

16 May 2017
[13–17]

Approval report – Application A1123

Isomalto-oligosaccharide as a Novel Food

Food Standards Australia New Zealand (FSANZ) assessed an Application made by Essence Group Pty Ltd via FJ Fleming Food Consulting Pty Ltd to permit isomalto-oligosaccharide as a novel food for use as an alternative (lower calorie) sweetener and bulk filler in a range of general purpose and special purpose foods, and prepared a draft food regulatory measure.

On 13 December 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 3 May 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 May 2017.

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

Table of contents

EXECUTIVE SUMMARY	3
INTRODUCTION	5
1.1 THE APPLICANT	5
1.2 THE APPLICATION	5
1.3 CURRENT STANDARDS	6
1.3.1 <i>Australia and New Zealand</i>	6
1.3.2 <i>International</i>	6
1.4 REASONS FOR ACCEPTING APPLICATION	6
1.5 PROCEDURE FOR ASSESSMENT	7
1.6 DECISION	7
2 SUMMARY OF THE FINDINGS	7
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	7
2.2 RISK AND TECHNICAL ASSESSMENT	10
2.3 RISK MANAGEMENT	11
2.3.1 <i>Novelty</i>	11
2.3.2 <i>Nutrition implications for use of IMO as an alternative sweetener</i>	12
2.3.3 <i>Foods permitted to have IMO added</i>	12
2.3.4 <i>Labelling of food products with added IMO</i>	13
2.3.5 <i>Specifications for IMO</i>	15
2.3.6 <i>Analytical methods for analysis</i>	16
2.4 RISK COMMUNICATION.....	16
2.4.1 <i>Consultation</i>	16
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	16
2.5.1 <i>Section 29</i>	16
2.5.2 <i>Subsection 18(1)</i>	17
6 REFERENCES	18
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	20
ATTACHMENT B –EXPLANATORY STATEMENT.....	22
ATTACHMENT C – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS)	24

Supporting documents

The [following documents](#)¹, which informed the assessment of this Application, are available on the FSANZ website:

- SD1 Risk and technical assessment report (at Approval)
- SD2 Assessment against the Policy Guidelines (at Approval)

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1123IMOasaNovelFood.aspx>

Executive summary

Essence Group Pty Ltd made an Application seeking approval of isomalto-oligosaccharide (IMO) as a novel food for use as an alternative (lower calorie) sweetener and as a bulk filler. The Applicant sought to market IMO in a number of food categories including carbonated beverages, sports and energy drinks, soy milks, milk-based drinks, milk-based and non-milk-based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionery at levels up to 15 g IMO/serving. The Applicant stated that it was not the intention that IMO be added to foods for infants or supplementary formulated foods for young children².

The Applicant did not request a specific energy factor for IMO or a specific method of analysis for dietary fibre.

IMO is manufactured from starch and contains a mixture of short-chain carbohydrates, including both digestible and non-digestible saccharides. The Applicant noted the relative sweetness of IMO as approximately 60% that of sucrose and the energy value as 6.3 kJ/g (1.5 kcal/g). As well as commercial manufacture, IMO occurs naturally in fermented foods such as rice, miso, soy sauce, and sake. It is approved in a number of overseas jurisdictions including the United States of America, Canada and Europe.

The [Advisory Committee on Novel Foods](#)³ (ACNF) previously considered that IMO does not have a history of consumption in Australia and New Zealand and as such, meets the definition of non-traditional food in the *Australia New Zealand Food Standards Code* (the Code). Therefore, as a new food ingredient, IMO required a safety assessment prior to approval for use in Australia and New Zealand.

FSANZ's assessment concluded that IMO meets the stated purpose of a bulk filler when used as an ingredient to replace sucrose in food. In addition, according to the Applicant's reported IMO composition (i.e. lower levels of mono- and di-saccharides than sucrose) and FSANZ's proposed specification for IMO, IMO could be used as a sweetener with approximately 60% sweetness compared to sucrose. To meet nutrition labelling requirements, the manufacturer will need to know the monosaccharide and disaccharide content of an IMO ingredient, as well as its available and unavailable carbohydrate content.

IMO has a history of safe use in humans in overseas countries and is well tolerated i.e. no abdominal symptoms (e.g. laxative effects) in healthy humans (i.e. excluding certain individuals with sucrase-isomaltase deficiency, see below) up to a single daily (bolus⁴) 40 g dose. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is considered appropriate. However, it is anticipated that IMO will be poorly tolerated by individuals with congenital or acquired sucrase-isomaltase deficiency (see SD1). FSANZ considers that the existing generic labelling requirements along with additional information provided to relevant health professional bodies, will manage the potential risk to these individuals (see below).

The predicted mean dietary exposures to IMO over 24 hours based on the Applicant's proposed list of foods (assuming 50% replacement of added sugars) were below 40 g for all population groups assessed (scenario 1).

² FSANZ advised the Applicant that "foods for infants" were taken to include infant formula products; there was no objection. Therefore, these food categories were not assessed under A1123.

³ <http://www.foodstandards.gov.au/industry/novel/novelreocs/pages/default.aspx>

⁴ Bolus can be defined as a single dose, administered over a short period of time.

FSANZ also assessed the predicted mean exposures (assuming 50% replacement of added sugars) for a second scenario where IMO is added to all nearly food categories (except infant formula products, infant foods and formulated supplementary foods for young children). For this second scenario, exposures were < 40 g IMO for ages 2–8 years and 51 years and over. For ages 9–50 years, the predicted mean exposures were > 40 g IMO (up to 58 g). High consumers of IMO (P97.5) may also exceed 40 g of IMO.

Noting the lack of an identifiable hazard, and that a single dose of 40 g has been demonstrated to be well tolerated, these exposures do not raise any public health concerns.

Furthermore, due to the assumptions made in the second scenario (IMO added to nearly all food categories), the predicted exposures are likely to be considerably over-estimated and are not considered realistic because the scenario is unlikely to reflect normal consumption patterns of IMO-containing foods. The Applicant suggests that no more than two foods containing IMO would be consumed in a day based on experience from mature markets overseas. The Applicant also notes that for organoleptic reasons i.e. matching the sweetness profile of sucrose, IMO is unlikely to be used alone (at the theoretical maximum sugar replacement level) in high sweetness products and instead is more likely to be used as a part of a blend of sweeteners.

Therefore, FSANZ has approved IMO as a novel food, including the extension of the Applicant's original list of foods to all foods except infant formula products, infant foods and formulated supplementary foods for young children. In addition, a limit per serving, as proposed by the Applicant, is not considered necessary to manage potential risk. Generic labelling requirements will provide consumers with information about the presence of IMO in food to enable informed choice. FSANZ also considered the need for a mandatory advisory labelling statement about possible laxative effects and determined, based on the risk assessment conclusions, that such a requirement was not warranted.

Broadening the permission to nearly all food categories will not pose a risk to healthy consumers. However, (if the variation to the Code is ultimately gazetted) additional information about the IMO permissions in the Code, and what to look for on a label will be provided to health professional bodies whose members educate and support individuals with sucrose-isomaltase deficiency. This will reduce the likelihood of adverse effects for these individuals, noting that they already need to avoid sucrose.

1 Introduction

The Application sought the approval of isomalto-oligosaccharide (IMO) as a novel food, specifically as a bulk filler and an alternative sweetener. A separate energy factor for IMO was not requested.

IMO is manufactured from starch and is a mixture of short-chain carbohydrates based on glucose that are predominantly linked by α -D-(1,6) linkages. IMO contains both digestible and non-digestible saccharides. The Applicant noted the relative sweetness of IMO as approximately 60% that of sucrose and the energy value as 6.3 kJ/g (1.5 kcal/g). As well as commercial manufacture, IMO occurs naturally in fermented foods, such as rice miso, soy sauce, and sake⁵.

A previous Application [A578 – Isomaltulose as a Novel Food](#)⁶ was approved by FSANZ in 2007. Some aspects of A578 are relevant to this Application and have been considered in the assessment. Isomaltulose is a disaccharide linked by the same α -D-(1,6) linkages as IMO but comprises two hexoses, glucose and fructose.

1.1 The Applicant

Essence Group Pty Ltd is an Australian-based importer of specialty food ingredients.

1.2 The Application

The Application sought an amendment to Schedule 25 – Permitted novel foods to permit IMO in a selected range of foods at levels up to 15 g IMO/serving. Essence Group applied to market IMO (powder) as an alternative (lower calorie) sweetener and bulk filler in food categories including carbonated beverages, sports and energy drinks, soy milks, 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 specific list of foods requested is available in supporting document 1 (SD1). The Applicant does not intend that formulated supplementary food for young children or foods for infants be permitted to contain IMO⁷ (i.e. nominated exemptions).

The Applicant stated that IMO can be used as:

- an alternative to other carbohydrate bulk sweeteners such as sucrose, glucose, fructose and high fructose or maltose syrups
- an alternative filler to provide bulk and texture to other currently available food ingredients, such as fructo-oligosaccharides (FOS), inulin, polydextrose and dextrans.

The Applicant further stated that at the theoretical maximum sugar replacement level, IMO is unlikely to be used alone in high sweetness products and instead is more likely to be used as a part of a blend of sweeteners (i.e. for matching the sweetness profile of sucrose).

The Applicant also noted it is not the intention to market or support the use of IMO as a prebiotic, to make nutrition content claims or general level health claims.

⁵ The Application refers to levels of 0.5–1.1% (0.5–1.1 g/100 g) of IMO present in honey, sake and miso in Japan (2008), noting that the level of IMO in soy was not available.

⁶ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa578isoma3297.aspx>

⁷ FSANZ advised the Applicant that “foods for infants” were taken to include infant formula products; there was no objection. Therefore, these food categories were not assessed.

The Applicant did not apply for an additional method of analysis for dietary fibre and noted that to support a nutrition content claim about dietary fibre, the product would need to meet relevant Code requirements in Standards 1.2.8 – Nutrition information requirements and 1.2.7 – Nutrition, health and related claims.

1.3 Current standards

1.3.1 Australia and New Zealand

[Standard 1.5.1 – Novel foods](#)⁸ permits food offered for retail sale to consist of, or have as an ingredient, a novel food which has had a pre-market assessment and approval by FSANZ. These permissions are listed in Schedule 25.

A ‘novel food’ is defined in the Code as a ‘non-traditional food’ that requires an assessment of public health and safety considerations having regard to:

- (a) *the potential for adverse effects in humans; or*
- (b) *the composition or structure of the food; or*
- (c) *the process by which the food has been prepared; or*
- (d) *the source from which it is derived; or*
- (e) *patterns and levels of consumption of the food; or*
- (f) *any other relevant matters.*

Therefore, a novel food must first be considered to be a ‘non-traditional’ food which is also defined in the Code as, among other things, a food that does not have a history of human consumption in Australia or New Zealand.

Specifications in Schedule 3 – Identity and purity, and the calculation of values for nutrition information panels in Schedule 11 – Calculation of values for nutrition information panel, are also relevant.

1.3.2 International

IMO is permitted in several overseas jurisdictions:

- USA – IMO has FDA Generally Recognized as Safe (GRAS) status (GRAS GRN 246) for a list of foods similar to the Applicant’s request.
- Canada – in 2009, Health Canada had no objection to the use of IMO as a food ingredient.
- UK/EU – IMO was permitted to be placed on the EU market in July 2013 (as a novel food).
- Japan – IMO has been on the FOSHU (Food for Specified Health Uses) ingredient list for more than 10 years.
- China has a National Standard for IMO – GB/T 20881 – 2007.
- Korea – oligosaccharides are listed under section 10 of Article 5: Standards and Specifications for Each Food Product of the Food Code.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2); and

⁸ <https://www.legislation.gov.au/Series/F2015L00403>

- it related to a matter that might be developed as a food regulatory measure or warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation, as proposed following assessment, was approved with amendment as follows.

For amendment of the specifications, see Section 2.2 and SD1.

In addition, two minor amendments were made to the draft variation to reflect changes to Schedule 3 made by other applications. The following section numbers were renumbered as follows:

- S3—35 to S3—36; and
- S3—36 to S3—37.

The variation takes effect on gazettal. The approved draft variation, as varied after consideration of submissions, is at Attachment A. The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation. The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Six submissions were received i.e. three from government jurisdictions, two from the food industry and one from a health professional organisation. All submitters generally supported amending the Code to permit IMO, subject to further consideration of the substantive issues listed in Table 1.

Table 1: Summary of issues raised and the FSANZ response

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Queries the assumption made in the dietary exposure assessment, where IMO replaced added sugars on a gram for gram basis to predict the dietary intake of IMO. Notes that, in the Applicant’s example recipe, added sugar was replaced with IMO using a conversion factor of 1.67 (given the relative sweetness of IMO is approx. 60% that of sucrose).</p>	<p>Vic Health</p>	<p>FSANZ has further considered these points.</p> <p>The potential exposure to IMO has been revised. The dietary modelling was re-run using a conversion factor of sugar: IMO of 1.6 based on the relative sweetness of IMO of approximately 60% compared to sucrose and also the Applicant’s data. See SD1 and section 2.2 and 2.3.3 in this report.</p> <p>Two scenarios were modelled with IMO replacing 50% of added sugars on a 1.6 gram for 1 gram basis:</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>This suggests that in estimating dietary exposure to IMO, one gram of added sugar should be replaced with 1.67 g IMO, to more closely reflect predicted exposure. Using this conversion factor, the daily dose for some population groups is likely to be higher than 40 g IMO per day, at which level, evidence for adverse effects in healthy humans is lacking.</p>		<ul style="list-style-type: none"> • Scenario 1 – only those foods proposed by the Applicant • Scenario 2 – all foods (excluding infant formula products, infant foods and formulated supplementary foods for young children). <p>The predicted dietary exposures were compared to levels of IMO reported to be well tolerated in the literature i.e. a single dose (40 g) of IMO. In summary, for scenario 1, the predicted mean dietary exposures to IMO were < 40 g/day IMO for all age groups. For Scenario 2, predicted mean exposures for some age groups were > 40 g/day IMO.</p> <p>However, this level of exposure is considerably overestimated and not considered to be realistic, particularly scenario 2 as it is unlikely to reflect consumption patterns of IMO-containing foods. Scenario 2 also includes a broader range of foods than those proposed by the Applicant. Based on Canadian data on market penetration, the market share for IMO is expected to be approximately 10% of the maximum predicted from proposed uses. The Applicant also notes that for organoleptic reasons i.e. matching the sweetness profile of sucrose, IMO is unlikely to be used alone (at the theoretical maximum sugar replacement level) in high sweetness products and instead is more likely to be used as a part of a blend of sweeteners.</p> <p>Noting the lack of an identifiable hazard and that a 40 g single dose is well tolerated, the proposed use of IMO is unlikely to pose a risk to public health.</p>
<p>The unknown effects of IMO at levels above 40 g per day, the reported gastrointestinal effects in haemodialysis patients, and the limits set for IMO in foods in the USA, UK and EU suggests further consideration of the conditions of use is needed.</p>	Vic Health	<p>FSANZ considers that the proposed conditions of use do not need to be re-visited for the following reasons:</p> <ul style="list-style-type: none"> • The hazard assessment (SD1) considered that the study based on haemodialysis patients is of limited relevance to the assessment of tolerance of IMO by healthy individuals. See section 3.6.1 of SD1. • The IMO limits for use in foods in the US and EU (which includes UK) are not based on risk. The regulatory systems in the US, Canada and the EU have different approaches for novel food approval. Thus, the use levels listed reflect the approach applied in the relevant regulatory system. • Use level in foods will be limited for technical reasons e.g. when used for bulking properties it increases the quantity of the final food; and for organoleptic reasons i.e. matching the sweetness profile of sucrose.

Issue	Raised by	FSANZ response (including any amendments to drafting)
		<p>As noted in the Application, it is likely that IMO will be used as a part of a blend of sweeteners, which also limits the amount added.</p> <ul style="list-style-type: none"> SD1 shows no identified risk from the intended use of IMO. Thus, a prescribed limit is not warranted.
<p>Notes no evidence of abdominal symptoms (e.g. laxative effects) up to a single daily dose of 40 g. Concerned about possible excess when a combination of products containing IMO is consumed in the same day. It is acknowledged that consumption of these products will not result in excesses of 40 g in a single dose, but may result in over 40 g of IMO being ingested in one day. Requests clarity from FSANZ.</p> <p>Should consumption of over 40 g of IMO in a single day, but not as a single dose, be associated with abdominal symptoms, then advisory labelling such as 'excess consumption may have a laxative effect' may be warranted e.g. flavoured milks, soft drinks and chocolate, as identified by FSANZ in SD1.</p>	<p>NSW Food Authority</p>	<p>Available evidence indicates no abdominal symptoms (e.g. laxative effects) up to a single dose of 40 g (excluding those with sucrase-isomaltase deficiency). In the absence of any identifiable hazard, FSANZ has assigned an Acceptable Daily Intake (ADI) of 'not specified'. The available scientific evidence does not identify a threshold at which IMO might cause any gastrointestinal effects in healthy individuals. Nor is there available evidence that identifies changes to gastrointestinal function as a result of consuming IMO multiple times a day rather than as a single daily dose.</p> <p>Please also see FSANZ's response provided above regarding predicted exposure to IMO. In addition, information from mature markets overseas (e.g. Canada) indicates that general consumption levels of foods containing IMO are about 2 serves/day. No available evidence suggests the Australian and New Zealand consumption will be any different.</p> <p>The current levels in the Code that trigger a statement on possible laxative effects were previously determined from evidence based on a single dose, and this approach has been applied to this Application. Proposal P202 – Low joule foods, determined the trigger levels based on evidence of laxative effects in humans from a single dose of either 10 g or 25 g of the substance. If evidence showed that no laxative effects occurred with the consumption of the substance, then it was determined that a statement about laxative effects need not apply to that substance. For example, P202 determined that a 'laxative effects' statement was not required for the addition of glycerol to food.</p> <p>In line with P202, the use of IMO in a food will not require the display of a statement about possible laxative effects, as available evidence shows no effect up to a single dose of 40g. Also, such a statement was not required for the use of isomaltulose in a food under A578.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Does not support the proposed specification for IMO – requests FSANZ consider closer alignment with international specifications, including the draft specification under development for Food Chemicals Codex (FCC).</p>	<p>Ingredient</p>	<p>FSANZ has further considered these points.</p> <p>In response, FSANZ undertook targeted consultation with several manufacturers and reviewed the proposed specifications. As a result, two amendments have been made to the specifications proposed with the call for submissions, to align the specifications more closely with overseas product specifications (see Attachment A and SD1). The Applicant accepted these amendments. However, it is not appropriate to align with FCC at this time, as the proposed FCC specifications are still at a draft stage with an unknown timeline. If the FCC IMO specifications are eventually approved, they would be seen as a primary source of specifications under Schedule 3.</p> <p>See section 2.3.5 below.</p>

2.2 Risk and technical assessment

FSANZ conducted a risk assessment on the proposed use of IMO as a novel food for use as a bulk filler and alternative sweetener in a range of foods. The full assessment is provided at SD1 and contains a food technology report, a hazard assessment and a dietary exposure assessment.

The food technology assessment concluded that, when IMO is used as an ingredient to replace sucrose in a food, it meets the stated purpose of a bulk filler. Also, according to the Applicant's reported composition of IMO (i.e. lower levels of mono- and di-saccharides than sucrose) and FSANZ's proposed specification for IMO, it could be used as a sweetener with approximately 60% sweetness compared to sucrose. The Applicant did not request a separate energy factor for IMO.

In response to a submission, FSANZ further considered the IMO specification that was proposed in the call for submissions. The submission highlighted the need for consistency in domestic and international regulations, and referred to a recent draft Food Chemicals Codex (FCC) IMO specification (see Table 1 above). After consideration, the proposed specifications were modified as described in section 2.3.5 below.

IMO has a history of safe use in healthy humans (i.e. excluding those with sucrose-isomaltase deficiency, see below) in countries other than Australia and New Zealand. IMO is not efficiently converted to glucose in the small intestine, so the majority (~60–70%) of the ingested IMO is likely to pass unchanged into the colon. There is no evidence of adverse gastro-intestinal effects (e.g. diarrhoea) in healthy humans (i.e. excluding those with sucrase-isomaltase deficiency) up to a single bolus dose of 40 g₉. Furthermore, IMO did not cause any abdominal symptoms (e.g. laxative effects) in any subjects at this level. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is considered appropriate.

⁹ A study discussed in SD1 (Oku and Nakamura (2003) cites a previous study (1999) showing that a single dose of IMO of 1.5 g/kg bodyweight does not cause diarrhoea in humans. The study is also cited by Health Canada, who estimated that for a 70 kg person, this equates to 105 g IMO. However, the 1999 study was not reviewed by FSANZ because it is not in English. Therefore, although the dose/kg body weight was included in the dietary exposure assessment for completeness, it was not part of FSANZ's risk management considerations for A1123.

However, it is noted that IMO is likely to be poorly tolerated by individuals with congenital or acquired sucrase-isomaltase deficiency (SD1). The prevalence of congenital sucrase-isomaltase deficiency is estimated to be in the range of 0.05% to 0.2% in children of European descent (Geng et al. 2014). The prevalence of acquired sucrase-isomaltase deficiency is unknown, and it may be underdiagnosed (Cohen 2016) (SD1). (Risk management measures for these individuals are considered below).

In the absence of an identifiable hazard, and as an ADI is not specified, a chronic dietary exposure assessment (DEA) was not required.

However, as a single bolus dose of 40 g/day was reported in the literature to be well-tolerated a DEA was undertaken to enable comparison to the well tolerated level. The assessment focused on a more acute or short term exposure and assessed two separate scenarios using consumption data (for day 1 only) from the most recent national nutrition survey for Australia:

- Scenario 1: IMO assumed to replace 50% of added sugars on a 1.6 gram for 1 gram basis *in only those foods proposed by the Applicant.*
- Scenario 2: IMO assumed to replace 50% of added sugars on a 1.6 gram for 1 gram basis *in nearly all foods* (excluding infant formula products, infant foods and formulated supplementary foods for young children).

The predicted dietary exposures were then compared to levels of IMO reported to be well tolerated in the literature i.e. a single dose (40 g) of IMO.

For the food categories proposed by the Applicant (scenario 1), for all age groups assessed, the predicted mean dietary exposures to IMO over 24 hours were < 40 g IMO. For all food categories containing added sugars with nominated exemptions (scenario 2), the estimated mean dietary exposures to IMO over 24 hours were < 40 g IMO for 2–8 years and 51 years and over; however, mean exposures were > 40 g IMO for those aged 9–50 years (up to 58 g/day). High consumers of IMO-containing foods may also exceed 40 g of IMO.

However, due to the assumptions made in scenario 2, predicted exposures are not considered realistic because the scenario is unlikely to reflect normal consumption patterns of IMO-containing foods. The Applicant suggests that no more than two foods containing IMO would be consumed in a day based on mature markets overseas e.g. Canada.

In conclusion, as no threshold at which IMO may cause adverse effects has been identified, IMO may be considered safe and suitable to be added to food offered for retail sale (see section 2.4 for risk management of those individuals with sucrase-isomaltase deficiency). The addition of IMO to infant formula products, infant foods and formulated supplementary foods for young children was excluded from the dietary exposures assessment because the permission does not extend to those categories of food.

2.3 Risk management

In addition to the outcomes of the risk and technical assessment, the following points were considered when determining relevant risk management measures.

2.3.1 Novelty

The ACNF has considered that IMO does not have a history of consumption in Australia and New Zealand twice before (2011, 2012). As IMO met the Code definition of a 'non-traditional food' and, as a new food ingredient, it has undergone a safety assessment prior to approval for use in Australia and New Zealand and was found to be safe and suitable. Novel food ingredients can also perform a technological function in a food. Therefore, IMO is suitable to be added to Schedule 25 – Permitted novel foods.

2.3.2 Nutrition implications for use of IMO as an alternative sweetener

The Applicant proposed the use of IMO as an alternative sweetener and, although not applying for a specific energy factor in the Code, considered the energy value to be 6.3 kJ/g (1.5 kcal/g).

As a comparison, [Health Canada](#)¹⁰ considered the caloric (energy) value for the particular IMO under their consideration to be 2.4 kcal/g. The UKFSA determined that there was insufficient evidence to show that the IMO had a significantly reduced energy content compared with other digestible carbohydrates (UKFSA 2012).

Typically, IMOs are glucose oligomers with predominantly α -D-(1, 6) glycosidic linkages. Some of the α -D-(1, 6) linked fractions will be digested in the small intestine and absorbed as glucose. However, the majority (~60–70%) of the ingested IMO would likely pass unchanged into the colon (SD1). Carbohydrates that pass into the colon contribute less energy than those fully digested in the small intestine. The Applicant's IMO preparation consists of 20–43% monosaccharides and disaccharides (SD1). We note that the IMO Health Canada considered was composed of 15–20% smaller saccharides and 70–80% larger oligosaccharides.

2.3.3 Foods permitted to have IMO added

Based on the risk assessment conclusions, FSANZ considered it appropriate to extend the requested list of foods that may contain added IMO to nearly all foods, except infant formula products (Standard 2.9.1)¹¹, food for infants (Standard 2.9.2) and formulated supplementary foods for young children (Standard 2.9.3, Division 4), and not to impose a limit per serving.

In the absence of an identifiable hazard, FSANZ considered that broadening the permission would not pose a risk to the health and safety of the population.

Although the addition of IMO to nearly all food categories (scenario 2, section 2.2), predicted the mean dietary exposures to IMO over 24 hours could be >40 g for some age groups (ages 9–50 years), these predicted exposures are considered to be an overestimate and not likely to be realistic for the general population. As noted in section 2.2 above and SD1, it is unlikely that 50% of added sugars in every food in every food category would be replaced with IMO, or that individuals would consume every one of these foods with added IMO in one day. The Applicant suggests no more than two foods in a day containing IMO are likely to be consumed based on overseas market experience e.g. Canada. The Applicant also notes that for organoleptic reasons i.e. matching the sweetness profile of sucrose, IMO is unlikely to be used alone (at the theoretical maximum sugar replacement level) in high sweetness products and instead is more likely to be used as a part of a blend of sweeteners.

Health Canada's exposure assessment also considered that it is unlikely that all food will contain IMO, or that a consumer would buy all the food products containing IMO, or that all IMO food bought would be consumed together. Based on data on Canadian market penetration, the market share for IMO-containing foods is expected to be approximately 10% of the maximum predicted from proposed uses.

¹⁰ Health Canada – Novel food information – Isomalto-oligosaccharide (Vitasugar), Appendix 7 of A1123 or <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/isomalto-oligosaccharide-eng.php>

¹¹ The Applicant indicated no intention for formulated supplementary food for young children or foods for infants to contain added IMO; this exception includes infant formula products.

Furthermore, as no effects have been reported at the 40 g single dose level (excluding those with sucrase-isomaltase deficiency), FSANZ has used this level as the most appropriate benchmark for considering risk management options for this Application.

2.3.4 Labelling of food products with added IMO

The addition of IMO to food will be subject to a number of existing generic labelling requirements in the Code that provide information to enable consumers to make informed choices. FSANZ has not identified a need to apply additional labelling requirements specifically to the use of IMO.

2.3.4.1 Statement of ingredients

Standard 1.2.4 – Information requirements – statement of ingredients requires food for sale to be labelled with a statement of ingredients unless exempt. Should manufacturers choose to add IMO to a food, then IMO is required to be declared in the statement of ingredients using a name by which it is commonly known; or a name that describes its true nature. These requirements will assist consumers to identify the presence of IMO in a food. This is particularly important for those individuals with congenital or acquired sucrase-isomaltase deficiency who are likely to poorly tolerate IMO, noting that they already need to avoid sucrose.

2.3.4.2 Mandatory advisory statements and declarations

Allergen declarations

IMO can be produced using starch obtained from wheat, barley or oats. Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations, requires certain substances to be declared including cereals containing gluten i.e. wheat, oats, barley, rye and their hybrids if present in a food. Standard 1.2.3 requirements will apply to products containing IMO to provide information to consumers on the presence of allergens.

Advisory statement on laxative effects

Standard 1.2.3 also requires that foods containing certain substances (primarily polyols) above a threshold level (10 g/100 g or 25 g/100 g depending on the substance) must display a statement to the effect that excess consumption can produce laxative effects. This requirement was based on evidence that demonstrated laxative effects in humans from a single bolus dose of either 10 g or 25 g of the substance¹². However if the evidence showed that no laxative effects occurred with the consumption of the substance, then it was determined that a statement about possible laxative effects need not apply to that substance.

The need for a statement about possible laxative effects was also considered during Application A578 – Isomaltulose as a Novel Food. Evidence showed that there were no adverse effects in human volunteers with doses up to 50 g/day. Therefore, it was determined that the use of a laxative effects statement was not warranted for the use of isomaltulose in a food.

Based on the risk assessment, FSANZ is not proposing to apply an advisory statement on potential laxative effects to the use of IMO. This is consistent with the approach taken for Application A578, and for Proposal P202 – Review of Provisions for Low Joule Foods & Carbohydrate-modified Foods (see section 2.4 for other risk management measures).

¹² This labelling advisory statement arose from FSANZ's assessment of P202 in 1999 (not available on the FSANZ website).

2.3.4.3 Nutrition information – contribution of IMO to carbohydrate and energy content declarations

Standard 1.2.8 – Nutrition information requirements requires the sugars content to be listed separately from the total carbohydrate content in the nutrition information panel (NIP). The definition of ‘sugars’ in Standard 1.1.2, as applicable to the declaration of sugars content in the NIP required by Standard 1.2.8, means *monosaccharides and disaccharides*. As such, the monosaccharide and disaccharide components (20–43%) of the Applicant’s IMO preparation would contribute to the declared sugars content on a food’s NIP.

The total carbohydrate content in the NIP is calculated using section S11—3 (Calculation of values for nutrition information panel)¹³ of Schedule 11. Based on these calculations, the **available** carbohydrate component of IMO will need to be displayed in the NIP unless it is calculated by difference¹⁴, since the definition of ‘carbohydrate’ in Standard 1.1.2 refers to available carbohydrate. In relation to IMO, the available carbohydrate component would depend on its proportion of ‘available’ sugars and oligosaccharides. The Code does not specifically define ‘available’ sugars etc. or ‘unavailable carbohydrate’ or provide any categorisation of individual food ingredients into ‘available’ or ‘unavailable’ groups.

FSANZ has not assessed the energy value of IMO. The type of carbohydrates in IMO will influence how total energy contents are declared in the NIP on product labels. Schedule 11 lists several energy factors (for determining a food’s total energy content) for different types of carbohydrates.

Assigned energy factors for the general components—available carbohydrates and unavailable carbohydrates—are 17 kJ/g and 8 kJ/g respectively. Therefore, the energy contribution of IMO will depend on the proportion of its carbohydrate content considered to be available or unavailable.

To meet the requirements for displaying the sugars, carbohydrate and energy contents on the label of a food containing IMO, a food manufacturer will need to know the monosaccharide and disaccharide content, and the available and unavailable carbohydrate content of the IMO ingredient. A manufacturer should have access to this information, as Standard 1.2.1 – Requirements to have labels or otherwise provide information, requires that the purchaser (of IMO) must be provided with any information they request as necessary to enable them to comply with labelling requirements.

2.3.4.4 Nutrition information – contribution of IMO to dietary fibre

Standard 1.2.8 includes a definition of dietary fibre that includes a condition that dietary fibre has a degree of polymerisation greater than two. IMO that is added to a food could potentially meet this definition, and therefore contribute to the dietary fibre content when included in the NIP. However, for the IMO to contribute to dietary fibre, a food manufacturer would first need to demonstrate that the profile of the specific IMO added to the food met the definition of dietary fibre in Standard 1.2.8.

¹³ Standard 1.1.2 refers to section S11—3 in respect of the definition of ‘carbohydrate’ (which is also defined as ‘available carbohydrate’ or ‘available carbohydrate by difference’). This section states that available carbohydrate is calculated by summing the average quantity in the food of total available sugars and starch, and any available oligosaccharides, glycogen and maltodextrins (if they are quantified or added to the food).

¹⁴ Alternatively, available carbohydrate can be calculated by difference. This calculation involves subtracting from 100 the average quantity in the food (expressed as a percentage) of water, protein, fat, dietary fibre, ash, alcohol, any other unavailable carbohydrate, and a substance listed in subsection S11—2(3). If the available carbohydrate is calculated by difference, the unavailable carbohydrate component is also required to be declared in the NIP.

The food manufacturer would need to analyse the dietary fibre content of the final food using the methods set out in Schedule 11 (Calculation of values for nutrition information panel). It should be noted, that not all of an IMO ingredient would necessarily contribute to a food's dietary fibre content when analysed, even if it met the definition of dietary fibre in the Code.

2.3.4.5 Nutrition content and health claims

Requirements for making nutrition content and health claims are set out in Standard 1.2.7 – Nutrition, health and related claims.

The Applicant has indicated that IMO will be marketed as a lower calorie replacement for sugar (sucrose). If a food manufacturer intends to make nutrition content or health claims about the energy or sugar/s content of products containing IMO, then these foods will need to meet the requirements in Standard 1.2.7. The specific conditions for making claims about energy and sugar/s are in Schedule 4 (Nutrition, Health and Related Claims).

In the case of dietary fibre, Standard 1.1.2—9 permits the declaration of dietary fibre in the NIP without it constituting a nutrition content claim if the food contains less than 2 g of dietary fibre per serving. Otherwise, a manufacturer of a food that contains IMO may make nutrition content or health claims about dietary fibre only if the claim conditions in Schedule 4 are met.

2.3.4.6 Glycaemic response

The Advisory Committee on Novel Foods and Processes of the UKFSA has assessed the literature on IMO (UKFSA, 2012), and considered that IMO has a similar glycaemic response to glucose. The UKFSA approved the use of IMO on this basis but only on the condition that there is a statement on the label of a food containing IMO indicating that it is not suitable for diabetics (UKFSA, 2013). The reason given for the statement is that individuals with diabetes may perceive IMO to be a prebiotic dietary fibre rather than a mixture of carbohydrates that may have an impact on blood glucose levels.

FSANZ considered that the glycaemic response to foods is highly variable and depends greatly on the food matrix, rather than the presence of a single ingredient. Other ingredients could also moderate a food's glycaemic response despite the presence of IMO. Therefore, a mandatory labelling statement in relation to diabetes was not proposed.

2.3.5 Specifications for IMO

Subsection 1.1.1—15(2) and Schedule 3 – Identity and purity regulate the identity and purity of substances. Schedule 3 adopts specifications for food additives and other substances in foods by reference to specific sources including specifications established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). If a suitable specification is not included in these sources, Schedule 3 provides distinct specifications for some ingredients and substances.

IMO is not covered by a specification identified in Schedule 3 or in any of the primary or secondary specification sources approved for use by FSANZ. Therefore, FSANZ prepared a draft specification for the call for submissions (Attachment C). One submitter recommended closer consistency with other overseas specifications and suggested alignment with draft specifications currently being developed by the US Pharmacopoeia for inclusion in the Food Chemicals Codex list (FCC). FSANZ reviewed the proposed specifications and consulted with several manufacturers including the Applicant. As a result, the specifications were amended to ensure closer consistency with other overseas product specifications (see SD1 and the revised specifications in Attachment A). The Applicant was advised of the amendments.

However, FSANZ considers alignment with the draft FCC specifications is not appropriate at this time as they are only in the early stage of consultation. The FCC is included as a primary source listed in section S3—2 (1)(c) of Schedule 3 of the Code, so if the draft IMO specifications were adopted by FCC on the future, they would be referenced in the Code as an alternative specification.

2.3.6 Analytical methods for analysis

There are analytical methods available that can separate and analyse the individual oligosaccharides in the IMO preparation. High performance liquid chromatography (HPLC) is the analytical method of choice. The Application contains a HPLC analytical method (Appendix 14 of the Application).

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

The Applicant, previous submitters, subscribers, and interested parties were notified of the assessment and call for submissions via the FSANZ Notification Circular, a media release, FSANZ's social media tools and Food Standards News.

Submissions were called for on 13 December 2016 for an eight-week consultation period. Six submissions were received and reviewed by FSANZ staff and Board members (see section 2.1). FSANZ acknowledges the time taken by individuals and organisations who made submissions. Although comments submitted may not always be adopted, they contribute to the rigour of our assessment.

In addition, if the amendments to the Code are finally gazetted, information will be provided to relevant health professional bodies so that their members can advise patients with sucrose-isomaltase deficiency of the Code requirements and the relevant information to look for on food labels.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The direct and indirect benefits that could arise from the approved variation to the Code as a result of Application A1123 are likely to outweigh the costs to the community, government or industry from the regulatory measure.

In June 2016, the OBPR advised¹⁵ that, based on the information provided, the Application appeared to be machinery in nature and would not have adverse impacts on business, community organisations or individuals. Therefore, a Regulation Impact Statement (RIS) was not required.

¹⁵ OBPR ID 20966

Notwithstanding the above exemption, FSANZ considered the costs and benefits of this Application for the purposes of section 29 following the assessment prior to the call for submissions. This is not intended to be an exhaustive, quantitative economic analysis. Rather, the assessment considered the qualitative impacts of the approved variation.

That analysis found that approving the use of IMO as a novel food could benefit consumers generally and food manufacturers. Benefits for consumers include an alternative sweetener on the market, possibly with a preferred taste profile. Food manufacturers will have an alternative bulk sweetener available which could provide an opportunity to reformulate or develop new products.

As this is a voluntary permission, any increased costs would be a business decision based on expected returns. Also, as the permission is voluntary and as IMO is not expected to be added to every food, there will still be choice for those individuals who wish or need to avoid IMO (e.g. those with sucrose-isomaltase deficiency).

No costs were identified that would offset these benefits to different stakeholders.

FSANZ concluded that the direct and indirect benefits that would arise from the food regulatory measure developed as a result of the Application outweighed any costs to the community, government or industry that would arise from the measure. Therefore, the preferred option was to prepare a variation to the Code to approve IMO as a novel food.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

All affected standards are joint Australia New Zealand standards. There are no relevant New Zealand Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ concluded that approval of IMO as a novel food as proposed above, does not pose a risk to human health for Australian or New Zealand consumers, except for individuals with sucrose-isomaltase deficiency.

Specific information will be provided to health professional bodies, to assist their members in advising these individuals of the new permissions and labelling requirements in the Code.

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

The generic labelling requirements will provide consumers with information to assist them make informed choices, including those individuals with sucrose-isomaltase deficiency.

2.5.2.3 The prevention of misleading or deceptive conduct

The generic labelling requirements in the Code including for voluntary nutrition content and health claims, prevent the likelihood of consumers being misled.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's risk analysis relied on the best available scientific evidence (SD1).

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

Internationally, IMO is permitted in a number of jurisdictions (section 1.3.2) and the approved variations to the Code (including the updated specifications) will promote consistency with these other approvals.

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

Approval of IMO could increase the international competitiveness of Australian and New Zealand businesses by potentially gaining access to overseas markets. The permission will ensure that IMOs approved for use in trading partner countries and foods containing IMO, can be imported into Australia and New Zealand, providing Code requirements are met.

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

No issues were identified.

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

There are [two guidelines](#)¹⁶ that relate to IMO:

- Policy Guideline on Novel Foods
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

FSANZ's assessment against these policy guidelines is provided at SD2.

6 References

UKFSA (2012). Initial Opinion: Isomalto-oligosaccharide as a novel food ingredient; and UKFSA (2013). Isomalto-oligosaccharide as a novel food ingredient, (accessed 22 July 2016) <https://acnfp.food.gov.uk/committee/acnfp/assess/fullapplies/Isomalto-oligosaccharide>.

Attachments

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

¹⁶ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

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



Food Standards (Application A1123 – Isomalto-oligosaccharide as a Novel Food) Variation

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

Dated [To be completed by Standards Management Officer]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1123 – Isomalto-oligosaccharide as a Novel Food) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 3 is varied by

[1.1] inserting into the table to subsection S3—2(2), in alphabetical order

isomalto-oligosaccharide section S3—37

[1.2] inserting after section S3—36

S3—37 Specification for isomalto-oligosaccharide

For isomalto-oligosaccharide (IMO), the specifications are the following:

- (a) chemical structure—IMO is a mixture of glucose oligomers with α 1→6 glycosidic linkages that include isomaltose, panose, isomaltotriose, isomaltopentaose and various branched oligosaccharides;
- (b) description—a white crystalline powder or transparent clear pale yellow coloured syrup;
- (c) IMO content (dry weight)—not less than 90% (powder) and not less than 75% (syrup);
- (d) oligosaccharides—not less than 55% with a degree of polymerisation of 3 or more;
- (e) glucose (dry weight)—not more than 5%;
- (f) moisture—not more than 5% for the powder, not applicable for syrup;
- (g) ash (dry weight)—not more than 0.3%.

[2] Schedule 25 is varied by inserting into the table to section S25—2, in alphabetical order

Isomalto-oligosaccharide

- 1. Must not be added to:
 - (a) infant formula products; and
 - (b) food for infants; and
 - (c) formulated supplementary food for young children.

Attachment B – Explanatory Statement

1. Authority

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

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

FSANZ accepted Application A1123 which sought to permit isomalto-oligosaccharide as a novel food, to be used as an alternative sweetener and bulk filler in a range of foods. The Authority considered the Application in accordance with Division 1 of Part 3, and has approved a draft variation.

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

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

2. Purpose

Isomalto-oligosaccharide is currently not permitted under the Code. The Authority has approved a draft variation that will amend the table to section S25—2 to permit IMO to be used in in food offered for retail sale other than infant formula products, infant food and formulated supplementary foods for young children. The variation will also amend Schedule 3 to provide specifications for IMO's identity and purity.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1123 included one round of public consultation following an assessment and the preparation of a draft variation and associated reports. Submissions were called for on 13 December 2016 for an eight-week consultation period.

A Regulation Impact Statement was not required because the variations to Schedules 3 and 25 are deemed to be deregulatory in nature (see OBPR ID 20966) and likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

6.1 Schedule 3

Subitem [1.1] amends the table to subsection S3—2(2) by inserting references to isomalto-oligosaccharide and section S3—37.

Subitem [1.2] inserts new section S3—37. The proposed subsection sets specifications for isomalto-oligosaccharide's identity and purity for the purposes of section 1.1.1—15 of the Code.

6.2 Schedule 25

Item 2 inserts a reference to and conditions of use for isomalto-oligosaccharide into the table to section S25—2. The effect of the amendment is to provide a permission for isomalto-oligosaccharide as a novel food in food offered for retail sale for the purposes of section 1.1.1—10 of the Code. The permission is for food (other than infant formula products, food for infants and formulated supplementary food for young children) to consist of isomalto-oligosaccharide or have isomalto-oligosaccharide as an ingredient. The conditions prohibit the addition of isomalto-oligosaccharide to infant formula products (Standard 2.9.1), food for infants (Standard 2.9.2) and formulated supplementary food for young children (Standard 2.9.3, Division 4).

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (Application A1123 – Isomalto-oligosaccharide as a Novel Food) Variation

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

Dated [To be completed by Standards Management Officer]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1123 – Isomalto-oligosaccharide as a Novel Food) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 3 is varied by

[1.1] inserting into the table to subsection S3—2(2), in alphabetical order

isomalto-oligosaccharide section S3—36

[1.2] inserting after section S3—35

S3—36 Specification for isomalto-oligosaccharide

For isomalto-oligosaccharide (IMO), the specifications are the following:

- (a) chemical structure—IMO is a mixture of glucose oligomers with α 1→6 glycosidic linkages that include isomaltose, panose, isomaltotriose, isomaltopentaose and various branched oligosaccharides;
- (b) description—a white crystalline powder or transparent clear pale yellow coloured syrup;
- (c) IMO content (dry weight)—not less than 96% (powder) and not less than 75% (syrup);
- (d) oligosaccharides—not less than 55% with a degree of polymerisation of 3 or more;
- (e) glucose (dry weight)—not more than 5%;
- (f) moisture—not more than 4% for the powder, not applicable for syrup;
- (g) ash (dry weight)—not more than 0.3%.

[2] Schedule 25 is varied by inserting into the table to section S25—2, in alphabetical order

isomalto-oligosaccharide

Must not be added to:

- (a) infant formula products; and
- (b) food for infants; and
- (c) formulated supplementary food for young children.