21 May 2021
156-21

Call for Submissions

A1178 – AOAC 2017.16 as a new method of analysis for total dietary fibre

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Grains and Legumes Nutrition Council of Australia to permit a new voluntary method of analysis for total dietary fibre (AOAC 2017.16) 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) 22 June 2021

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 documents which informed the assessment of this application are available on the FSANZ website:

SD1	Risk and technical assessment report
SD2	Assessment of galacto-oligosachardies against three beneficial physiological effects

Executive summary

This application by the Australian Grains and Legumes Nutrition Council (GLNC) seeks to amend section S11—4 of the Australia New Zealand Food Standards Code (the Code) to permit *AOAC Method 2017.16 - Rapid Integrated Total Dietary Fibre Method* (AOAC 2017.16), as a new method of analysis for measuring total dietary fibre[1] content in food and food ingredients. Currently, section S11—4 of the Code prescribes three methods for analysing total dietary fibre and four methods for analysing certain specifically named fibres.

Method of analysis AOAC 2017.16 has been assessed by FSANZ. Consideration was given to AOAC 2009.01 because it is the predecessor method to AOAC 2017.16. AOAC 2009.01 is not permitted in the Code but is accepted as a method of analysis for total dietary fibre by Codex and countries comparable to Australia and New Zealand such as Canada, the United States and European Union. Codex is currently considering replacing AOAC 2009.01 with AOAC 2017.16. FSANZ's assessment found the method AOAC 2017.16:

- is more comprehensive than older methods in the Code for measuring total dietary fibre
- has a similar level of precision compared to older methods in the Code for total dietary fibre (AOAC 985.29, 991.43 and 2001.03)
- has good recovery (mean recovery of 97.4% from 7 samples)
- avoids the need to account for the double counting of specific dietary fibre fractions if total dietary fibre is measured by two or more methods
- has an incubation temperature that matches physiological conditions (37°C) and incubation time (4 h) that, compared with existing methods, aligns closer to conditions for the digestion of dietary fibre in the small intestine
- has substantially increased enzyme levels (compared to AOAC 985.29, 991.43 and 2009.01) so that the resistant starch values are in line with those seen in AOAC 2002.02 and underestimation of fructo-oligosaccharide and overestimation of resistant maltodextrin seen in AOAC 2009.01 are resolved.

AOAC 2017.16 detects non-digestible oligosaccharides, galacto-oligosaccharides (GOS) and isomalto-oligosaccharides (IMO), which were given further consideration as part of assessing this application A1178. Other fractions measured by AOAC 2017.16 are also measured by other methods of analysis permitted by the Code (two measuring total dietary fibre and four measuring specifically named dietary fibre). Another method of analysis permitted by the Code for determining total dietary fibre (including resistant maltodextrins), AOAC 2001.03, detects low molecular weight dietary fibre; GOS and IMO are picked up in this fraction.

FSANZ's assessment concluded GOS in any form does not meet all criteria for the Code's definition of dietary fibre. Based on available information suggesting levels of IMO in the Australian and New Zealand food supply are lower than GOS, FSANZ has not considered IMO in relation to meeting the requirements of the Code's dietary fibre definition as part of this application A1178.

FSANZ considered three risk management options for this application A1178:

1. Maintain the status quo by not permitting AOAC 2017.16 as a dietary fibre method of analysis.
2. Permit AOAC 2017.16 as a dietary fibre method of analysis with restrictions against its use on foods containing GOS and IMO.

[1] All references in this report to 'dietary fibre', which are made in relation to requirements in the Code, are references to 'dietary fibre' as defined by the Code (unless specified otherwise). 'Total dietary fibre' refers to the value measured by one or more specified method of analysis, values may be higher or lower depending on method used.

3. Permit AOAC 2017.16 without restriction.

A considerable overestimation of total dietary fibre by methods of analysis could alter food composition data, dietary fibre values on nutrition information panels (NIP), and the determination of fibre points (F points) for the purpose of determining the nutrient profiling scoring criterion (NSPC).

FSANZ sought to quantify any potential overestimation of total dietary fibre on GOS-containing foods analysed using AOAC 2017. This would indicate if consumers' ability to make informed choices around dietary fibre would be adversely impacted by permitting AOAC 2017.16. From limited data, naturally-occurring GOS appears to contribute about 3-6% of total dietary fibre in GOS-containing foods measured by AOAC 2017.16. FSANZ found that naturally-occurring GOS could increase total dietary fibre values in plant foods on average by 0.85 g/100g, and in dairy products by up to 0.6 g/100 g. Based on a survey undertaken by the applicant, GOS is not added to many general purpose foods in Australia or New Zealand (n=5).

FSANZ is proposing to amend section S11—4 to permit AOAC 2017.16 as a new voluntary method of analysis to determine total dietary fibre in food, without restrictions, for the following reasons:

- At present there is no single method of analysis that can comprehensively measure all low and high molecular weight dietary fibre. AOAC 2017.16 is the most comprehensive method FSANZ has assessed to date.
- AOAC 2017.16, like all methods of analysis, has limitations such as over or underestimation of dietary fibre. It is the role of manufacturers and analysts to understand what each method is best suited for, including any limitations, and apply them to food samples appropriately.
- This is the most proportionate response given the advantages of the method for analysing foods containing both high and low molecular weight dietary fibre.
- The low levels of GOS in the food supply would not considerably alter food composition data, NIPs for dietary fibre or F point scores for the NPSC, therefore it is likely consumers will still be provided with sufficient information to enable informed choices on dietary fibre in food products. IMO has not been assessed against the definition of dietary fibre, but as IMO is less prevalent that GOS the above can be inferred for IMO.
- This is the most proportionate response given the advantages of the method for analysing foods containing both high and low molecular weight dietary fibre.
- This is a voluntary method that enables innovation by industry to measure total dietary fibre by a single more comprehensive method and enforcement agencies will not be significantly impacted by a permission for an additional method of analysis.
- The potential overestimate of total dietary fibre from GOS when measured by AOAC 2017.16 is at least proportionate to the current underestimate of total dietary fibre from FOS and total fructans by AOAC 985.29 and 991.43 of about 4g/100g.
- Permitting AOAC 2017.16 more closely harmonises the analysis of dietary fibre with Codex and countries comparable to Australia and New Zealand such as the European Union, United States and Canada who have embraced newer methods of analysis such as AOAC 2009.01 for total dietary fibre analysis.

1 Introduction

1.1 The Applicant

The Grains and Legumes Nutrition Council (the applicant) is a not-for-profit organisation promoting the nutrition and health benefits of grains and legumes. The applicant's mission is to promote grains and legumes as part of a balanced diet through evidence-based information, while supporting the industry to benefit all Australians. This application was submitted by the applicant on behalf of its Australian member grains and cereal manufacturers.

1.2 The Application

In May 2019, the applicant applied to amend section S11—4 of the Australia New Zealand Food Standards Code (the Code) to permit *AOAC Method 2017.16 - Rapid Integrated Total Dietary Fibre Method* (AOAC 2017.16), as a new method of analysis for measuring total dietary fibre[2] content in a food and food ingredients. The method is listed in the Official Methods of Analysis of AOAC International, twenty first edition, 2019 (AOAC 2019). At time of application submission, AOAC 2017.16 had obtained AOAC 'first action' status (where the method was validated by an inter-laboratory evaluation).

The application seeks to permit AOAC 2017.16 as an additional method of analysis that captures total dietary fibre as defined by Standard 1.1.2 in the Code. AOAC 2017.16 is a single method measuring all dietary fibre components, which currently can only be measured by applying one method measuring total dietary fibre in combination with multiple other methods measuring specifically named dietary fibre[3] (such as fructans, polydextrose and resistant starch). The application highlights AOAC 2017.16 measures galacto-oligosaccharides (GOS), which FSANZ considered against the Code's definition of dietary fibre as part of its assessment.

The application presented 2019 cost data for use of analytical methods currently in the Code which indicated that AOAC 2017.16 is almost three times more expensive than AOAC 985.29 (i.e. $635 compared to $230 per food sample analysis, respectively). The applicant also indicated that the 2019 cost of AOAC 2017.16 was lower than the cumulative cost of applying a total dietary fibre method (for high molecular weight dietary fibre (HMWDF)) with two or more methods for a specifically named dietary fibre (often for low molecular weight dietary fibre (LMWDF) or resistant starch) to determine a total dietary fibre value that aligns with that analysed by AOAC 2017.16.

1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the following requirements in the Code.

1.3.1 Regulation of dietary fibre

Standard 1.1.2 – *Definitions* defines dietary fibre as follows:

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

[2] All references in this report to 'dietary fibre', which are made in relation to requirements in the Code, are references to 'dietary fibre' as defined by the Code (unless specified otherwise). 'Total dietary fibre' refers to the value measured by one or more specified method of analysis, values may be higher or lower depending on method used.

[3] The Code refers to 'dietary fibre' as total dietary fibre and 'specifically named dietary fibre' for individual fibre components.

(a) is resistant to digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and
(b) promotes 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.

Section S11—4 currently requires the use of one or more of the following AOAC methods[4] to determine total dietary fibre and any specifically named fibre for the purposes of declaring dietary fibre in the nutrition information panel (NIP) (subsection 1.2.8—7(7)) and for determining F points for the purpose of determining if a product meets the nutrient profiling scoring criterion (NPSC) (subsection S5—6(2)):

a) for dietary fibre— AOAC sections 985.29 or 991.43
b) for dietary fibre (including all resistant maltodextrins)— AOAC section 2001.03
c) for inulin and fructooligosaccharide— AOAC section 997.08
d) for inulin— AOAC section 999.03
e) for polydextrose— AOAC section 2000.11
f) for resistant starch— AOAC section 2002.02.

1.3.2 Labelling requirements for dietary fibre

Declaration 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. A declaration of the presence or absence of dietary fibre must be included in the NIP if a nutrition content or health claim is made about:

- dietary fibre;
- any specifically named dietary fibre;
- sugars; or
- any other type of carbohydrate (subsection 1.2.8—6(5)).

This declaration must be made in accordance with the relevant prescribed format for the NIP. The format allows for the declaration of any sub-group nutrient of dietary fibre indented below the heading ‘Dietary fibre, total’ (section S12—3).

Conditions for making nutrition content and health claims are in Standard 1.2.7 and Schedule 4. Schedule 4 sets out the amount of dietary fibre a food must contain to make a nutrition content claim about dietary fibre, for example, a food with a ‘contains dietary fibre’ claim must contain at least 2g of dietary fibre per serving of the food.

Schedule 4 also sets out the health claims that are permitted to be made about foods, subject to meeting specified conditions. In relation to dietary fibre or specifically named dietary fibres, a general level health claim may be made for dietary fibre (contributes to regular laxation) and a high level health claim and general level health claim are permitted for beta-glucan, a specifically named dietary fibre (reduces blood cholesterol and reduces dietary and biliary cholesterol absorption, respectively).

[4] The permitted methods in section S11—4 are all established as official methods of analysis by The Association of Official Analytical Collaboration (AOAC) International, which is a globally recognised, independent association that develops consensus standards in the area of analytical chemistry.

Foods carrying health claims must meet the NPSC (paragraph 1.2.7—18(1)(a)). Breakfast cereal must also meet the NPSC in order to contain vitamin D that has been added as a nutritive substance (see section 1.3.2—6). Determination of the dietary fibre content in accordance with section S11—4 is required to calculate Fibre points (F points) for the purpose of determining if a food meets the NPSC (section S5—6). If F points are relied on for a food to meet the NPSC, the dietary fibre must be declared in the NIP (see sections 1.2.7—26 and 1.3.2—7).

1.4 International standards

Codex revised its definition of dietary fibre and reviewed the range of methods of dietary fibre analysis in 2009 (Codex 2009). Regulatory definitions of dietary fibre vary in between countries and have evolved over time with the greater understanding of the composition of foods and the development of methods of analysis that can measure more complex food matrices (Jones 2013; McCleary et al. 2010;McCleary et al. 2012; Philips 2013; Stephen et al. 2017). Below we have considered dietary fibre definitions, and methods of analysis accepted by Codex and generally comparable countries to Australia and New Zealand such as the United States (US) and Canada, and the European Union (EU).

1.4.1 Codex

A revised Codex Alimentarius definition was first published in 2009.The General Guidelines on Nutrition Labelling (Codex 2017) current defines dietary fibre as:

> ***Dietary fibre*** means carbohydrate polymers[2] with ten or more monomeric units[3], which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:
>
> - Edible carbohydrate polymers naturally occurring in the food as consumed,
> - Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
> - Synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.
>
> [2] When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds associated with polysaccharides in the plant cell walls. These compounds also may be measured by certain analytical method(s) for dietary fibre. However, such compounds are not included in the definition of dietary fibre if extracted and re-introduced into a food.
>
> [3] Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

The full list of countries that include monomeric units 3-9 in their definition is unclear in the literature (Jones 2014; Stephen et al. 2017), however it appears that in addition to Australia and New Zealand, the US, Canada, the EU, China, Chile (for labelling but not for health claims), Japan and Korea all accept 3-9 monomeric units as dietary fibre.

The acceptance of a physiological effect of benefit to health (called a beneficial physiological effect in the Code) varies from country to country. Some of these include effects on cardiovascular health, blood pressure, blood lipids, type 2 diabetes mellitus, cancer, body weight/energy intake, and gastrointestinal health.

Methods of analysis

There are currently 15 permitted methods of analysis for dietary fibre under *Recommended methods of analysis and sampling* (Codex, 1999).

In late 2019, AOAC 2017.16 was referred to the Codex Committee on Methods of Analysis and Sampling for consideration as a Type I method to replace AOAC 2009.01, which is the predecessor to AOAC 2017.16 (CCNFSDU 2019; CCNFSDU 2020) but is not permitted in the Code.

1.4.2 United States

In 2016, the US Food and Drug Administration (US FDA) announced the Nutrition and Supplement Facts label 'final rule', which included a definition of dietary fibre and identified seven isolated or synthetic non-digestible carbohydrates as meeting the dietary fibre definition.

The US FDA defines dietary fibre as:

> Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

The following are examples (not exhaustive) of beneficial physiological effects accepted by the US FDA for isolated or synthetic dietary fibres. One or more of the following must be met:

- Lowering blood glucose
- Lowering cholesterol levels
- Lowering blood pressure
- Increase in frequency of bowel movements (improved laxation)
- Increased mineral absorption in the intestinal tract
- Reduced energy intake (for example, due to the fiber promoting a feeling of fullness).

Methods of analysis

Under their Code of Federal Regulations (21CFR101 Food Labeling) (FDA 2020), the US FDA prescribes AOAC methods of analysis in some instances for dietary fibre, however indicates if no method is prescribed, the analyst is to use an appropriate method for the respective sample.

1.4.3 Canada

In 2012, Health Canada defined dietary fibre as:

> 1. carbohydrates with a DP of 3 or more that naturally occur in foods of plant origin and that are not digested and absorbed by the small intestine; and
> 2. accepted novel fibres.
>
> Novel fibres are ingredients manufactured to be sources of dietary fibre and consist of carbohydrates with a DP of 3 or more that are not digested and absorbed by the small intestine. They are synthetically produced or are obtained from natural sources which have no history of safe use as dietary fibre or which have been processed so as to modify the

properties of the fibre contained therein. Accepted novel fibres have at least one physiological effect demonstrated by generally accepted scientific evidence.

For novel fibres, Health Canada recognises four physiological effects of dietary fibre. One or more effect(s) must be met:

- improving laxation or regularity by increasing stool bulk
- reducing blood total and/or low-density lipoprotein cholesterol levels
- reducing post-prandial blood glucose and/or insulin levels, or increasing sensitivity to insulin
- providing energy-yielding metabolites through colonic fermentation.

Methods of analysis

Methods of analysis accepted by Health Canada are aligned with those accepted by Codex. For total dietary fibre, AOAC 2009.01 is the most recently listed.

1.4.4 European Union

The European Commission (EU, 2011) defines fibre as:

Carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories:

- edible carbohydrate polymers naturally occurring in the food as consumed,
- edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence,
- edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence'.

Fibre must have one or more beneficial physiological effects; the recognised beneficial physiological effects listed by the European Commission (EC 2008) are:

- decrease intestinal transit time
- increase stool bulk
- is fermentable by colonic microflora
- reduce blood total cholesterol
- reduce blood LDL cholesterol levels
- reduce post-prandial blood glucose, or reduce blood insulin levels.

Methods of analysis

Methods of analysis accepted by the European Commission (EC 2012) are aligned with those accepted by Codex. For total dietary fibre, AOAC 2009.01 is the most recently listed.

1.5 Reasons for accepting the application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the Food Standards Australia New Zealand Act 1991 (FSANZ Act); and

- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the Assessment

2.1 Risk assessment

Based on best available scientific evidence, FSANZ considers AOAC 2017.16 is a suitable regulatory method for manufacturers seeking to analyse foods having a wide range of HMWDF and LMWDF because it:

- is more comprehensive than older methods in the Code for measuring total dietary fibre
- has a similar level of precision compared to older methods in the Code for total dietary fibre (AOAC 985.29, 991.43 and 2001.03)
- has good recovery (mean recovery of 97.4% from 7 samples)
- avoids the need to account for the double counting of specific dietary fibre fractions if total dietary fibre is measured by two or more methods
- has an incubation temperature that matches physiological conditions (37°C) and incubation time (4 h) that, compared with existing methods, aligns closer to conditions for the digestion of dietary fibre in the small intestine
- has substantially increased enzyme levels (compared to AOAC 985.29, 991.43 and 2009.01) so that the resistant starch values are in line with those seen in AOAC 2002.02 and underestimations of fructo-oligosaccharide and overestimation of resistant maltodextrin seen in AOAC 2009.01 are resolved.

AOAC 2009.01 is the predecessor method to AOAC 2017.16. Although AOAC 2009.01 is not permitted in the Code, it is currently accepted as a method of analysis for total dietary fibre by Codex and countries comparable to Australia and New Zealand such as Canada, the United States and European Union. However, Codex is currently considering replacing AOAC 2009.01 with AOAC 2017.16.

AOAC 2017.16 will measure the components of dietary fibre that are measured by methods of analysis currently permitted by the Code for total dietary fibre (i.e. 985.29, 991.43 and 2001.03) and for specifically named dietary fibres. An exception is galacto-oligosaccharides (GOS). AOAC 2017.16, if permitted, will include GOS in its calculation and measurement of total dietary fibre. FSANZ therefore considered whether GOS met the Code's definition of dietary fibre.

GOS has been found to meet certain criteria for the definition: fraction of the edible part of plants or their extracts, or synthetic analogues (naturally-occurring GOS in dairy foods does not meet this); resistance to digestion and absorption in the small intestine; usually partial or complete fermentation in the large intestine; the minimum degree of polymerisation (by virtue of analytical methods); and is not lignin.

The definition also requires that GOS meet at least one of three beneficial physiological outcomes: laxation; reduction in blood cholesterol; and/or modulation of blood glucose.

The body of evidence about the physiological effects of GOS only includes results from clinical trials which used synthetic analogues, not the natural forms, and shows that GOS does not affect the three beneficial physiological effects listed in the Code. Therefore, insofar as naturally occurring GOS is concerned, the physiological effects are inferred on the basis of structural similarities to synthetic analogues and extend from an indirect body of evidence

(i.e. synthetic analogues). Based on the best available scientific evidence FSANZ concludes GOS in any form does not meet all criteria for the Code's definition of dietary fibre.

The above means that AOAC 2017.16, if permitted, may result in a substance that is not dietary fibre (based on the Code's definition) being counted as dietary fibre for the purposes of Code requirements relating to health claims and nutrition information labelling (see section 1.3 above).That is, use of AOAC 2017.16 may result in an overestimate of total dietary fibre in GOS-containing foods.

Based on the best available data, most pulses, dairy and wheat products, some other cereals, nuts, seeds and few vegetables contain naturally occurring GOS. In plant foods, GOS contributes on average about 0.85 g/100 g edible portion total while in dairy foods, GOS contributes up to 0.6 g/100 g edible portion total measured by AOAC 2017.16. From limited data, naturally-occurring GOS appears to contribute about 3-6% of total dietary fibre in GOS-containing foods measured by AOAC 2017.16. Based on a survey undertaken by the applicant, GOS is not added to many general purpose foods in Australia or New Zealand (n=5).

Variability in total dietary fibre values currently exist when measured using methods of analysis permitted by the Code. For example:

- older method for total dietary fibre AOAC 985.29 does not accurately measure LMWDF or resistant starch components therefore total dietary fibre may potentially be underestimated for the purposes of food labels and in food composition databases.
- if a manufacturer uses a food database to determine total dietary fibre of a food containing LMWDF this might only have data from AOAC 985.29
- AOAC 2001.03 for total dietary fibre is used by industry and it measures GOS.

3 Risk management

3.1 Current use of dietary fibre methods of analysis permitted in the Code

Subsection 1.2.8—7(7) of the Code requires the declaration of dietary fibre on an NIP to be a declaration of dietary fibre determined in accordance with section S11—4.

Table 1 in Supporting Document 1 (SD1) outlines dietary fibre components measured by AOAC methods of analysis in the Code in subsection S11—4(2). Of note, AOAC methods 985.29 and 991.43 measure HMWDF, also known as non-starch polysaccharides. However, these methods do not measure the LMWDF such as FOS, GOS, resistant maltodextrins, or polydextrose; they partially measure inulin and resistant starch. Method AOAC 2001.03 (total dietary fibre and resistant maltodextrins) is currently used to analyse foods containing LMWDF (H. Salman, pers.com)[5].

To fully capture the dietary fibre content of a food, manufacturers and/or analysts must select the method(s) of analysis that most align with the dietary fibre composition of the food of interest. This requires knowledge of the types of naturally occurring and added dietary fibre sources or ingredients.

An Australian food laboratory provided data to FSANZ indicating methods AOAC 985.29 and 991.43 are currently most frequently used to measure the total dietary fibre in foods, often in combination with one or more methods of analysis for specifically named dietary fibres[6].

[5] H. Salman, Business Manager – Analytical Services, Australian Export Grains Innovation Centre (AEGIC), personal communication, 22 May 2020

[6] H. Salman, Business Manager – Analytical Services, Australian Export Grains Innovation Centre (AEGIC), personal communication, 16 March 2021

Alternatively, a manufacturer could use pre-existing values to calculate the dietary fibre content of a food. For example, the Australian Food Composition database is a widely consulted source of dietary fibre values in Australia, which are mostly obtained using the earliest approved method in the Code, AOAC 985.29.

When determining total dietary fibre by adding together the results obtained from two or more methods, there is potential for 'double counting' fractions that are analysed by those methods. This issue is addressed to some degree under 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 can be 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. To do this requires the double counted component in the total dietary fibre result to be measured separately to quantify the amount to be subtracted.

Use of a method of analysis may also depend on a manufacturer's desire (or otherwise) to make a dietary fibre nutrition content or health claim, or for other reasons required by the Code. With multiple methods available, different amounts of dietary fibre may be declared on labels of foods with similar composition depending on the method or data source used. This may lead to a variety of dietary fibre values on similar products in the market place. For food with LMWDF, the use of a single simpler method such as AOAC 985.29 or data from the Australian Food Composition database will not capture all possible dietary fibre components and so underestimate the total dietary fibre content as recognised by the definition of dietary fibre in the Code.

Identification of dietary fibre in the Australian Food Composition database

The FSANZ food composition program currently determines total dietary fibre using AOAC 985.29, or older equivalent methods, noting that these methods underestimate LMWDF. FSANZ would not actively replace total dietary fibre values in our Australian Food Composition database with AOAC 2017.16 values, as this would be impractical and costly. FSANZ would accept data for foods analysed with AOAC 2017.16 if available. Data received would be provided with unique component codes depending on methods of analysis used.

3.2 Detection of Isomalto-oligosaccharides as dietary fibre by permitted methods of analysis and AOAC 2017.16

As with GOS, there are already methods permitted by the Code that are detecting isomalto-oligosaccharides (IMO). During the assessment for this application A1178, FSANZ noted IMO were identified as non-digestible oligosaccharides (NDO) measured as dietary fibre by AOAC 2017.16 (Codex 2021), AOAC 2001.03 (based on scientific literature) and AOAC 985.29 and 991.43 (McCleary and Cox 2017).

FSANZ sought to quantify levels of IMO in the Australian and New Zealand food supply. Naturally occurring IMO with a degree of polymerisation (DP)[7] 3-9 is found in fermented foods such as sourdough bread, kimchi, miso, sake, and soy sauce. FSANZ identified one reported value for naturally occurring levels of IMO in sake (Japanese alcoholic drink), which contained IMO with a DP 3 or more at levels of 0.112-0.234 g/100g (Hayakawa et al. 2000).

IMO can also be synthetically produced through the enzymatic hydrolysis of starch. FSANZ is not aware of many foods containing synthetically produced IMO in Australia and New

[7] The degree of polymerisation, or DP, is the number of single monosaccharide units in the carbohydrate molecule

Zealand, however note that IMO are permitted as novel foods in the Code[8] for use as an alternative (lower energy) sweetener and bulk filler in a range of foods such as carbonated beverages, sports and energy drinks, soy drinks, milk-based drinks, milk-based and non-milk-based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionery. Unlike GOS, IMO is not permitted for use in infant formula products, infant food and formulated supplementary foods for young children. (FSANZ 2016; FSANZ food composition database). FSANZ considered most of the above food products would not be best suited for analysis using AOAC 2017.16 unless they contained complex mixtures of LMWDF and HMWDF, and note there is little use in analysing products with methods of analysis where dietary fibre is added in pre-quantified levels.

FSANZ concluded that compared to GOS, there are even fewer foods containing naturally occurring IMO with a DP 3-9 in the Australian and New Zealand food supply, and foods containing added synthetic analogues of IMO less likely to be analysed using AOAC 2017.16. Given this, FSANZ has not considered IMO in relation to meeting the requirements of the Code's dietary fibre definition as part of this application A1178, and considered it appropriate to apply any risk management approach for GOS to IMO, with regards to considering permissions for use for AOAC 2017.16.

3.3 Risk Management options

As AOAC 2017.16 measures GOS of any form, which do not meet all criteria for the Code's definition of dietary fibre, FSANZ considered three risk management options during the assessment of this application A1178:

1. Maintain the status quo by not permitting AOAC 2017.16 as a dietary fibre method of analysis.
2. Permit AOAC 2017.16 as a dietary fibre method of analysis with restrictions against its use on foods containing GOS and IMO.
3. Permit AOAC 2017.16 without restriction.

In considering these options, FSANZ notes that AOAC 2001.03, a method of analysis already permitted in the Code, also measures GOS. FSANZ notes any risk management approach could justifiably be applied to IMO, which are not as prevalent in the Australian and New Zealand food supply as GOS.

FSANZ also considered the Code's definition of dietary fibre against those of countries comparable to Australia and New Zealand, such as the US, Canada and the EU, noting some included additional beneficial physiological effects not listed in the Code's definition. Having noted differences between the Code's definition and those of the other countries, FSANZ concluded that amending the Code's definition of dietary fibre would require further assessment and is beyond the scope of this application A1178.

Option 1 – not permit AOAC 2017.16 as a dietary fibre method of analysis

The risk assessment conclusions in SD1 found that AOAC 2017.16 was a suitable method of analysis for total dietary fibre, and has some advantages compared to current total dietary fibre methods of analysis in the Code. It provides a single, more comprehensive method to determine total dietary fibre for foods containing a complex mixture of HMWDF and LMWDF. It is less cost-effective but still suitable for use on samples containing only HMWDF and/or individual specifically named dietary fibres.

As part of assessing this application A1178, FSANZ considered if GOS in any form met the Code's definition of dietary fibre and concluded that it does not meet all criteria (specifically, it

[8] See A1123 – Isomalto-oligosaccharide as a Novel Food on the FSANZ website

does not promote one or more of the three listed beneficial physiological effects). During the assessment, FSANZ also noted the method detects IMO. Based on the low prevalence of naturally occurring IMO in the food supply and the types of foods with added synthetic analogues of IMO, further assessment of IMO was not considered necessary (see section 3.2 above). These were the only shortcomings that FSANZ identified in terms of permitting AOAC 2017.16.

AOAC 2017.16 was developed with the Codex definition of dietary fibre as its focus which, as discussed in Section 1.4.1, does not prescribe accepted beneficial physiological health effects and instead allows for each regulatory body to determine and specify these. Therefore, not all components measured by the method will align with every country's definition of dietary fibre. GOS is recognised as a dietary fibre in some countries comparable to Australia and New Zealand based on beneficial physiological effects that are not listed in the Code (such as Canada through the *provision of energy-yielding metabolites through colonic fermentation* and the US through the *promotion of calcium absorption*). FSANZ considered it beyond the scope of this application A1178 to assess whether the definition of dietary fibre should be amended to include any of the beneficial physiological effects for which GOS has been recognised overseas as a dietary fibre.

Rejecting AOAC 2017.16 on the basis it measures GOS and IMO as dietary fibre (noting, FSANZ has not assessed IMO against the Code's dietary fibre definition) would not fully address any potential overestimation of total dietary fibre from these oligosaccharides in food databases, on NIPs or towards F points for the NPSC because AOAC 2001.03, which also measures GOS and IMO, would still be in the Code. Removal of AOAC 2001.03 from the Code, which FSANZ understands may be used by industry, on the ground that it potentially results in an overestimation of total dietary fibre is not within scope for this application A1178. The risk assessment on GOS levels in the food supply found that any overestimate in values measured from AOAC 2017.16 for total dietary fibre in foods containing GOS is at least proportionate to the current underestimate of total dietary fibre from older, less comprehensive methods in the Code (up to 4g/100g). The low levels of GOS in the food supply would not considerably change many NIPs or the NPSC for many products, and therefore it is unlikely consumers will be misled into choosing one food over another. Consumers will still be provided with sufficient information to enable informed choices on the dietary fibre content of food. Naturally occurring IMO are even less prevalent in the food supply than GOS, and synthetic analogues of IMO appear to be added to products that are not best suited to the analysis with AOAC 2017.16.

Permitting AOAC 2017.16 in the Code, noting it is better suited to use on foods containing more complex dietary fibre mixtures from both HMWDF and LMWDF, has advantages that outweigh the actual impact of any potential measurement of GOS and IMO as dietary fibres.

Conclusion

Option 1 is not preferred and is considered a disproportionate response because:

- At present there is no single method of analysis that can comprehensively measure all low and high molecular weight dietary fibre. AOAC 2017.16 is the most comprehensive method FSANZ has assessed to date.
- AOAC 2017.16, like all methods of analysis, has limitations such as over or underestimation of dietary fibre. FSANZ considers the actual impact of the potential overestimation of total dietary fibre values in the small number of GOS-containing foods measured with AOAC 2017.16 is acceptable because it is small. The same applies for IMO.
- This is a voluntary method that enables innovation by industry to measure total dietary fibre by a single more comprehensive method.

Option 2 – Permit AOAC 2017.16 as a dietary fibre method of analysis with restrictions against its use on foods containing galacto-oligosaccharides and/or isomalto-oligosaccharides

In order to maintain consistency with the Code's definition of dietary fibre, FSANZ considered permitting AOAC 2017.16 except on those food products containing naturally occurring or added synthetic GOS and IMO. FSANZ notes that if this option were to proceed it would require an impact assessment and consultation around imposing a similar restriction on the currently permitted method AOAC 2001.03, as manufacturers may be currently using the method.

The proposed restriction would extend to food products with added GOS and any GOS-containing ingredients e.g. wheat flour, milk, legumes, and IMO-containing products such as carbonated beverages, sports and energy drinks, soy drinks, milk-based drinks, milk-based and non-milk-based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionery.

This would severely restrict the use of AOAC 2017.16 on foods containing certain LMWDF. Given these methods cannot separately identify values for individual LMWDF[9], if the presence of GOS or IMO was known or suspected, manufacturers and analysts would be required to adopt the current system of using multiple methods which is less comprehensive and efficient. Additionally, enforcement agencies would be required to enforce this by monitoring specific analytical methods used for total dietary fibre, and it would require extensive knowledge of food composition.

FSANZ sought to quantify a potential overestimation of reported total fibre in foods containing GOS and analysed using AOAC 2017.16. FSANZ's assessment of limited data on naturally occurring GOS in 32 plant foods and 6 dairy foods found that GOS could increase naturally occurring total dietary fibre values in plant foods on average by 0.85 g/100 g and up to 4 g/100 g; and in dairy products by up to 0.6 g/100 g. From further limited data, naturally occurring GOS appeared to contribute about 3-6% of total dietary fibre in GOS-containing foods measured by AOAC 2017.16. FSANZ's limited assessment on IMO suggested that IMO are even less prevalent in the Australian and New Zealand food supply than GOS.

FSANZ also considered prohibiting the use of AOAC 2017.16 on foods that contained added synthetic GOS only. Based on the findings in Section 4.4 of SD1, synthetic GOS is added to only a few general purpose foods made in Australia and no general purpose foods made in New Zealand. FSANZ sighted few products containing added GOS, however those observed listed 'galacto-oligosaccharide' itself on the NIP, rather than as 'dietary fibre'. FSANZ also considered the use of GOS in special purpose foods to be out of scope for this application A1178, as separate permissions have been granted in previous applications. FSANZ notes IMO, like GOS, are intended for use is some foods at pre-quantified levels and FSANZ's assessment of AOAC 2017.16 indicated this method would not be appropriate for use on most of these products.

FSANZ acknowledges that GOS and IMO are more commonly added to foods in other countries and some of these may be imported into Australia and New Zealand. That country must comply with labelling requirements for dietary fibre set out in the Code (including permitted methods of analysis), meaning some foods from overseas my contribute to any potential overestimate in total dietary fibre from GOS and IMO however FSANZ does not consider this will considerably impact consumers ability to make informed choices on foods around dietary fibre.

[9] AOAC 2017.16 cannot separately identify values for individual LMWDF, meaning the method cannot be used to determine GOS values alone. There is an AOAC method for determining GOS (AOAC 2002.02), however this is not permitted in the Code and it is for the analysis of trans-GOS only so would not detect naturally occurring GOS.

Conclusion

Option 2 is not preferred and is considered disproportionate because:

- The potential overestimate of about 3-6% total dietary fibre for GOS-containing foods measured using AOAC 2017.16 is at least proportionate to the current underestimate of total dietary fibre from the measurement of FOS and total fructans by older, less comprehensive methods in the Code AOAC 985.29 and 991.43.
- FSANZ has not identified any reason to treat IMO any differently with relation to AOAC 2017.16.
- General purpose foods identified by FSANZ as containing added GOS declare GOS as itself in the NIP, rather than dietary fibre.
- AOAC 2017.16 has advantages for foods containing a mixture of HMWDF and LMWDF - implementing a restriction of the method on such complex food matrices is unrealistic and disproportionate to the level of potential overestimation.
- This option would adversely impact industry and enforcement agencies as it requires prior knowledge of GOS and IMO content, and methods of analysis used on each food product. It is unlikely consumers would be able to make a more informed choice with this restriction.

Option 3 - Permit AOAC 2017.16 as a method of analysis for dietary fibre, without restrictions

This option provides a new permission for AOAC 2017.16, which is the most comprehensive method for total dietary fibre currently available, when compared to permitted total dietary fibre methods of analysis (AOAC 985.29, 991.43 and 2001.03), and its predecessor AOAC 2009.01. AOAC 201.16 is cost effective for foods containing both HMWDF and LMWDF compared to the use of older total dietary fibre methods (when used with additional specific dietary fibre methods for the LMWDF fraction). It also removes the issue of double counting when using multiple methods.

This option would allow industry to use AOAC 2017.16 without any restriction related to food containing GOS or IMO, as is currently the case with AOAC 2001.03. Unlike Option 2, enforcement agencies will not need to monitor foods for GOS and IMO content and methods of analysis used on these food products. Consumers will still be provided with enough information to make informed choices around dietary fibre values in food.

FSANZ is not aware of regulatory authorities in other countries who have assessed AOAC 2017.16 as a method of analysis, however the method's predecessor AOAC 2009.01 is currently accepted by Codex and other countries. It has recently been approved as 'final action' by the AOAC International (meaning it is validated and has support of an expert panel) and is under consideration by Codex to replace its predecessor AOAC 2009.01. Given this, it is expected that this method will be considered more broadly internationally into the future.

Conclusion

Option 3 is preferred because:

- There is already existing variability in dietary fibre values depending on the method(s) used or where the values are obtained from (i.e. food databases).
- It is the most proportionate response given the advantages of the method for analysing foods containing both HMWDF and LMWDF. Manufacturers and analysts should understand what each method is best suited for, including any limitations, and apply them to food samples appropriately.

- This is a voluntary method that enables innovation by industry to measure total dietary fibre by a single more comprehensive method.
- Enforcement agencies will not be impacted by this permission.
- It more closely harmonises the analysis of dietary fibre with Codex and comparable countries such as the EU, US and Canada who appear to be embracing newer methods of analysis.

3.4 Updating reference to the AOAC Official Methods of Analysis edition in the Code

To permit AOAC 2017.16 in the Code, it is also necessary to amend subsection S11—4(4), which currently only refers to the 18th edition of AOAC Official Methods of Analysis (2005), to refer instead to the 21st Edition (AOAC, 2019). An amendment is needed because the 18th edition does not include AOAC 2017.16.

FSANZ notes AOAC 2017.16 is available in the printed 21st edition (2019) as 'first action' status. The online 21st edition contains AOAC 2017.16 as 'final action'. FSANZ understands that future print revisions of the 21st edition (2019) will list AOAC 2017.16 as 'final action'.

In order to update the reference, it is important to know if any change to permitted methods had occurred between editions, and to assess the impact of these.

FSANZ has determined that the only change between editions occurred in 2013 and relates to AOAC 997.08 – inulin and FOS. The 18th edition allowed analysts the choice of either a two- or three-enzyme solution as part of the hydrolysis process. The two enzyme solution did not completely hydrolyse levan (i.e. a class of fructans) whereas the third solution more completely hydrolyses the levan. The 21st edition (AOAC, 2019) refers only to the three enzyme solution.

FSANZ understands that certain inulin and FOS data measured by AOAC 997.08 and using the two enzyme solution could exist in food databases used for label declaration. These data would technically become non-compliant with the Code if the AOAC edition were to be updated. To assist FSANZ assess the impact of updating to the most recent edition, FSANZ welcomes stakeholder input on the following question:

Question:

1. Are there any dietary fibre values currently declared on food labels that have been determined by AOAC 997.08 prior to 2013 using the two enzyme solution?

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ has developed a communication strategy for this application. Subscribers and interested parties have been notified about this call for submissions via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards' development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by this application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all submissions received from this call for submissions.

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 the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to permit method AOAC 2017.16 for the analysis of total dietary fibre is unlikely to have a significant effect on international trade as method AOAC 2017.16 would be added to the existing list of permitted methods of analysis in section S11—4 (as an alternative to those other methods), which are all established as official methods of AOAC International. 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.

5 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:

5.1 Section 29

5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications requesting the use of optional methods of analysis (OBPR correspondence dated 16 April 2013, reference number 14943). This standing exemption was provided as permitting the optional method of analysis is voluntary and likely to not have more than a minor economic impact on businesses or individuals.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from option 1 - status quo (rejecting the application). This analysis considers two alternative options to the status quo: approving the application with restrictions on using AOAC 2017.16 for foods containing GOS and IMO; or approving the application as it stands. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by considering the two alternative options.

Costs and benefits of Option 2 – Permit AOAC 2017.16 as a dietary fibre method of analysis with restrictions against its use on foods containing GOS and IMO.

This option permits the use of AOAC 2017.16 with the condition that foods containing GOS and IMO would be excluded from using the method of analysis.

Industry will benefit from having an additional total dietary fibre method of analysis permitted by the Code. Each of the methods of analysis are better suited to certain circumstances. Due to the voluntary nature of the permission, industry will choose the method of analysis likely to provide them the most benefit.

Products containing GOS and IMO would not be permitted to use AOAC 2017.16.

The divergence of the treatment of GOS and IMO with some of our major trading partners will not encourage trade in foods with these added oligosaccharides that include, or would prefer to include, GOS/IMO in the dietary fibre declaration for international markets. Where products with added GOS/IMO are traded, and declare total dietary fibre on their NIP, they may choose to use differing methods of analysis for the different markets and hence require different labels.

Consumers are unlikely to be adversely affected by this option. Consumers wishing to consume a certain amount of dietary fibre, as currently defined by the Code, will be able to do so using the NIP. However there is variability in the determinations of total dietary fibre across the methods. For instance, methods AOAC 985.29 and 991.43 may underestimate total dietary fibre unless used in combination with individual methods of analysis for specifically named dietary fibre.

Option 2 introduces complexity into regulatory enforcement as only some products would be entitled to use AOAC 2017.16. As stated above, if this option is chosen, consideration of imposing the same restriction on method AOAC 2001.03, which is already permitted in the Code, will need to be addressed. It is expected that this would place a similar burden on government regulatory agencies as AOAC 2017.16, and additionally impact manufacturers who currently use AOAC 2001.03 as they would have to revert to using older, less comprehensive methods permitted in the Code for total dietary fibre analysis.

Costs and benefits of Option 3 – Permit AOAC 2017.16 without restrictions

Industry will benefit from having an additional total dietary fibre method of analysis permitted by the Code. Each of the methods of analysis are better suited to certain circumstances. Due to the voluntary nature of the permission, industry will choose the method of analysis likely to provide them the most benefit.

International definitions of dietary fibre differ, and GOS/IMO are considered to be a dietary fibre in some comparable economies. GOS/IMO are reported to be more commonly added as ingredients internationally. Unlike Option 2, this option would not be a barrier to trade in foods containing GOS/IMO.

Consumers are unlikely to be adversely affected by this option. Any overestimate of total dietary fibre would only occur on foods containing GOS (and IMO, noting FSANZ has not assessed it against the Code's definition of dietary fibre), and this is likely to be proportionate to the existing variance in total dietary fibre values presented on NIPs using older methods (including a potential underestimate of total dietary fibre).

Adopting Option 2 would, for consistency, require the same considerations of restrictions on AOAC 2001.03 as under the Status Quo. Additionally, Option 2 would permit another voluntary method (AOAC 2017.16), giving potential net benefits to industry compared to the

Status Quo, whilst noting government enforcement agencies are unlikely to be significantly affected by this option.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from both Options 2 and 3, most likely outweigh the associated costs.

However, Option 3 provides more flexibility for industry, no further burden on enforcement agencies than existing methods in the Code, and on balance is likely to provide the greatest net benefit.

Option 3 is FSANZ's preferred option at this stage; feedback received through this process will inform FSANZ's final recommendation.

5.1.2 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.

5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

5.1.4 Any other relevant matters

Other relevant matters are considered below.

5.2 Subsection 18(1)

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

5.2.1 Protection of public health and safety

There is no risk to public health and safety as a result of the proposed permission for AOAC 2017.16 as an alternative method of analysis in the Code for total dietary fibre.

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

The provision of adequate information is not affected by permitting AOAC 2017.16 as it does not affect when dietary fibre values appear on NIPs. There is not currently another method of analysis that can provide a more comprehensive value of total dietary fibre (specifically for foods containing more complex mixtures of both HMWDF and LMWDF components), so even though total dietary fibre values determined using AOAC 2017.16 presented on an NIP may differ compared to other methods of analysis it would not be so much as to prevent consumers from being able to make an informed choice.

5.2.3 The prevention of misleading or deceptive conduct

Consumers are unlikely to be adversely affected (misled) by the inclusion of GOS and IMO in total dietary fibre values from AOAC 2017.16 because:

- Only foods containing GOS (and potentially IMO) are affected by any potential overestimation of total dietary fibre in relevant foods measured by AOAC 2017.16.
- Only a small proportion of foods contain naturally occurring GOS (up to 4g/100g in plant foods and 0.6g/100g in dairy foods) and GOS is not added to many foods in Australia and New Zealand (n=5). IMO are even less prevalent in the food supply than GOS.
- All methods of analysis have a degree of inaccuracy when measuring dietary fibre.
- Methods of analysis permitted by the Code inaccurately measure total dietary fibre (overestimate or underestimate).
- AOAC 2017.16, when used on GOS-containing foods, could result in a small potential overestimation of total dietary fibre (about 3-6% total dietary fibre measured which on average from foods analysed is 0.85 g/100g GOS) .
- This would not alter food composition data, NIP values or F points for the NPSC calculations enough to stop consumers from making informed choices.
- AOAC 2017.16 overestimate of total DF is proportionate to the underestimate of total DF produced by some other methods, and therefore may be cancelled out in some cases.
- Dietary fibre values must still be stated in NIPs regardless of AOAC 2017.16.

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 considers the best available scientific evidence was reviewed in assessing AOAC 2017.16. FSANZ reviewed data and information provided by the applicant, relevant stakeholders and identified other relevant scientific literature where appropriate. A narrative review and meta-analyses were undertaken to assess the relationship of GOS with the each of the Code's three accepted beneficial physiological effects for dietary fibre.

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

As discussed in Section 1.4, AOAC 2017.16 is currently being considered by Codex as a replacement for its predecessor AOAC 2009.01. Many countries (other than Australia and New Zealand) accept AOAC 2009.01 as a suitable method of analysis for total dietary fibre.

FSANZ has considered how other countries generally regulate dietary fibre, with a particular interest in the beneficial physiological effects accepted in Section 1.4. In all comparable countries reviewed, GOS is considered a dietary fibre because it meets one or more beneficial physiological effects recognised under that country's dietary fibre definition.

A review of the Code's definition of dietary fibre was beyond the scope of this application A1178 however FSANZ's proposed regulatory approach promotes a greater level of consistency between domestic and international standards.

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

Permitting AOAC 2017.16 will ensure that Australia and New Zealand can maintain an efficient and internationally competitive food industry for the analysis for dietary fibre.

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

Prescribing AOAC 2017.16 as an alternative method of analysis for total dietary fibre would promote fair trading in food by allowing relevant foods containing LMWDF to present a more comprehensive and in some instances, precise value than currently permitted methods for total dietary fibre.

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

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

6 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.

7 References

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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 A1178 – Method AOAC 2017.16 as a new method of analysis for total dietary fibre) Variation

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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 Delegate]

Glen Neal
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 A1178 – Method AOAC 2017.16 as a new method of analysis for total dietary fibre) 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

[1.1] omitting paragraph S11—4(2)(a), substituting

(a) for dietary fibre—sections 985.29, or 991.43, or 2017.16;

[1.2] omitting subsection S11—4(4), substituting

(4) In this section:

AOAC means the *Official Methods of Analysis of AOAC International*, twenty first edition, 2019, published by AOAC International, Maryland USA.

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.

The Authority accepted Application A1178 which sought an amendment to the Code to permit the use of a new method of analysis for determining total dietary fibre in food. The method is AOAC[10] Official Method 2017.16 (Rapid Integrated Total Dietary Fibre method of analysis) (AOAC 2017.16). The Authority considered the Application in accordance with Division 1 of Part 3 of the FSANZ Act and has prepared a draft variation.

2. Purpose

The Authority prepared the draft variation, which amends section S11—4 of the Code, to permit the use of AOAC 2017.16 when determining the total amount of dietary fibre in food in accordance with section S11—4 of the Code for the purposes of subsections 1.2.8—7(7) and S5—6(2) of the Code.

3. Documents incorporated by reference

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

However, the draft variation will amend a provision of the Code that incorporates methods of analysis by reference to a specific document that is or will be in force or existing at the commencement of the variation; namely, a specified edition of the *Official Methods of Analysis of AOAC International*, published by AOAC International. The draft variation will amend the provision to refer to a new edition of that publication.

This reference by incorporation is consistent with the current practice in the Code, particularly section S11—4 and Schedule 3.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1178 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a RIS for applications requesting the use of optional methods of analysis (OBPR correspondence dated 16 April 2013, reference number 14943). This standing exemption was provided as permitting the optional method of analysis is voluntary and likely to not have more than a minor economic impact on businesses or individuals.

[10] ***AOAC*** means the *Official Methods of Analysis of AOAC International*, twenty first edition, 2019, published by AOAC International, Maryland USA.

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 of the Code.

Section S11—4 requires the total dietary fibre (including the amount of any specifically named fibre) in a food to be determined in accordance with one or more methods contained in specified sections of the *Official Methods of Analysis of AOAC International*, eighteenth edition, 2005 (the previous AOAC), for the purposes of subsections 1.2.8—7(7) and S5—6(2) of the Code.

Sub-item [1.1] of the draft variation amends section S11—4 of the Code by omitting paragraph S11—4(2)(a) and substituting:

> '(a) for dietary fibre—sections 985.29, or 991.43, or 2017.16;'

Section 2017.16 is a section of the *Official Methods of Analysis of AOAC International,* twenty first edition, which describes this particular AOAC method of analysis for determining total dietary fibre in foods and food ingredients—AOAC 2017.16.

AOAC 2017.16 would be listed in the Code, in addition and as an alternative to the other abovementioned methods of analysis, which are currently listed in paragraph S11—4(2)(a) as permitted methods of analysis for determining total dietary fibre in food.

Sub-item [1.2] of the draft variation amends section S11—4 Code by omitting subsection S11—4(4) and substituting it with a new subsection S11—4(4), stating that in section S11—4:

> '***AOAC*** means the *Official Methods of Analysis of AOAC International*, twenty first edition, 2019, published by AOAC International, Maryland USA.'

Subsection S11—4(4) currently refers to the previous AOAC, which does not list AOAC 2017.16.

In the *Official Methods of Analysis of AOAC International,* twenty first edition, 2019 (the current print version of the AOAC), AOAC 2017.16 is listed as only having a 'First Action' status. However, AOAC 2017.16 was accorded a 'Final Action' status in 2020, which is reflected in the online version of the *Official Methods of Analysis of AOAC International,* twenty first edition. FSANZ understands that future revision of the current print version of the AOAC will reflect the AOAC 2017.16's 'Final Action' status.

The effects of both amendments would be to:

- for the purposes of subsections 1.2.8—7(7) and S5—6(2)—permit the use of the AOAC 2017.16 when determining the total amount of dietary fibre in food under section S11—4; and
- replace the current references in section S11—4 to the eighteenth edition of the AOAC with references to the twenty first edition of the AOAC, so that references in section S11—4 to methods of analysis contained in specified sections of the AOAC would be references to methods of analysis contained in specified sections of the twenty first edition of the AOAC.