8 November 2021

177-21

Approval report – Application 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 to permit the use of AOAC 2017.16 as a new method of analysis for total dietary fibre.

On 21 May 2021, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received ten submissions and one late submission.

FSANZ approved the draft variation on 27 October 2021.The Food Ministers' Meeting[1] was notified of FSANZ's decision on 8 November 2021.

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

[1] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting documents

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

SD1	Risk and technical assessment report (at Approval)
SD2	Assessment of galacto-oligosaccharides against three beneficial physiological effects (at Approval)

Executive summary

Grains and Legumes Nutrition Council lodged an application 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 food and food ingredients.

Section S11—4 of the Code prescribes three methods for analysing total dietary fibre and four methods for analysing certain specifically named fibres. Food Standards Australia New Zealand (FSANZ) assessed AOAC 2017.16 and determined it to be the most comprehensive method available for measuring total dietary fibre (i.e. both high and low molecular weight dietary fibres), improving on older methods currently permitted in the Code. As part of the low molecular weight fraction, the method measures non-digestible oligosaccharides, including galacto-oligosaccharides (GOS) and isomalto-oligosaccharides (IMO). The status of these oligosaccharides had not been considered by FSANZ against the Code's *dietary fibre* definition so were considered for the purposes of this application. Key findings included:

- An existing permitted method (AOAC 2001.03) for measuring total dietary fibre including resistant maltodextrin also analyses GOS and IMO as part of the low molecular weight dietary fibre fraction. However, in permitting AOAC 2001.03, FSANZ intended that this method be used for the analysis of samples specifically containing resistant maltodextrin.
- GOS did not meet all criteria required under the Code's definition of dietary fibre. Specifically, the body of evidence did not support the promotion of at least one of three listed beneficial physiological effects.
- A considerable overestimation of total dietary fibre (as defined in the Code) 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 (NPSC). FSANZ quantified any potential overestimation of total dietary fibre by determining the extent of GOS in the Australian and New Zealand food supply.
- From the seven foods with available naturally occurring GOS data that were also measured using AOAC 2017.16, it appears that naturally occurring GOS contributes about 3-6% of total dietary fibre in GOS-containing foods. IMO are less prevalent in the food supply than GOS, and are permitted as a novel food for purposes other than as a dietary fibre. The regulatory approach considered by FSANZ for GOS was considered applicable to IMO.
- Available evidence on usage trends suggests that GOS (and IMO) is added to very few foods in Australia and New Zealand. The cost and purpose of addition of these (i.e. as prebiotics (for GOS and IMO) and a low calorie sweetener (for IMO) rather than dietary fibre) are limiting factors in the levels added by industry.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 21 May to 22 June 2021. Eleven submissions were received, five from government agencies and six from industry stakeholders. In general, the government agencies expressed concerns related to AOAC 2017.16's limitations, while industry fully supported the proposed draft variation. Shortly after consultation opened, Codex indicated AOAC 2017.16 is an item for formal adoption at CAC44 in November 2021[3].

[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] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-715-41%252FFinal%252520Report%252FREP21_MASe.pdf

FSANZ undertook additional targeted consultation with submitting government agencies and key industry representatives. The outcome was increased stakeholder confidence with FSANZ's proposed regulatory approach (see Section 2.1 of this report for details of submissions made and targeted consultation).

Based on the information above and on other relevant considerations set out in this report, FSANZ concludes the most appropriate response is to permit AOAC 2017.16 without restriction because:

- No single method of analysis can comprehensively measure all low and high molecular weight dietary fibre. Of all methods FSANZ has assessed to date, AOAC 2017.16 provides the most comprehensive dietary fibre value, and resolves some limitations seen in older methods of analysis for dietary fibre.
- It is expected that consumers will continue to be provided with adequate information to enable informed choice about dietary fibre in food products because:
    - the low levels of GOS (and IMO) in the food supply would not considerably alter food composition data, NIPs for dietary fibre or F point scores for the NPSC;
    - existing labelling requirements in the Code would continue to ensure that consumers are provided with adequate information relating to the dietary fibre content of food to enable informed choices.
- This is a voluntary method that enables innovation by, and promotes trade opportunities for industry to measure dietary fibre by a single comprehensive method that is accepted internationally.
- Permitting AOAC 2017.16 provides international harmonisation with Codex and countries comparable to Australia and New Zealand such as the United States (US), Canada, and countries in the European Union (EU), who have embraced newer methods of analysis for total dietary fibre.

Based on the information above and on other relevant considerations set out in this report, FSANZ has decided to approve the draft variation proposed following assessment, without change. The approved draft variation will permit the voluntary use of AOAC 2017.16 as a method of analysis for total dietary fibre, by amending section S11—4 of the Code.

FSANZ will continue to consider the following elements relevant to this permission:

- Codex's final decision on the adoption of AOAC 2017.16 in early November 2021;
- the currency of the Code's definition of dietary fibre, including alignment internationally; and
- a watching brief on the uptake of AOAC 2017.16 and trends in reported total dietary fibre values, in particular any significant changes to front-of-pack label reporting.

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

The Applicant sought to amend 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[4] content in food and food ingredients. The method is listed in the Official Methods of Analysis of AOAC International, twenty first edition, 2019 (AOAC 2019). At the time of application submission, AOAC 2017.16 had obtained AOAC 'first action' status meaning the method had been validated by an inter-laboratory evaluation. Note: it has since been granted 'final action' status by the AOAC.

The application sought to permit AOAC 2017.16 as an additional method of analysis that captures total dietary fibre as defined in Standard 1.1.2 of the Code. AOAC 2017.16 is the first single method available which measures all (high *and* low molecular weight) dietary fibre components including galacto-oligosaccharides (GOS).

The application provided comparative cost data on the use of analytical methods currently in the Code compared to AOAC 2017.16 and determined costs range from $230 to $635 per food sample analysed[5]. However the application also indicated that the relative cost of AOAC 2017.16 was lower than the cumulative cost incurred through current practice which requires the use of a total dietary fibre method (for high molecular weight dietary fibre (HMWDF)) with two or more methods for a specifically named dietary fibre (often a low molecular weight dietary fibre (LMWDF) or resistant starch) to determine a total dietary fibre value[6] that aligns with that analysed by AOAC 2017.16.

1.3 The current standard

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:
>
> (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:

[4] 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.
[5] Cost are for permitted method AOAC 985.29 and AOAC 2017.16, respectively.
[6] The Code refers to 'dietary fibre' as total dietary fibre and 'specifically named dietary fibre' for individual fibre components.

(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[7] 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 fibre points (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 fructo-oligosaccharides (FOS)—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 (i.e. contributes to regular laxation); and a high level health claim and general level health claim are permitted

[7] 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.

for beta-glucan, a specifically named dietary fibre (i.e. reduces blood cholesterol and reduces dietary and biliary cholesterol absorption, respectively).

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 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 between countries and have evolved over time with 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) currently 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 comprehensive list of countries that include monomeric units 3–9 in their definition has not been identified in the literature (Jones 2014; Stephen et al. 2017). However, based on available information, 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 acceptable physiological effects of benefit to health for dietary fibre (called beneficial physiological effects in the Code) are not set by Codex, and it is therefore not surprising these can vary from country to country.

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, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to refer AOAC 2017.16 to the Codex Committee on Methods of Analysis and Sampling (CCMAS) 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. In May 2021, CCMAS supported the adoption of AOAC 2017.16 in place of AOAC 2009.01 (which picks up the same low and high molecular weight dietary fibres) as a Type 1 method for use on all foods (applicable for determining the content of dietary fibres of higher and lower molecular weight in food that may, or may not, contain resistant starches). This is an item for formal adoption at the Codex meeting CAC44 in early November 2021 (CCMAS 2021).

1.4.2 United States

In 2016, the US Food and Drug Administration (US FDA) announced the Nutrition and Supplement Facts label 'final rule' (US FDA 2016), 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 follows:

> 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[8]. 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 (Health Canada, 2013) defined dietary fibre as:

[8] Available the US FDA Questions and Answers on Dietary Fiber (webpage)

1. carbohydrates with a degree of polymerization 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 degree of polymerization 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 dietary 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.

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

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on 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.

2. Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 21 May to 22 June 2021. Eleven submissions were received, five from government agencies and six from industry stakeholders (including one late submission). Several submitters (government agencies and industry) supported FSANZ's conclusion that AOAC 2017.16 is more comprehensive than current permitted methods for total dietary fibre analysis. Generally, the government agencies had concerns with the potential implications of the method's limitations, while industry fully supported the application and proposed draft variation.

After reviewing submissions and due to the likely adoption of AOAC 2017.16 by Codex, FSANZ undertook targeted consultation with submitting government agencies and key industry representatives. FSANZ presented a discussion paper that addressed the key submission concerns (which has formed the basis for the risk management considerations at Section 3 of this report). There were three key outcomes from the targeted consultation:

1. Significantly increased comfort from all stakeholders in permitting the method without restriction if Codex adopts AOAC 2017.16 as proposed.
2. Agreement that AOAC 2017.16 is a more comprehensive method of analysis than current permitted methods, despite the known limitations.
3. It is important to include further narrative around the economical and food technology perspectives for adding (or not adding) GOS or IMO to food products for the purpose of dietary fibre claims.

Table 1: Summary of issues

	Issue	Raised by	FSANZ response
	Regulatory options		
1.	Support for a restriction on the use of AOAC 2017.16 on foods that contain GOS or IMO due to concerns that consumers may be misled regarding the total dietary fibre content of foods. It was proposed that a restriction may allow for more accurate reporting of fibre against the definition in the Code and better informed consumers, while allowing analysts to benefit from permissions to use the method.	QLD Health (QLD) NSW Food Authority (NSW) WA	FSANZ acknowledges this suggestion and, as noted above, has consulted further with submitting jurisdictions and industry representatives regarding the practicality and validity of imposing a restriction on AOAC 2017.16. After considering the information provided during this consultation and for reasons set out in Section 3 of this report, FSANZ's view remains that overall benefits in permitting this method outweigh the

	Issue	Raised by	FSANZ response
	Some jurisdictions suggested that synthetic analogues of GOS which are added as an ingredient to food for sale could be subtracted from the total dietary fibre value to improve accuracy in reporting of total dietary fibre against the definition in the Code. Other jurisdictions stated that this is not a 'metrologically valid' approach as individual methods are validated and standalone, unless otherwise specified.	Department of Health (WA) NZ Food Safety (NZ)	possibility of a small overestimation of total dietary fibre from the measurement of GOS (and IMO) in limited foods. FSANZ has provided further discussion on this issue under section 3 of this report.
2.	FSANZ's justification for accepting a potential overestimation of dietary fibre from GOS and/or IMO was not supported for various reasons: - Overestimation of total dietary fibre is not the same as an underestimation. Overestimation has a higher risk of misleading consumers on potential health effects of a food and enabling products to make claims. - There is the potential for industry to 'method shop' to derive an inflated dietary fibre figure. - Existing limitations of other methods are not justification for permitting a new method without restriction.	QLD NSW WA Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions (VIC)	FSANZ acknowledges the concerns raised and sought further information from industry regarding the extent of the issues raised, including cost data and use of GOS and IMO in the Australian and New Zealand food supply FSANZ has also given greater consideration to the limitations in the Code's definition of dietary fibre based on its original intent, international adoption of GOS (and IMO in some countries) as a dietary fibre, and the advantages of AOAC 2017.16 compared to current permitted methods of analysis in the Code. For the reasons stated in section 3 of this report and section 4.4 of SD1 (including information and data provided by industry), FSANZ is satisfied that overestimation will not lead to consumers being misled in terms of dietary fibre in food. From both an economical and food technology perspective, the likelihood of GOS and/or IMO being added to inflate dietary fibre values is not supported by information provided by industry, usage levels or costing data.

	Issue	Raised by	FSANZ response
3.	In permitting AOAC 2017.16, the purpose for adding GOS as a food ingredient and its use in foods should be considered further. It is suggested that the use of GOS in foods has changed from a protective focus and usage increased (since AOAC 2001.03 was gazetted in 2003) with a focus on the functional purposes e.g. prebiotics, sweetener, bulking agent.	QLD NSW	FSANZ acknowledges this concern raised and sought further information from industry regarding the use of GOS and IMO in the Australian and New Zealand food supply. GOS is used mainly as a prebiotic and IMO is used as a low calorie sweetener with a prebiotic effect. Based on available data from industry, FSANZ reaffirmed its conclusions that GOS and IMO are not added to many foods in Australia and New Zealand, with cost and suitability of use both factors that limit the levels added to products. As stated above, FSANZ is satisfied this issue is addressed under section 3 of this report, and in section 4.4 of the SD1.
	International permissions for AOAC 2017.16		
4.	Concerns were raised regarding international consistency as AOAC 2017.16 had not been accepted by other international jurisdictions (US, EU or Health Canada) or Codex. Further information was sought on the implications or benefits on trade if other countries have not accepted AOAC 2017.16, including any potential trade barriers.	NSW WA QLD VIC	FSANZ acknowledges this concern and notes there is already potentially an existing trade barrier for Australia and New Zealand between countries whom have adopted AOAC 2009.01, which is not permitted by the Code. In permitting AOAC 2017.16, FSANZ is removing this issue as both methods pick up the same low and high molecular weight dietary fibres (meaning dietary fibre values will be more closely aligned). AOAC 2009.01 may continue to be used by some countries, but as it measures the same low and high molecular weight dietary fibre as AOAC 2017.16, this is not expected to result in significant dietary fibre value variations (it will be less than the current variation with current permitted methods AOAC 985.29 and 991.41). FSANZ notes that during the CFS, a report by CCMAS (2021) indicated AOAC 2017.16 is supported for adoption by Codex in place of its predecessor, AOAC 2009.01 at CAC44 (November 2021). FSANZ considers permitting AOAC 2017.16 will promote greater consistency between domestic and international food standards. For the reasons stated above, FSANZ remains satisfied that approval of the method will not itself have an adverse impact on trade.

	Issue	Raised by	FSANZ response
5.	At CCNFSDU41, the EU expressed some concerns with AOAC 2017.16 and the measurement of dietary fibres which have undetermined health benefits (NFSDU/41 CRD 52).	NZ	FSANZ acknowledges this concern, however notes the EU indicated they would monitor the review of the method by CCMAS, and in the CCMAS (2021) support for the method, nil concerns were raised by the EU. FSANZ understands that there has been long standing contention between what should be considered a dietary fibre, accepted beneficial physiological effects and the level of evidence required to justify an effect. As outlined in section 3.2.4 of this report, GOS and IMO are accepted as dietary fibre in other countries (including the EU) for beneficial physiological effects associated with fermentation. FSANZ is satisfied permitting this method will not negatively impact public health and safety.
6.	Concerns were raised regarding notable discrepancies between the Code's dietary fibre definition and the methods of analysis permitted, compared to other countries and Codex. Some calls for FSANZ to review these elements of the Code were received.	NSW WA QLD	FSANZ acknowledges these concerns however it is not within scope of A1178 to review the definition of dietary fibre and/or raise a Proposal. FSANZ understands that the body of evidence around beneficial physiological effects of dietary fibres is expanding and will consider this with any future update to the Code.
	Dietary fibre labelling issues		
7.	It was highlighted that further ambiguity is added in that the Code permits dietary fibre to be expressed per serving size, where serving sizes are not prescribed, and this leads to potentially misleading labelling for consumers.	VIC	FSANZ acknowledges this concern. However, requirements to make declarations per serving size in the NIP are not limited to dietary fibre and consequently, assessment of and any changes to those requirements are outside the scope of A1178 but can be considered during any future review of the standard.
8.	Concern a permission without restriction will negatively impact on Health Star Ratings (HSR) and modelling would be required to fully understand the impact e.g. for products on the cusp of another star rating it may increase their rating.	NZ	FSANZ understands that these concerns (which are not unique to added GOS or IMO) were raised during the five year HSR review and existed irrespective of this application. FSANZ notes that no changes to the dietary fibre algorithm were recommended in the HSR Five

	Issue	Raised by	FSANZ response
	In the HSR five year review, stakeholders expressed concern with the current types of dietary fibre permitted under the Code's definition and questioned whether all types would promote the same benefit. Allowing GOS (particularly synthetic forms) to contribute to dietary fibre content, despite it not meeting the Code's definition, may add to concerns around the integrity of the HSR system.		Year Final Review Report. From both an economical and food technology perspective, the likelihood of GOS and/or IMO being added to inflate dietary fibre values is not supported by technological information provided by industry, usage levels or costing data.
	Policy guidance		
9.	It was suggested that FSANZ should have considered the *'Policy guideline on food labelling to support consumers to make informed healthy food choices'*.	NZ	Although this policy guideline is not directly related to a permission for a new method of analysis for dietary fibre, FSANZ has had regard to the guideline. Having considered the guideline, FSANZ remains of the view that (for reasons set out in this report) permitting the voluntary use of AOAC 2017.16 will continue to allow consumers to be provided with adequate information, enabling informed choice about dietary fibre in food products. FSANZ has addressed this issue in Section 5.3 of this report.

Table 2: Summary of support

Contributing Submitters	Comment
Healthy Grain Australian Food and Grocery Council New Zealand Food and Grocery Council Sanitarium Kelloggs Australia	• Supports permission of AOAC 2017.16 without restriction. Restriction limits the use of the method on many products and increases the complexity of the regulatory environment. • Dietary fibre measured by AOAC 2017.16 better corresponds with the Codex definition of fibre. International harmonisation results in greater trade opportunities and reduces costs associated with labelling. • AOAC 2017.16 measures dietary fibre components that other methods for total dietary fibre analysis do not, therefore consumers will be better informed of true dietary fibre values. • Voluntary permission for AOAC 2017.16 will encourage innovation in the food industry with the capacity to measure total dietary fibre by a single, more comprehensive method; new or novel fibre products can be declared in NIP. • Measurement of IMO is not a major issue as it is not widespread in the Australian and New Zealand food supply. • Many major manufacturers do not currently use GOS or IMO.

2.2 Risk assessment

AOAC 2017.16 is an analytical method for the determination of total dietary fibre[9] in foods and food ingredients. During the assessment of A1178, consideration was given to AOAC 2009.01 (the predecessor method to AOAC 2017.16). AOAC 2009.01 is not permitted in the Code but was accepted as a method of analysis for total dietary fibre by Codex and is used by some countries comparable to Australia and New Zealand such as Canada, the US, and the EU. Codex is likely to adopt AOAC 2017.16 in place of AOAC 2009.01 (for action at CAC44 in November 2021). AOAC 2009.01 may continue to be used by some countries, but as it measures the same low and high molecular weight dietary fibre as AOAC 2017.16, this is not expected to result in significant dietary fibre value variations (less than the current variation with AOAC 985.29 and 991.41). Based on best available scientific evidence, FSANZ considers AOAC 2017.16 is a more suitable method than those currently permitted in the Code for analysis of foods containing a wide range of high and low molecular weight dietary fibres because it:

- is more comprehensive than older methods in the Code for measuring total dietary fibre
- has a similar level of precision 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 seven 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 more closely 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 it more closely measures resistant starch values in line with those seen in AOAC 2002.02, and resolves the underestimation of fructo-oligosaccharide and overestimation of resistant maltodextrin as seen in AOAC 2009.01.

AOAC 2017.16 measures 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 GOS. AOAC 2017.16 includes GOS in its measurement of total dietary fibre. FSANZ therefore considered whether GOS meets 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 promotes at least one of three beneficial physiological effects: 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. FSANZ's assessment found that the consumption of GOS does not promote the three beneficial physiological effects listed in the Code. Therefore, insofar as naturally occurring GOS is concerned, similar

[9] 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.

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 evidence FSANZ concludes GOS in any form does not meet all criteria for the Code's definition of dietary fibre.

The above means that the use of AOAC 2017.16 would result in an overestimate of total dietary fibre in GOS-containing foods based on the Code's definition of dietary fibre.

Based on the available data, plant-based foods contain naturally occurring GOS at levels on average of 0.85 g/100 g and up to 4 g/100 g for a small number of foods, and dairy products up to 0.6 g/100 g. GOS was present in about 25% of the surveyed plant foods. From the seven foods with available naturally occurring GOS data that were also measured using AOAC 2017.16, it appears that naturally occurring GOS contributes about 3-6% of total dietary fibre in GOS-containing foods. Likely due to its cost, GOS is not added to many foods in Australia and New Zealand beyond infant formula products, infant food and formulated supplementary foods for young children. Halmos et al. (2015) estimated a daily GOS consumption of 1.1 g/day in Australian adults. Based on the Code's definition of dietary fibre, a small number of GOS-containing foods measured with AOAC 2017.16 will have a slight overestimation of dietary fibre values.

3. Risk management

3.1 Limitations and benefits of current 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 a NIP to be a declaration of dietary fibre determined in accordance with section S11—4. Table 1 in Supporting Document 1 (SD1) outlines the dietary fibre components each method in section S11—4 measures. FSANZ is not proposing to remove these methods from the Code but they are discussed in this report within the context of limitations and benefits of individual methods.

AOAC methods 985.29 and 991.43 have been permitted for use in Australia and New Zealand for some time and are affordable for industry to measure samples containing HMWDF, also known as non-starch polysaccharides.

A limitation of older methods permitted in the Code is that they do not measure LMWDF such as FOS, resistant maltodextrins, or polydextrose; and they only partially measure inulin and resistant starch. Method AOAC 2001.03 (total dietary fibre and resistant maltodextrins) is currently used to analyse foods containing LMWDF[10], however it too underestimates resistant starch.

To fully capture the dietary fibre content of a food, manufacturers and/or analysts must select permitted 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.

To measure the true value for total dietary fibre, it is currently necessary for analysts to combine one or more methods. 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 permitted by the Code for specifically named dietary fibres[11].

[10] H. Salman, Business Manager – Analytical Services, Australian Export Grains Innovation Centre (AEGIC), personal communication, 22 May 2020.
[11] H. Salman, Business Manager – Analytical Services, Australian Export Grains Innovation Centre (AEGIC), personal communication, 16 March 2021.

When determining total dietary fibre by adding together the results obtained from two or more methods, there is potential for 'double counting' of certain fractions that are analysed by both 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.

A manufacturer could also use pre-existing values determined using methods permitted by the Code 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. These values are mostly obtained using AOAC 985.29 and therefore most do not account for LMWDF fractions from the sample, resulting in values which likely underestimate total dietary fibre values.

Overall it is clear that limitations exist with the practicality and comprehensiveness of current permitted methods of analysis for total dietary fibre. AOAC 2017.16 was designed to resolve many of these limitations.

3.2 Limitations and benefits of AOAC 2017.16

The technical aspects of AOAC 2017.16 outlined in the assessment at SD1 demonstrate extensive benefits regarding the comprehensiveness of the method, compared to current permitted methods.

However, methods of analysis have evolved significantly along with consideration of what is captured as a dietary fibre. This required FSANZ to undertake further assessment and have regard for the Code's definition of dietary fibre in its risk management considerations.

3.2.1 Regulation of dietary fibre differs between countries comparable to Australia and New Zealand

AOAC 2017.16 was developed to align with the Codex definition of dietary fibre. Dietary fibre definitions differ between countries, particularly for beneficial physiological effects. As discussed above in section 1.4.1, Codex leaves this criteria up to national regulatory bodies to determine based on generally accepted scientific evidence. The Code's definition of dietary fibre is limited to three listed beneficial physiological effects compared to countries equivalent to Australia and New Zealand such as the US, Canada and countries in the EU.

The Code regulates dietary fibre in two ways, through permitted methods of analysis and through the definition (see subsection 1.4.1). FSANZ was therefore required to assess both the technical aspects of the method of analysis and the dietary fibre components measured against the Code's dietary fibre definition.

For application A1178, this assessment was undertaken for GOS only because other dietary fibre components measured by AOAC 2017.16, as defined in the application, had all previously been assessed by FSANZ. Through the assessment, FSANZ further identified isomalto-oligosaccharides (IMO) as an additional component measured by the method which was yet to be considered by FSANZ. After reviewing levels in the food supply and the intended purpose of IMO under application A1123 – Isomalto-oligosaccharide as a Novel Food, FSANZ determined additional assessment was not required and IMO could be managed in the same way as GOS (see section 3.2.2 below).

3.2.2 Consideration of isomalto-oligosaccharides

During the assessment for this application, FSANZ noted IMO were identified as non-digestible oligosaccharides 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. Based on limited data, FSANZ identified that naturally occurring IMO with a degree of polymerisation (DP)[12] 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/100 g (Hayakawa et al. 2000).

IMO can also be synthetically produced through the enzymatic hydrolysis of starch. It is currently permitted by FSANZ as a Novel Food in the Code[13] 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. The specifications for IMO state that a maximum of 43% (range 20–43%) of the IMO preparation would be DP 1 and DP 2, hence its use as a low calorie sweetener. AOAC 2017.16 would not detect DP 1-2 components. The DP 3 and over components have prebiotic effects.

Unlike GOS, IMO is not permitted for use in infant formula products, infant food and formulated supplementary foods for young children (FSANZ 2016; Australian Food Composition Database).

In considering permissions for use for AOAC 2017.16, FSANZ considered levels of IMO with a DP > 2 would be lower than GOS and therefore considered it appropriate to apply any risk management approach for GOS equally to IMO.

3.2.3 Synthetic analogues of GOS and IMO in foods in Australia and New Zealand

Confidential data provided by members and representatives of industry and the Applicant after the call for submissions confirmed the findings from the SD1 and CFS that GOS and IMO are not added to many foods.

Permissions exist for the use of GOS in infant formula products and formulated supplementary foods for young children. Other foods containing GOS are mostly dairy products. The purpose of addition is as a ‘prebiotic’ and it is not marketed as a dietary fibre.

IMO appear to be added to wider variety of food products than GOS, but are prohibited for use in infant formula products and formulated supplementary foods for young children. As outlined above under section 3.2.2, the purpose of addition is as a dietary fibre.

Feedback received through the consultation process indicated that the higher cost of GOS and IMO compared to comparable oligosaccharides such as FOS and polydextrose are limiting factors for the addition of the two substances in foods.

FSANZ considered the addition of GOS and IMO to foods as ‘dietary fibre’ to be inappropriate given they do not meet all criteria required under the Code’s dietary fibre definition, and acknowledged similar concerns were raised by stakeholders. FSANZ will maintain a watching brief on the uptake of AOAC 2017.16 and trends in reported total dietary fibre values, in particular any significant changes to front-of-pack label reporting.

3.2.4 The beneficial physiological effects recognised by other countries for

[12] The degree of polymerisation, or DP, is the number of single monosaccharide units in the carbohydrate molecule.
[13] See application A1123 – Isomalto-oligosaccharide as a Novel Food.

dietary fibre

The Code requires a dietary fibre (regardless of if it is naturally occurring or a synthetic analogue) to promote one or more of the three listed beneficial physiological effects. The body of evidence assessed at SD2 did not find that GOS demonstrated any of the three listed beneficial physiological effects.

However, FSANZ has given consideration to countries comparable to Australia and New Zealand with more recently updated dietary fibre definitions. GOS and IMO are considered a dietary fibre in other countries due to the outcomes of their (partial) fermentability. For example, the production of energy yielding microbes in Canada; fermentable by colonic microflora (among others) in the EU; and enhanced mineral absorption (for GOS only) in the US.

Reviewing the Code's dietary fibre definition to assess additional beneficial physiological effects is not within the scope of Application A1178. FSANZ will continue to consider the currency of the Code's definition of dietary fibre, including alignment internationally.

3.2.5 Practical considerations with a restriction of AOAC 2017.16 on GOS or IMO containing foods

Given the limitations in demonstrating the beneficial physiological effect of GOS as a dietary fibre, FSANZ considered permitting AOAC 2017.16 with a restriction on its use with foods containing GOS and/or IMO. A restriction would severely limit the use of AOAC 2017.16 on foods containing certain LMWDF, including any food containing dairy or wheat. Such a restriction on the use of the method would not be consistent with current approvals for methods of analysis in the Code (which are not restricted for use on certain foods), and would be imposing a regulatory burden on for enforcement and industry.

Further, 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 (including managing the issue of double counting), which is less comprehensive and efficient[14]. Additionally, enforcement agencies would be required to enforce this restriction by monitoring the specific analytical methods used for determining total dietary fibre in the entire food supply. This would be resource intensive and not a proportionate response to the identified limitation.

FSANZ identified that an existing permitted method in the Code, AOAC 2001.03, for measuring total dietary fibre (including resistant maltodextrin) also analyses GOS and IMO as part of the LMWDF fraction. This method is permitted unrestricted and FSANZ noted it was intended for the specific analysis of samples containing resistant maltodextrin. No issues with the use of this method, or it's presented values, have been raised with FSANZ to date in the past. The proposed permission for permitting AOAC 2017.16 is not expected to impact the current permission for AOAC 2001.03 in the Code.

3.2.6 AOAC 2017.16 adoption by Codex

It is acknowledged that, at the time of Approval, AOAC 2017.16 is pending final adoption by Codex in early November 2021 at CAC44 (CCMAS 2021). AOAC 2017.16 has been supported by CCNFSDU, who referred it to CCMAS which considers, amends (if necessary) and endorses (as appropriate) methods of analysis and sampling proposed by Codex (Commodity) Committees.

3.3 Updating reference to the AOAC Official Methods of

[14] 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 (synthetic analogues of GOS) only so would not detect naturally occurring GOS.

Analysis edition in the Code

To permit AOAC 2017.16 in the Code, it is 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 noted AOAC 2017.16 was available in the printed 21st edition (2019) as 'first action' status. The online 21st edition contained 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'.

To update the reference, it was important to know if any change to other methods permitted in the Code had occurred between editions, and to assess the impact of these.

FSANZ 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) referred 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.

During the CFS, FSANZ sought available information or data on products that had been measured using AOAC 997.08 prior to the change in 2013. Two submitters responded indicating they were not aware of any existing data, however FSANZ did receive advice from an analyst[15] suggesting AOAC 997.08 is not used in Australia as it required ion exchange chromatograph, and no labs performed this. No information on the method's use in New Zealand was provided.

FSANZ concluded, based on available information, it is appropriate to amend the Code with the 21st edition, which is necessary to ensure a permission for AOAC 2017.16 is compliant with the Code.

3.4 Risk Management Conclusion

In determining the most proportionate regulatory decision, FSANZ weighed the limitation of a small overestimation of total dietary fibre (based on the definition of dietary fibre in the Code) from the measurement of GOS (and IMO) against the overall benefits of permitting the method:

- No single method of analysis can comprehensively measure all low and high molecular weight dietary fibres. Of all methods FSANZ has assessed to date, AOAC 2017.16 provides the most comprehensive dietary fibre value, and resolves some limitations seen in older methods of analysis for dietary fibre.
- Available evidence suggests that GOS (and IMO) is added to a small amount of foods in Australia and New Zealand. The cost and purpose of addition of these (i.e. as prebiotics (for GOS and IMO) and a low calorie sweetener (for IMO), rather than dietary fibre) are limiting factors controlling the levels added by industry.
- It is expected that consumers will continue to be provided with adequate information to enable informed choice about dietary fibre in food products because:

[15] H. Salman, Business Manager – Analytical Services, Australian Export Grains Innovation Centre (AEGIC), personal communication, 15 March 2021

    - the low levels of GOS (and IMO) in the food supply would not considerably alter food composition data, NIPs for dietary fibre or F point scores for the NPSC;
    - existing labelling requirements in the Code would continue to ensure that consumers are provided with adequate information relating to the dietary fibre content of food to enable informed choices.
- This is a voluntary method that enables innovation by, and promotes trade opportunities for, industry to measure dietary fibre by a single comprehensive method that is accepted internationally.
- Permitting AOAC 2017.16 provides international harmonisation with Codex and countries comparable to Australia and New Zealand such as the United States (US), Canada, and countries in the European Union (EU), who have embraced newer methods of analysis for total dietary fibre.

Having considered the submissions and weighed all aspects of the assessment against the statutory requirements including the Ministerial Policy Guidelines, FSANZ decided to approve a draft variation to the Code to permit the voluntary use of AOAC 2017.16 as a method of analysis for total dietary fibre, by amending section S11—4 of the Code.

FSANZ will continue to consider the following elements relevant to this permission:

- Codex's final decision on the adoption of AOAC 2017.16 in early November 2021;
- the currency of the Code's definition of dietary fibre, including alignment internationally; and

  a watching brief on the uptake of AOAC 2017.16 and trends in reported total dietary fibre values, in particular any significant changes to front-of-pack label reporting.

4. Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application.

FSANZ undertook a public call for submissions from 21 May 2021 to 22 June 2021. Subscribers and interested parties were notified about the public consultation period via the Food Standards Notification Circular. Public notification was made via media release, FSANZ social media and Food Standards News. Ten submissions and one late submission were received.

FSANZ also presented a paper on this work to the Retailers and Manufacturers Liaison Committee (RMLC) on 28 July 2021, and held a targeted consultation with key industry and jurisdictional submitters on 19 August 2021.

As part of its assessment, FSANZ had regard to all submissions received for this application. FSANZ acknowledges the time taken by individuals and organisations who made submissions, attended consultations and provided further data to inform FSANZ's assessment. All submissions were considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

5. FSANZ Act assessment requirements

5.1 Section 29

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:

5.1.1 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 applies here as permitting the optional method of analysis is voluntary and unlikely to 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 away 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.

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 are 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.

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 do not measure LMWDF and, unless used in combination with individual methods of analysis for specifically named dietary fibre, will underestimate actual total dietary fibre in a food product.

Option 2 introduces complexity into regulatory enforcement as it limits products 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. In May 2021, CCMAS recommended replacement of AOAC 2009.01 with AOAC 2017.16 (added as an item at CAC44, November 2021). Several countries have been using AOAC 2009.01 as their listed method for total dietary fibre analysis. Given Australia and New Zealand have not adopted AOAC 2009.01 but other countries use it and it measures the same low and high molecular weight dietary fibre as AOAC 2017.16, an existing trade barrier is resolved with the adoption of AOAC 2017.16. If other countries continue to use AOAC 2009.01 a small variation will exist but given the improvements from AOAC 2009.01 in AOAC 2017.16 it is anticipated countries will move to align with Codex.

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 3 would, for consistency, require the same considerations of restrictions on AOAC 2001.03 as under the status quo. Additionally, Option 3 would permit another voluntary method (AOAC 2017.16), giving potential net benefits to industry compared to the status quo, while noting government enforcement agencies are unlikely to be significantly affected by this option.

5.1.2 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 and places no further burden on enforcement agencies than required for enforcing permitted methods of analysis in the Code. On balance, Option 3 is likely to provide the greatest net benefit.

5.1.3 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.

5.1.4 Any relevant New Zealand standards

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

5.1.5 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.

- **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.

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

Existing labelling requirements will continue to ensure that consumers are provided with adequate information relating to the dietary fibre content of food to enable informed choices.

- **The prevention of misleading or deceptive conduct**

FSANZ undertook additional consultation with government agencies and industry, retaining the conclusion that no issues were identified with this application relevant to this objective.

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 considered the best available scientific evidence in assessing AOAC 2017.16. FSANZ reviewed data and information provided by the Applicant, submitters, key stakeholders and identified other relevant scientific literature where appropriate, including undertaking a meta-analysis to consider the effect of GOS on the Code's three listed beneficial physiological effects.

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

FSANZ considered how other countries regulate dietary fibre, with a particular interest in adopted methods of analysis and beneficial physiological effects, as discussed in section 1.4. Codex is likely to adopt AOAC 2017.16 in place of AOAC 2009.01 (for action at CAC44 in November 2021).

In all comparable countries reviewed, at least AOAC 2009.01 has been adopted and substances measured by AOAC 2017.16 are generally considered dietary fibres based on beneficial physiological effects recognised under that country's dietary fibre definition. Permitting AOAC 2017.16 with therefore promote consistency between domestic and international food 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**

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

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

FSANZ has had regard to the *Policy Guideline on Food labelling to Support Consumers to Make Informed Healthy Food Choices*, noting this guideline is not directly relevant to consideration of a method of analysis that measures a nutrient presented on a food label.

FSANZ considers that in permitting the voluntary use of AOAC 2017.16, consumers will continue to be provided with adequate information to enable informed choice about dietary fibre in food products.

6. References

CCMAS (2021) Report of the 41st session of the codex committee on methods of analysis and sampling; Virtual 17 – 21 and 25 May 2021. Codex Alimentarius Commission, Rome/ Available from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-715-41%252FFinal%252520Report%252FREP21_MASe.pdf

CCNFSDU (2019) Proposal for introduction of ICC standard no. 185 (AOAC method 2017.16) to replace AOAC method 2009.01. Codex Alimentarius CODEX NFSDU/41 CRD 6. Codex Alimentarius Commission, Rome. Available from: http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=41

CCNFSDU (2020) Report of the forty-first session of the Codex Committee on Nutrition and Foods for Special Dietary Uses REP20/NFSDU. Codex Alimentarius Commission, Rome. Available from http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FReport%252FAdoption%252FREP20_NFSDUe.pdf

Codex (1985) Guidelines on Nutrition Labeling, Codex Alimentarius CODEX CAC/GL 2–1985. Codex Alimentarius Commission, Rome, Last Amended 2017. Available from: http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/

Codex (1999) Recommended Methods of Analysis and Sampling. Codex Alimentarius CODEX CXS 234-1999. Codex Alimentarius International, Rome. Last amended 2009. Available from: http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/it/

Codex (2021) Information and comments submitted by AOAC and ICC supporting replacement of AOAC 2009.01/AACCI 32-45.01 with AOAC 2017.16/ ICC Standard 185 in CXS 234-1999 as a Type I method for the measurement of Total Dietary Fibre MAS-CRD/03. Codex Alimentarius Commission, Rome. Available from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-715-41%252FCRD%252Fma_CRD03x.pdf

EC (2008) Commission Directive 2008/100/EC: amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions. 29.10.2008 *Official Journal of the European Union* 285(9). Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0100

EC (2012) Guidance document for competent authorities for the control of compliance with EU legislation on: Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs (and others) with regard to methods of analysis for determination of the fibre content declared on a label. European Commission, Brussels. Available from: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_legislation_guidance_methods_2012_en.pdf

EC (2020) Health promotion and disease prevention: Dietary Fibre. European Commission Health Promotion and Disease Prevention Knowledge Gateway. European Commission, Brussels. Available from: https://ec.europa.eu/jrc/en/health-knowledge-gateway/promotion-prevention/nutrition/fibre

EFSA (2010) Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. European Food Safety Authority Panel on Dietetic Products, Nutrition, and Allergies (NDA). EFSA Journal, 8(3) 1462. Available from: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2010.1462

EU (2011) Regulation (EU) No 1169/2011 of the European parliament and of the Council on the provision of food information to consumers. *Official Journal of the European* Union (2011) (304)18–63. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=EN

FDA (2016) Food and Drug Administration, Revision of the Nutrition and Supplement Facts Label, US Federal Register (2016), Vol.81, No.103. Available from: https://www.regulations.gov/contentStreamer?documentId=FDA-2012-N-1210-0875&contentType=pdf

Halmos EP, Christophersen CT, Bird AR, Shepherd SJ, Gibson PR, Muir JG (2015) Diets that differ in their FODMAP content alter the colonic luminal microenvironment Gut 64: 93-100. doi: 10.1136/gutjnl-2014-307264

Hayakawa K, Ando K, Yoshia N, Yamamoto A, Matsunaga A, Nishimura M. Kitaoka M, and Matsui K (2000) Determination of saccharides in sake by high-performance liquid chromatography with polarized photometric detection. *Biochemical Chromatography* 14: 75.

Health Canada (2013) Bureau of Nutritional Sciences Food Directorate, Health Products and Food Branch, Health Canada: Policy for labelling and advertising of dietary fibre-containing food. Available from: https://www.canada.ca/en/health-canada/services/publications/food-nutrition/labelling-advertising-dietary-fibre-food-products.html

Jones JM (2013) Dietary fiber future directions: integrating new definitions and findings to inform nutrition research and communication. Advanced Nutrition 4(1):8–15. Available from: https://pubmed.ncbi.nlm.nih.gov/23319118/

Jones JM (2014) CODEX-aligned dietary fiber definitions help to bridge the 'fiber gap'. *Nutrition Journal* 13(34). Available from: https://doi.org/10.1186/1475-2891-13-34

McCleary BV, DeVries JW, Rader JI, Cohen G, Prosky L, Mugford DC, Champ M, and Okuma K (2012) Determination of insoluble, soluble, and total dietary fiber (CODEX definition) by enzymatic-gravimetric method and liquid chromatography: collaborative study. *J.AOAC Int.,* 95(3): 824-44

McCleary BV, Cox J (2017) Evolution of a Definition for Dietary Fiber and Methodology to Service this Definition. Luminacoids Research 21(2) 9-20.

Phillips, GO (2013) Dietary fibre: A chemical category or a health ingredient? *Bioactive Carbohydrates and Dietary Fibre* 1(1): 3-9.

US FDA (2016) Food and Drug Administration, HHS. Food Labeling: Revision of the Nutrition and Supplement Facts Labels. Final rule. Fed Regist. 2016 May 27;81(103):33741-999. Available from: https://www.govinfo.gov/content/pkg/FR-2016-05-27/pdf/2016-11867.pdf

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 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 – 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[16] 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 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting[17], 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 has approved 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 approved draft variation amends 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 approved draft variation amends 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 21 May 2021 for a four-week consultation period.

FSANZ received ten submissions and one late submission during the public consultation for A1178. Further consultation was undertaken after these were reviewed. FSANZ presented a paper to industry stakeholders at the July 2021 Retailers and Manufacturers Liaison

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

[17] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum). The Forum name change took effect on 21 February 2021 following a decision by Ministers.

Committee meeting and held a targeted consultation with key industry representatives and submitting jurisdictions in August 2021.

A Standards Development Committee (SDC) was established with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to the Authority throughout the standard development process. The SDC contributed a broad spectrum of knowledge and expertise covering industry, government, research and consumers

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.

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 approved 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 approved 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 approved 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.