the *Australia New Zealand Food Standards Code* (the Code) to include a specific method of analysis (MoA) for resistant starch as a specifically named dietary fibre in the section's list of prescribed MoAs. The MoA is AOAC¹ Official Method 2002.02² – Resistant starch in starch and plant materials. Ingredion considered that this method was needed to accurately analyse resistant starch in food products to enable declaration in the nutrition information panel on a food label, as a type of dietary fibre. This would distinguish resistant starch from other forms of dietary fibre present in a food. They noted that AOAC 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. This definition captures a broad range of dietary fibres, including 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. These 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; 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 indented below the heading 'Dietary fibre, total' (section S12—3). If a relevant nutrition content or health claim is made about of 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 and Schedule 4.

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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related 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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Seven submissions (and one late comment) were received including, four from food industry, two from government agencies and one from a health professional organisation. All supported amending the Code as proposed, although some issues were raised for consideration. The issues raised are summarised in the following table.

Table 1: Summary of issues raised in submissions

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|--|-------------------------------|---|
| Refers to FSANZ conclusion that resistant starch fulfils the definition of dietary fibre, and draws attention to a current evidence review for 'Replacement of digestible starch with resistant starch in a meal promotes modulation of blood glucose". MPI is aware that FSANZ is considering the EU claim about resistant starch and post-prandial blood glucose rise. Suggests an update on this work be provided. | MPI | The definition of dietary fibre in the Code (see 2.2.1) includes a requirement that dietary fibre promotes one or more of the following beneficial physiological effects: (<i>i</i>) laxation, (<i>ii</i>) reduction in blood cholesterol, (<i>iii</i>) modulation of blood glucose. FSANZ's assessment determined that RS has a positive impact on laxation, as well as modulation of blood glucose (see 2.2.1). Therefore, resistant starch satisfies two of the beneficial physiological effects required to meet the definition of dietary fibre. As indicated on the FSANZ website, FSANZ expects to complete the systematic review about a food health relationship between resistant starch and post-prandial blood glucose rise shortly. |
| MPI noted that some (possibly commercial in confidence) appendices are missing from A1142 on the FSANZ website including the data sheet for Hi-Maize. | MPI | Appendices were inadvertently omitted from the FSANZ website when the main Application document was posted. Some appendices are commercial in confidence, including Appendix 3 (Hi-Maize product data sheet). The non-CCI appendices were placed on the website on 11 December 2017. Submitters were advised and invited to provide further comment if they wished. No further comment was received. |
| A permission to add a dietary fibre is not necessarily conferred by the method of analysis as some forms of dietary fibre might be novel or nutritive and therefore require a premarket assessment by FSANZ. | MPI | FSANZ agrees that a MoA is not a permission to add a dietary fibre i.e. a MoA recognises the presence of dietary fibre in a food and measures the quantity present. |
| To determine an equation for double counting is not simple – there are five different types of resistant starch, of which the amount of fibre captured in the standard dietary fibre method (AOAC 985.29) may vary significantly. A possible solution would be to declare resistant starch as a subgroup of insoluble fibre if declared in the NIP. | Kelloggs (Aust) Pty Ltd | Declaration of soluble and insoluble dietary fibre is not specifically mentioned in the Code. See below. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|--|-------------------------------|--|
| If all subgroups of dietary fibre are listed in the NIP, (insoluble, soluble and resistant starch) the sum of dietary fibre content should be the sum of these subgroups declared. This is based on the assumption that adjustments are made for double counting and soluble fibre is determined by difference. | Kelloggs (Aust) Pty Ltd | The declaration of dietary fibre (including soluble and insoluble fibre) must be determined in accordance with the prescribed methods in S11—4. AOAC 991.43 is the only one of the three methods currently listed in the Code that requires analysts to measure and report insoluble (IDF) and soluble fibre (SDF). Any resistant starch captured by that method would be found only in the IDF fraction. However, AOAC 991.43 may underestimate total resistant starch. If resistant starch was then measured by the new approved method, the values could show a higher level of RS than IDF, depending on the presence of other types of IDF. |
| Notes that allowing a new quantification level may have broader effects i.e. more products may pass the NPSC and be eligible to make claims and may be able to obtain a higher Health Star Rating without any reformulation. DAA recommends such broader effects be considered. | DAA | FSANZ previously acknowledged this point (see section 2.3). The effects of including more resistant starch in the total dietary fibre amount and its subsequent impact on the NPSC will affect only fibre containing food and depend on how much resistant starch was initially included in the total dietary fibre amount before approval of the new method. |
| Recommends this is an opportunity for a broader review of total dietary fibre assessment. Consider adopting a newer and complete MoA such as Rapid Integrated Fibre method while phasing out older inferior methods. | DAA | A broader review of total dietary fibre assessment is outside scope of this Application. FSANZ understands there is stakeholder interest in applying for the Rapid Integrated Fibre method in the Code. |

2.2 Risk assessment

2.2.1 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.

When assessing the Application, it was 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 concluded that the evidence provided by the Applicant and other scientific literature reviewed 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.

2.2.2 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).

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

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 is 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 in the diet 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 concluded that 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.

2.3 Risk management

Based on the assessment outlined above and in SD1, FSANZ considers including AOAC 2002.02 as a new MoA, specifically for resistant starch in section S11—4, is appropriate. Including 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 measuring it.

Including this new MoA in section S11—4 means 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 must be measured using the prescribed MoA. In accordance with the prescribed format for nutrition information panels (see section S12—3), the entry for resistant starch in the nutrition information panel will be required to be indented below the heading 'Dietary fibre, total' (refer to section 1.3 above).

When resistant starch is specifically declared in the nutrition information panel (as a subgroup 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, 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.

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

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 when MoA AOAC 2002.02 is included in the Code. This 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 sets out the approved draft variation to the Code.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ acknowledges the time taken by individuals and organisations who made submissions. Every submission 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.

2.4.2 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 when a 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 under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 **FSANZ** Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The direct and indirect benefits that will arise from amending the Code as a result of this Application outweigh the costs to the community, government or industry that would arise from the variation.

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) advised that, based on the information provided, the proposed changes that would arise from Application A1142 are of a minor nature and that no Regulation Impact Statement was required for this Application (OBPR reference ID 22576). However, FSANZ undertook 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, but is required if a 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 (and % Daily Value for dietary fibre⁷) declared on a label.

These opportunities provide a benefit the food industry. Any additional costs of analysing resistant starch will be at the discretion of the food supplier.

Consumers will 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 will be provided, if resistant starch is specifically declared (as a subgroup nutrient of dietary fibre), based on a specific regulatory MoA listed in the Code.

Therefore, a net benefit to the community is expected to be achieved from the variation to the Code.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more costeffective than the food regulatory measure resulting from Application A1142.

⁷ The daily reference value (section 1.2.8-8) for dietary fibre includes resistant starch.

2.5.1.3 Any relevant New Zealand standards

There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

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

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

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

2.5.2.3 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 must 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 will help prevent misleading or deceptive declarations with respect to resistant starch.

2.5.3 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 risk assessment was based on the best scientific evidence available to FSANZ. 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 specific 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 will 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 formulated by the Ministerial Forum on Food Regulation that apply to this Application.

3 Variation to the Code

The approved draft variation to the Code is at Attachment A and will 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. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement

Attachment A – Approved 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 the Delegate]

[Name and position title of the Delegate responsible for A1142] 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 – 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 sought an amendment to the Code to permit the use of a method of analysis (MoA) for determining the quantity of resistant starch as a specific type of dietary fibre in food. The method was AOAC⁸ 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 approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority approved the variation to section S11—4 of the Code to prescribe AOAC Official Method 2002.02 as a 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.

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)).

At present, section S11—4 does not include a specific MoA for resistant starch. 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 approved draft variation will mean that food suppliers must use AOAC 2002.02 to determine the quantity of resistant starch in a food in accordance with section S11—4 if resistant starch is to be declared specifically as a sub-group nutrient of dietary fibre in a nutrition information panel on a food label.

⁸ **AOAC** means the *Official Methods of Analysis of AOAC International*, eighteenth edition, 2005, published by AOAC International, Maryland USA.

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. Submissions were called for on 20 October 2017 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation of section S11-4 is likely to have a minor impact on business and individuals.

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 inserting into subsection S11—4(2) the words 'for resistant starch—section 2002.02'.

Subsection S11—4(4) provides that this reference to section 2002.02 is a reference to section 2002.02 of the *Official Methods of Analysis of AOAC International*, eighteenth edition, 2005, published by AOAC International, Maryland USA. Section 2002.02 of that publication describes a method of analysis for resistant starch.

The effect of the amendment is to prescribe that method as a method for determining the amount of resistant starch in food for the purposes of subsections 1.2.8-7(7) and S5-6(2) of the Code.