APPLICATION

NOVEMBER 2015

TO:
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:
APPLICATION FOR APPROVAL OF ISOMALTO-OLIGOSACCHARIDE (IMO) AS A NOVEL FOOD

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To: Food Standards Australia New Zealand

In relation to: Application for approval of isomalto-oligosaccharide (IMO) as a Novel Food November 2015

* This information is commercial confidential information (CCI) and has been provided separately

ADMINISTATIVE INFORMATION

Applicant Details

(As per section 3.1.2 of the Application Handbook 1 September 2013, amended 1 June 2015)

Applicant: [redacted], Director

Organisation: Essence Group Pty Ltd (hereafter Essence Group)

ABN: 97 124 669 790

Address: G13, National Innovation Centre, Australian Technology Park,

4 Cornwallis Street, Eveleigh NSW 2015

Postal Address: PO Box 326, Alexandria NSW 2015

Telephone: [redacted]

Email address: [redacted]

Nature of Business

(As per section 3.1.2(f) of the Application Handbook 1 September 2013, amended 1 June 2015)

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

Essence Group provides tailored consultation services to clients to assist with new product development and innovation.

Details of Other Parties Associated with the Application

(As per section 3.1.2(g) of the Application Handbook 1 September 2013, amended 1 June 2015)

The following Scientific and Regulatory Consultants are involved in the preparation, submission and stewardship of this application:

[redacted]

[redacted]

1. APPLICATION INFORMATION

Assessment Procedure

(As per section 3.1.6 of the Application Handbook 1 September 2013, amended 1 June 2015)

Essence Group seeks to proceed with an **unpaid** application for consideration as a General Procedure, Level 2 (maximum of 650 hours).

Confidential commercial information

(As per section 3.1.7 of the Application Handbook 1 September 2013, amended 1 June 2015)

This application **does contain** information that is confidential commercial information (CCI).

Essence Group requests the information contained within **Appendix 1** (Letter of support for the application) be considered CCI.

The letter indicates interest in using the product.

Exclusive capturable commercial benefit

(As per section 3.1.8 of the Application Handbook 1 September 2013, amended 1 June 2015)

This application will **not confer** an exclusive capturable commercial benefit for Essence Group or any other individual company.

Exclusive use of Novel Foods

(As per section 3.2.5A of the Application Handbook 1 September 2013, amended 1 June 2015)

Essence Group is **not** seeking exclusive permission for use of IMO in Australia and New Zealand.

Status of Similar Applications

(As per Section 3.1.4 of the Application Handbook 1 September 2013, amended 1 June 2015)

There are no similar applications for approval of IMOs.

Prior to the development of the Novel Food Standard, similar products such as inulin and FOS were permitted to be sold as food ingredients without regulatory approval. Similar products, such as isomaltulose, introduced after the gazettal of the novel food standard, have been assessed by FSANZ and found to be safe and suitable.[1]

In May 2014, Bioneutra submitted an application to extend the uses of its isomalto-oligosaccharide into additional foods (desserts, crackers, nutritional food bars, edible ices, flavoured drinks, sweet sauces, toppings and syrups, ready-to-eat savouries and snacks and foods intended for particular nutritional uses). (BioNeutra, 2014)

1. http://www.foodstandards.gov.au/consumer/generalissues/Pages/Isomalt.aspx, accessed 05.10.15

2 PURPOSE OF THE APPLICATION

(As per section 3.1.3 of the Application Handbook 1 September 2013, amended 1 June 2015)

Essence Group is making this application to amend Schedule 25 – Permitted Novel Foods of the Australia New Zealand Food Standards Code (hereafter the Code).

The amendment will permit the sale and use of isomalto-oligosaccharide (hereafter IMO) as a food ingredient in Australia and New Zealand.

IMO can be used as an alternative to other carbohydrate bulk sweeteners such as sucrose, glucose, fructose and high fructose or maltose syrups. The applicant intends to market IMO (powder) as a general food ingredient for use as an alternative (lower calorie) sweetener and bulk filler in conventional foods. The relative sweetness of IMO is ~60% sweet as sucrose and the energy value is 156cal/100g (1.5kcal/g or 6.3kJ/g).

IMOs provide an alternative to currently available food ingredients, such as fructose oligosaccharides (FOS), inulin, polydextrose and dextrins, which can be added to foods as fillers to provide bulk and texture.

Essence Group intends to market IMO as a food ingredient in Australia and New Zealand for use as an alternative (lower calorie) sweetener and bulk filler 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 confectionary at levels up to 15g IMO/serving.

The Applicant advises that while it is proposed that foods intended for particular dietary uses are included in the proposed list of foods (formulated meal replacement and formulated supplementary food), there is no intention for formulated supplementary food for young children or foods for infants to contain IMO.

The range of foods and proposed usage rates are set out in **Appendix 2.**

The Applicant advises that the amount of IMO proposed to be added to the foods, as set out in Appendix 2, is consistent with the stated purpose for requesting approval of IMO as a novel food – that is, as an alternative (lower calorie) sweetener and bulk filler. For organoleptic reasons (i.e. matching the sweetness profile of sucrose) IMO is unlikely to be used alone in high sweetness product and instead is more likely to be used as a part of a blend of sweeteners rather than alone at the theoretical maximum sugar replacement level.

The Applicant acknowledges that the requested levels appear to be consistent with the levels associated with international approvals of the ingredient when it is being used in the context of its prebiotic and fibre properties. It is also noted that current authorizations and approvals for IMO

substances overseas are based on both the potential prebiotic or dietary fibre properties as well as its technological properties as a lower calorie sweetener and functional bulk filler.

The Applicant advises that they are **not** intending to market or support the use of IMO as a prebiotic.

This Application seeks **only** the approval of the safety of IMO as a novel food when used for technological purposes, as a lower calorie sweetener and functional bulk filler. This Application does not seek the use of IMO to support nutrition content claims or health claims associated with potential beneficial physiological or health-related effects. The applicant considers that, in order for IMO to be used in a product to support a nutrition content claim about dietary fibre, it would be incumbent on the manufacturer using it to first demonstrate that the oligosaccharide profile of the specific IMO being used met the definition of dietary fibre in Standard 1.2.8 and that the product as consumed, when analysed using the methods set out in Schedule 11 (Calculation of values for nutrition information panel) contained sufficient dietary fibre to meet the criteria for a claim in Schedule 4 (Nutrition, Health and Related Claims).

Similarly, in order for IMO to be used in a product to support a general level health claim (GLHC) about prebiotic functions, the food-health effect relationship for the specific or relevant oligosaccharide profile, would first need to be determined in accordance with Standard 1.2.7. It is noted that if a manufacturer chooses to explore using IMO as a prebiotic and making a general level health claim then they will need to make a separate application to FSANZ or prepare a Scientific Literature Review (SLR) to meet the requirements of Schedule 6.

3 JUSTIFICATION FOR THE APPLICATION

(As per section 3.1.4 of the Application Handbook 1 September 2013, amended 1 June 2015)

3.1 NEED FOR THE PROPOSED CHANGE

(As per section 3.14(a) of the Application Handbook 1 September 2013, amended 1 June 2015)

3.1.1 Approval for the use of a Novel Food

IMO is currently not permitted to be imported into or sold in Australia and/or New Zealand as it is considered to be a novel food and therefore requires pre-market clearance by Food Standards Australia New Zealand (FSANZ).

An application to vary the Code is required for approval of a new novel food or novel food ingredient.

In July 2012, the Applicant wrote to the Food Standards Australia New Zealand Advisory Committee on Novel Foods (ACNF), submitting a Novel Food questionnaire, with a request for the ACNF to review its published opinion, that IMO is a novel food on the basis that it is a new food ingredient which requires a safety assessment of proposed patterns and levels of use.

In August 2012, the ACNF advised the applicant as follows:

"The Committee has formed the view that the IMO meets the definition of 'non-traditional food' on the basis that it does not have a history of human consumption as a food in Australia or New Zealand (Part 1 of the Guidance Tool).

Part 2 of the Guidance Tool requires the Committee to consider whether IMO is a novel food and requires an assessment of public health and safety considerations. The Committee has undertaken a preliminary hazard identification process and formed the view than an assessment of public health and safety considerations is required. Based on the information available it is likely that IMO is considered to be within the scope of the definition of novel food for the purposes on Standard 1.5.1."

The correspondence in relation to this matter is provided under **Appendix 3.**

If IMO is not approved as a novel food it will not be permitted to be imported into or sold within Australia and/or New Zealand as an ingredient in itself or as an ingredient of another food.

3.1.2 Purpose of using IMO

Essence Group is seeking approval for IMO as an alternative to, and at similar levels to, other carbohydrate bulk sweeteners such as sucrose, glucose, fructose and high fructose or maltose syrups. The applicant intends to market IMO (powder) as a general food ingredient for use as an alternative lower calorie sweetener and bulk filler in conventional foods. The relative sweetness of IMO is ~60% sweet as sucrose and the energy value is 156cal/100g (1.5kcal/g or 6.3kJ/g).

IMOs provide an alternative to currently available food ingredients, such as fructose oligosaccharides (FOS), inulin, polydextrose and dextrin's, which can be added to foods as fillers to provide bulk and texture.

3.1.3 International Alignment

Internationally, IMO is recognised in a number of jurisdictions:

- **USA** - IMO has FDA GRAS status in the USA;
- **Canada** – in 2009 Health Canada notified BioNeutra that it has 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;
- **Japan** - IMO has been on the FOSHU ingredient list for more than 10 years;
- **China** has a National Standard for IMO – GB/T 20881 – 2007; and
- **Korea** - oligosaccharides are listed under Section 10 of Article 5. Standards and Specifications for Each Food Product of the Food Code.

International approval and regulation of IMO is discussed in detail under **Section 6** of the Application.

The proposed amendment will bring Australia and New Zealand into line with other jurisdictions that have approved the use of IMO as a novel food and/or permit its use as a food ingredient.

3.1.4 Trade Barriers

IMO is being commercially manufactured predominately in China and Japan. IMO is currently not produced within Australia or New Zealand, although there are no technical reasons why local starch processors would not produce it if it were approved as a food ingredient. The proposed change will ensure that IMOs, which are approved for use in trading partner countries, can be imported into Australia and New Zealand, eliminating a regulatory barrier to trade.

3.2 ADVANTAGES OF THE PROPOSED CHANGE

(As per Section 3.1.4(b) of the Application Handbook 1 September 2013, amended 1 June 2015)

The advantages of the proposed change include:

- opportunity for companies to import IMO for use in food manufacturing or to import products containing IMO;
- opportunity for manufacturers to produce foods containing IMO;
- increase choice for consumers who will have access to foods containing IMO; and
- International alignment of regulations which will reduce the potential for creation of regulatory trade barriers.

The approval of IMO as a novel food will provide manufacturers with additional choice of a safe and suitable lower calorie bulk sweetener. IMO will also provide an alternative to currently available food ingredients, such as fructose-oligosaccharides (FOS), inulin, polydextrose and dextrin which are commonly added to foods as fillers to provide bulk and texture.

Approval of IMO will provide increased choices for consumers who will have access to both imported and locally produced food products containing IMO. Consumers will have access to products with an alternative ingredient or new products developed using IMO.

International alignment and reduction in potential for creation of trade barriers has been addressed under Sections 3.1.3 and 3.1.4.

3.3 DISADVANTAGES OF THE PROPOSED CHANGE

IMO is not currently produced within Australia or New Zealand and therefore approval will not disadvantage local manufactures.

Imported products containing IMO will be required to be labelled so consumers will be able to make a choice as to whether they purchase foods containing IMO.

4 REGULATORY IMPACT INFORMATION

(As per section 3.1.4 A of the Application Handbook 1 September 2013, amended 1 June 2015)

4.1 COSTS AND BENEFITS – CONSUMER

The benefit to consumers include additional choice of an alternative ingredient in a product or additional products which become available due to the availability of IMO for Australian and New Zealand food manufactures, and access to food products containing IMO that are currently manufactured overseas. The cost of the raw material (IMO) is currently less than alternative bulk sweeteners potentially leading to a cost saving for the end customer.

The proposed amendment places no additional economic cost on consumers – IMO will be labelled and consumers can chose if they wish to purchase a product containing IMO.

4.2 COSTS AND BENEFITS - INDUSTRY AND BUSINESS

Use of IMO will be at the discretion of business, therefore there are no direct costs imposed on industry. Approval of IMO will benefit manufacturers in that this will extend the options to source new and lower cost ingredients.

Suppliers of alternative sugar replacers currently available such as inulin and maltodextrin may be disadvantaged if these products cost significantly more than IMO. However, by offering a competitively priced product, IMO affords food manufacturers the opportunity to reformulate products or develop new products while maintaining or lowering their cost base.

4.3 COSTS AND BENEFITS – GOVERNMENT

The proposed amendment places no additional regulatory costs on government beyond the initial regulatory cost of approving IMO as a novel food and for enforcement agency laboratories in developing analytical capability to enforce the amended standard.

4.4 IMPACT ON INTERNATIONAL TRADE

The Applicant notes that, in developing food standards, FSANZ must have regard to its WTO obligations; the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. These matters encompass consideration of international standards and trade issues.

This amendment would bring Australia and New Zealand into line with other countries where IMO is approved for use.

Products containing IMO currently manufactured in other markets will be permitted to be imported into Australia and New Zealand which will reduce the barrier to entry for these products.

Businesses in Australia and New Zealand will also have access to IMO to enable them to develop and manufacture products to compete with imported products.

5 INFORMATION TO SUPPORT THE APPLICATION

(As per section 3.1.5 of the Application Handbook 1 September 2013, amended 1 June 2015)

5.1 Data Requirements

The primary reference source for studies relevant to the safety assessment of IMO was the previously published safety evaluation contained in the BioNeutra Expert Panel Report concerning the Generally Recognised as Safe (GRAS) status of VITASUGAR™, as an isomalto-oligosaccharide (IMO) mixture for use in foods (2008) (BioNeutra GRAS) and BioNeutra Application for the Approval of IMO under regulation (EC) No 258/97 of the European Parliament and of the Council of 27th January 1997 concerning novel foods and novel food ingredients (2008).[2]

A discussion on the equivalence of COFCO IMO to the BioNeutra IMO product is provided under Section 6.

A search of the PubMed and TOXLINE databases was conducted using the search term “isomalt AND oligosaccharide OR isomaltooligosaccharide”. No date/time limits were entered. A total of 73 and11 studies were returned from the two databases, respectively. A full list of retrieved studies is attached as **Appendix 4.** The search did not reveal any studies relevant to the safety assessment of IMO that has not been identified previously from primary sources and therefore full copies of these studies are not provided with the Application.

5.2 FSANZ Act Objectives

Information is provided in this application to enable the objectives specified in Section 18 of the FSANZ Act to be addressed as follows:

(a) The protection of public health and safety: information to support objective (a) is provided in Sections 7.2 (Information on the Safety of IMO); 7.3 (Information on dietary exposure to the novel food) and 7.4 (Information on the nutritional and health impact of the novel food) of the Application.

(b) The provision of adequate information relating to food to enable consumers to make informed choices: data to support objective (b) is provided in Section 7.5 (Information related to potential impact on consumer understanding and behaviour).

(c) The prevention of misleading or deceptive conduct: information supporting objective (c) is provided in Section 7.5.

2 both of these documents are provided with the references for the Application

5.3 Public Health and Safety Issues

This matter is addressed within Sections 7.2 and 7.3 of this application.

The data indicates that IMO poses no public health and safety issues to consumers at the levels of use proposed.

The Applicant considers there is a substantial body of evidence to support the safety of IMO. On the basis of the available toxicology data, nutritional evaluations, and appropriate food-grade specifications and manufacturing protocols in accordance with GMP, it is concluded that IMO does not present a significant risk for human health at the intake which would result from its intended uses in food. The use of IMO in foods at the levels proposed by the Applicant is not expected to lead to any adverse health effects.

5.4 Consumer Choice

IMO will be required to be labelled enabling consumers to choose if they wish to purchase a product containing IMO.

5.5 Support for the Proposed Change

A letter of support from a company who has an interest in importing IMO is provided in **Appendix 1** and is considered as confidential.

5.6 Policy Guidelines

(As per section 3.5.2 of the Application Handbook 1 September 2013, amended 1 June 2015)

Information is provided in this section to address the high order and specific principles in the Ministerial Council Policy Guidelines on Novel Foods[3] and the Policy Guideline - Addition to Food of Substances other than Vitamins and Minerals[4].

3 https://www.health.gov.au/internet/main/publishing.nsf/Content/4DCF744789D1AF64CA257BF0001C9622/$File/novel_guidelines.pdf, accessed 05.10.15

4 http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf, accessed 05.10.15

5.6.1 Novel Foods

High Order Principles	Section of Application
To ensure that priority is given to the protection and improvement of public health and safety in relation to food matters.	7.2; 7.3; 7.4
To ensure that consumers have access to sufficient information to enable informed and healthy food choices.	7.5
Be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion.	N/A
To draw on the best elements of international regulatory systems (i.e. protocols, standards, guidelines, assessment processes) and be responsive to future trends and developments (i.e. CODEX, WHO/FAO).	6
To provide a regulatory environment that is timely, cost effective, transparent and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation and international trade.	3.1.4; 4.4; 6
Specific Principles	
To ensure that public and industry confidence in the food system is maintained.	Application process ensures this
To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.	CCI protected by the process
To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.	7.4; 7.5

5.6.2 Addition to Food of Substances other than Vitamins and Minerals

The addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function should be permitted where:

Specific Order Policy Principles – Any Other Purpose	Section of Application
a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose'); and	3.1
b) the addition of the substance to food is safe for human consumption; and	7.2; 7.3
c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and	7.2; 7.3
d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and	7.2; 7.3; 7.4
e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.	7.5

6 INTERNATIONAL AND OTHER NATIONAL STANDARDS

(As per section 3.1.9 of the Application Handbook 1 September 2013, amended 1 June 2015)

The status of IMO with respect to other national standards or regulations is discussed under this section of the Application.

The Applicant is applying for approval of IMO produced and supplied by COFCO Corporation (COFCO), China's largest diversified products and services supplier in agribusiness and food industry.[5]

Equivalence of COFO IMO

Chemical structure/nature

Appendix 5 sets out the description of saccharides in typical IMO products and shows the compositional parameters for BioNeutra GRAS IMO and COFCO IMO. The purpose of this comparison is to show that COFCO IMO is essentially equivalent to the BioNeutra IMO.

Control of the specific manufacturing conditions (eg temperature and time in contact with enzymes etc., (**Figure 3,** section 7.2.5) allows the production of IMOs with specific saccharide profiles to match the end use. Both COFCO and BioNeutra IMO products are manufactured to have essentially similar saccharide profiles (**Appendix 5**). Consequently, conclusions drawn about the safety of the BioNeutra product are also applicable to the equivalent COFCO product.

Proposed usage

Essence Group intends to market IMO as a food ingredient in Australia and New Zealand for use as an alternative lower calorie sweetener and bulk filler in a variety of food categories at levels up to 15g IMO/serving. Essence Group estimates that the intake of IMO would be similar to that proposed by BioNeutra of 30g/person/day based on two servings of foods with the highest use level being 15g/serve.

The FDA conclusion is based on BioNeutra's estimates that the intake of IMO would be approximately 30 grams per person per day. This estimate is based on the assumed consumption of two servings of foods containing the highest use level identified (15g/serving).

The Health Canada position is based on BioNeutra's estimates that the intake of IMO would be approximately 30 grams per person per day. This estimate is based on the assumed consumption of two servings of foods containing the highest use level identified (15g/serving).

The UK FSA permission to place IMO on the EU market was for similar use levels to those proposed for COFCO IMO in this application.

5http://www.cofco.com/en/, accessed 05.10.15

6.1 INTERNATIONAL STANDARDS

There is no CODEX standard applicable to IMO.

6.2 OTHER NATIONAL STANDARDS OR REGULATIONS

6.2.1 United States of America

In February 2009, the CFSAN/Office of Food Additive Safety of the US FDA advised that:

"Based on the information provided by BioNeutra, as well as other information available to the FDA, the agency has no questions at this time regarding BioNeutra's conclusion the IMOM is GRAS under the intended conditions of use."[6]

A copy of the Agency no objection letter (GRAS Notice No. GRN 000246) is provided under **Appendix 6.**

The FDA position is based on BioNeutra's estimates that the intake of isomalto-oligosaccharide mixture (IMOM) would be approximately 30 grams per person per day. This estimate is based on the assumed consumption of two servings of foods containing the highest use level identified (15g/serving).

The intended uses, maximum use levels and amount of IMO per serving for the BioNeutra product are set out in **Appendix 2**. These are comparable to those proposed for the COFOC IMO.

Appendix 5 provides a comparison of IMO produced by COFCO and BioNeutra to demonstrate that IMO produced by COFCO is comparable to IMO produced by BioNeutra.

6.1.2 Canada

On 22nd December 2009 Health Canada notified BioNeutra that it has no objection to the use of IMO as a food ingredient.

Health Canada found that, based on the evidence provided, the toxicological evaluation concluded that there are no toxicological issues with IMO at the proposed maximum intake of 30 g/person/day, for the general population. Health Canada's review of the information presented in support of the use of IMO as a food ingredient concluded that there are no food safety concerns. Health Canada is of the opinion that IMO can be added to a variety of foods.[7]

A copy of the Health Canada advice is provided under **Appendix 7.**

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6 GRAS Notice No. GRN 000246, http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154409.htm, accessed 10.05.14

7 Health Canada, Novel Food Information – IMO (Vitasugar™) http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/isomalto-oligosaccharide-eng.php, accessed 10.05.14

Appendix 5 provides a comparison of IMO produced by COFCO and BioNeutra to demonstrate that IMO produced by COFCO is comparable to IMO produced by BioNeutra for use in the Canadian market.

6.1.3 United Kingdom/Europe

In January 2009, an Application was made to the UK Food Standards Agency by Bioneutra Inc, for the authorisation of isomalto-oligosaccharide (IMO) under the Novel Food Regulation (EC) 258/97. The Applicant was seeking authorisation of their IMO as a general food ingredient.

The Advisory Committee on Novel Foods and Processes (ACNFP) concluded that there were no safety concerns relating to IMO and recommended that it is labelled as unsuitable for diabetics (ACNFP 2012).

In July 2013, the Food Standards Agency advised that:

"It is established that Bioneutra's Isomalto-oligosaccharide powder and syrup (Annex 1) complies with the criteria laid down in Article 3(1) of Regulation 258/97 when placed on the market in accordance with the conclusions of the initial assessment report, namely:

I. Isomalto-oligosaccharide may be added to the foods listed in Annex 2 at up to the specified maximum levels.

II. Foods containing Bioneutra's Isomalto-oligosaccharide must be labelled as unsuitable for diabetics."

A copy of the Food Standards Agency advice is provided as **Appendix 8.**

6.2.3.1 Application for Extension of use and Label Correction of the Novel Ingredient IMO (May 2014)

In May 2014 BioNeutra submitted an application to the UK Food Standards Agency to extend the use of Isomalto-oligosaccharide in a limited number of additional foods under the Novel Food Regulation (EC) 258/97.

Bioneutra has submitted an application to extend the uses of its isomalto-oligosaccharide into additional foods (desserts, crackers, nutritional food bars, edible ices, flavoured drinks, sweet sauces, toppings and syrups, ready-to-eat savouries and snacks and foods intended for particular nutritional uses). (BioNeutra, 2014)

BioNeutra is requesting a change to the label wording regarding IMO to bring it in line with other novel food ingredients. The IMO novel food approval stipulates that BioNeutra's IMO must be labelled as being "unsuitable for diabetics", however such a warning label is currently unprecedented within Europe and therefore they have requested an amendment to the wording to indicate the IMO is a "source of glucose" thereby informing diabetics that the product contains a substance producing glucose. This labelling approach is similar to that of other approved glycemic carbohydrate including sucromalt, isomaltulose and trehalose.

Comments on this application closed on 05 June 2014[8].

6.1.4 Japan

FOSHU (Foods for Specified Health Use) refers to foods containing ingredients with functions for health and officially approved to claim its physiological effects on the human body. In order to sell a food as FOSHU, the assessment for the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the Ministry of Health, Labour and Welfare (MHLW).[9]

IMO has been on the FOSHU ingredient list for more than 10 years. Over 50% of the 324 FOSHU foods in Japan in 2002 incorporated oligosaccharides as the functional component. The demand for IMO in Japan was 15000 metric tons/year (Nakakuki, 2003).

A copy of the Approved FOSHU Products is provided as **Appendix 9.**

6.1.5 China

China has a National Standard for IMO – GB/T 20881 – 2007. An English translation is provided under **Appendix 10.**

8 http://acnfp.food.gov.uk/assess/fullapplics/imo, accessed 02.05.2015
9 http://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html, accessed 10.05.14

6.1.6 Korea

Oligosaccharides are listed under Section 10 of Article 5 Standards and Specifications for Each Food Product of the Food Code.

The provisions contained in the Food Code are applicable to all foods under the Food Sanitation Act.

A copy of the relevant section of the Food Code is provided under **Appendix 11.**

7 NOVEL FOOD

(As per section 3.5.2 of the Application Handbook 1 September 2013, amended 1 June 2015)

7.1 TECHNICAL INFORMATION ON THE NOVEL FOOD

(As per section 3.5.2B of the Application Handbook 1 September 2013, amended 1 June 2015)

The material described in this section is representative of the commercial COFCO IMO product.

No studies have been carried out on the specific COFCO IMO product which is the subject of this application.

Both COFCO and BioNeutra IMO products are manufactured to have essentially similar saccharide profiles (Appendix 5). Consequently, conclusions drawn about the safety of the BioNeutra product are also applicable to the equivalent COFCO product.

7.1.1 Information on the type of Novel Food

Category: Dietary macro-component (as per 3.5.2 B.1. (v) of the Application Handbook)

Trade Name: the name that COFCO IMO will be marketed under is unknown at the time of submitting the Application.

The term *oligosaccharide* encompasses carbohydrates that are larger than simple di- or tri-saccharides, but smaller than polysaccharides (greater than 6 units). Isomalto-oligosaccharides (IMOs), specifically, are glucose oligomers with α-D-(1,6) linkages, including among others isomaltose, panose, isomaltotetraose, isomaltopentaose, nigerose, kojibiose, and higher branched oligosaccharides.

7.1.2 Information on the purpose of adding a novel food ingredient to food

The purpose of this application is to seek approval for the addition of COFCO IMO to food for the following purposes:

- an alternative to, and at similar levels to, other carbohydrate bulk sweeteners such as sucrose, glucose, fructose and high fructose or maltose syrups; and
- an alternative to currently available food ingredients, such as FOS, inulin, polydextrose and dextrin's, which can be added to foods as fillers to provide bulk and texture.

  IMO may be used as a bulking agent in a variety of foods in which it serves as a source of reduced energy carbohydrate for use as a sugar replacer, humectant, binder, fat-replacer and texture modifier.

This Application **does not** relate to a potential beneficial physiological or health-related benefit.

The Applicant acknowledges that IMO, like other oligosaccharide/polysaccharide ingredients, may have prebiotic and dietary fibre properties and that some manufacturers may wish to use IMO in their products in order to support claims about these properties. It is also noted that current authorizations and approvals for IMO substances overseas are based on both the potential prebiotic or dietary fibre properties as well as its technological properties as a lower calorie sweetener and functional bulk filler.

This Application seeks **only** the approval of the safety of IMO as a novel food when used for technological purposes, as a lower calorie sweetener and functional bulk filler. This Application does not seek the use of IMO to support nutrition content claims or health claims associated with potential beneficial physiological or health-related effects. The applicant considers that, in order for IMO to be used in a product to support a nutrition content claim about dietary fibre, it would be incumbent on the manufacturer using it to first demonstrate that the oligosaccharide profile of the specific IMO being used met the definition of dietary fibre in Standard 1.2.8 and that the product as consumed, when analysed using the methods set out in Schedule 11 (Calculation of values for nutrition information panel) contained sufficient dietary fibre to meet the criteria for a claim in Schedule 4 (Nutrition, Health and Related Claims).

Similarly, in order for IMO to be used in a product to support a general level health claim (GLHC) about prebiotic functions, the food-health effect relationship for the specific or relevant oligosaccharide profile, would first need to be determined in accordance with Standard 1.2.7. It is noted that if a manufacturer chooses to explore using IMO as a prebiotic and making a general level health claim then they will need to make a separate application to FSANZ or prepare a Scientific Literature Review (SLR) to meet the requirements of Schedule 6.

Use of IMO as an alternative sweetener

The nutritional information for COFCO IMO is set out in Appendix 12. The relative sweetness is ~60% sweet as sucrose and the energy value is 156cal/100g (1.5kcal/g or 6.3kJ/g).

For the purpose of food labelling, Roberfroid (1999) recommended that chicory inulin and oligofructose, like all the other carbohydrates that are more or less completely fermented in the human colon, should be given a caloric value of 1.5 kcal/g (6.3 kJ/g OR 630kJ/100g).

In comparison to IMO, the energy value of cane sugar is 1700kJ/100g or 17kJ/g[10].

Product example:

As an example, the nutrition information for two versions of a basic Butter Cake was calculated using the Nutrition Panel Calculator (NPC) tool available on the FSANZ website.[11]

The versions were as follows:

1. Basic Butter Cake – white sugar; and

2. Basic Butter Cake – IMO replacing white sugar.

The amount of IMO added was calculated based on the relative sweetness to sugar (60%).

The resulting nutrition information for each version is shown below:

Version 1:

Nutrition Information

Servings per package:	7.00
Serving size:	104.00 g

	Average Quantity per Serving	Average Quantity per 100 g
Energy	1620 kJ	1560 kJ
Protein	7.0 g	6.8 g
Fat, total	16.9 g	16.2 g
- saturated	10.5 g	10.1 g
Carbohydrate	50.7 g	48.7 g
- sugars	23.4 g	22.5 g
Sodium	427 mg	411 mg

Version 2:

Nutrition Information

Servings per package:	8.00
Serving size:	104.00 g

	Average Quantity per Serving	Average Quantity per 100 g
Energy	1310 kJ	1260 kJ
Protein	6.3 g	6.0 g
Fat, total	15.0 g	14.4 g
- saturated	9.3 g	9.0 g
Carbohydrate	56.7 g	54.5 g
- sugars	3.0 g	2.9 g
Sodium	388 mg	373 mg

10 http://www.csrsugar.com.au/csr-sugar/our-products/everyday/white-sugar, accessed 06.01.15

11 http://www.foodstandards.gov.au/industry/npc/Pages/Nutrition-Panel-Calculator-introduction.aspx

The cake formulated with IMO has a lower level of energy (per 100g) compared to the cake formulated with sugar.

The full nutrition calculations are provided as Appendices 2a and 2b.

7.1.3 Information on the physical and chemical properties of novel food ingredient

Property	Description
Common or usual name	Isomalto-oligosaccharide (IMO)
Chemical name	Isomalto-oligosaccharide (IMO)
CAS Register Number	Not applicable
Molecular Formula	Refer to Appendix 5

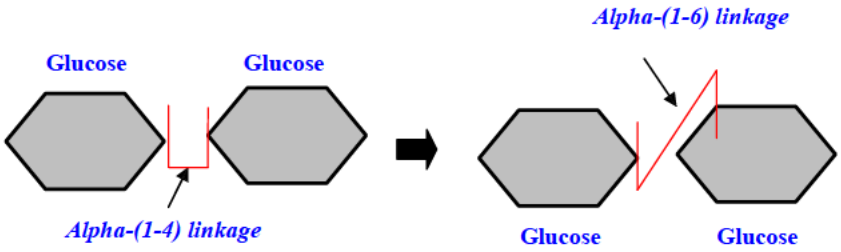
Structure

Commercial preparations of IMO contain a range of 1-6 linked di-, tri-, and oligosaccharides as indicated in **Appendix 5.** The exact specifications of each product are determined by the specific manufacturing conditions.

The majority of oligosaccharides found in IMO consist of 3 to 7 monosaccharide units linked together; however, disaccharides, as well as longer polysaccharides (up to 9 units) also are present. The disaccharide fraction of IMO consists of the α-1→4 linked maltose and the α-1→6 linked isomaltose (both shown in **Figure 1**) while maltotriose, panose, and isomaltotriose make up the trisaccharide fraction. Maltotetraose, maltopentaose, maltohexaose, maltoheptaose, and small amounts of oligomers with 8 or more degrees of polymerization comprise the remaining oligomers in the product.

Structural Formulas of the mono-, di-, and oligosaccharides (DP3 to DP5) identified in Isomalto-oligosaccharide (IMO) products are shown in **Figure 2.**

Figure 1: Structure of IMO [12]



12 Source: BioNeutra Application, 2008

Figure 2: Structural formula of IMO [13]

13 Source: BioNeutra Application, 2008

Stability

IMOs are stable under acidic or alkaline conditions, over a range from pH 2.0 to pH 10. IMO has been found to be > 99% stable at pH 2.0 when incubated for up to one year at three given storage temperatures - room temperature (25 ºC), refrigerator temperature (4 ºC), and high temperature (45 ºC).

This data is based on BioNeutra IMO (BioNeutra 2008). **Appendix 5** provides a comparison of IMO produced by COFCO and BioNeutra to demonstrate that IMO produced by COFCO is comparable to IMO produced by BioNeutra.

7.1.4 Information on the impurity profile for a typical preparation

Table 1: Impurities and by products present in IMO

Impurity	COFCO IMO	BioNeutra IMO (Powder)
Moisture (%)	Max 4	Less than or equal to 4
Glucose (% dry basis)	Max 5	Less than or equal to 5
Ash (sulphated ash (g/100g)	Max 0.3	Less than or equal to 0.3
Lead (mg/kg)/ppm	Max 0.5 on a dry weight basis	Less than or equal to 0.5
Arsenic (mg/kg)/ppm	Max 0.5 on a dry weight basis	Less than or equal to 0.5
Cadmium (mg/kg)/ppm	< 1ppm on a dry weight basis	Not specified
Mercury (mg/kg)/ppm	< 1ppm on a dry weight basis	Not specified

7.1.5 Manufacturing process for a novel food ingredient

Figure 3 sets out the process steps involved in manufacture of IMO from maize starch by COFCO.

IMO is manufactured from starch by a series of controlled enzymic processes which are well established in the hydrolyzed starch/sugar syrup industry and are not dissimilar to processes used in the production of beer and other alcoholic beverages from cereals.

In summary, IMO is prepared from starch that may be sourced from a range of foods (e.g. wheat, barley, corn, pulses (peas, beans, lentils) oats, tapioca, rice, potato). In the case of the current application the source food is maize. The starch is enzymically hydrolyzed, using amylases and pullulanse to produce a high maltose syrup, which is then further treated with transglucosidase resulting in enzymatic conversion of α (1, 4) glycosidic linkages into α (1,6) glycosidic linkages. All of the enzymes used are food grade enzymes listed in Standard 1.3.3 – Processing Aids of the Australia New Zealand Food Standards Code.

Yeast is then added to remove fermentable mono and disaccharides including maltose and glucose resulting in a product rich in isomalto-oligosaccharides, which is then purified and concentrated to produce IMO. The yeast cells are removed from the culture broth by filtration. Residual ethanol generated during yeast fermentation is completely evaporated off during the purification and concentration steps.

Table 2: Materials used in the manufacturing process for COFCO IMO

Material	Description
Starch	Corn/Maize
The following materials used in the manufacture of IMOs are permitted to be used as processing aids in Standard 1.3.3 and comply with relevant monographs of purity and identity in Standard 1.3.4.	
Enzymes	α–Amylase (EC 3.2.1.1) Pullulanase (EC 3.2.1.41) Transglucosidase (EC 2.4.1.24)
Yeast	*Saccharomyces cerevisiae*
Sodium Carbonate (monohydrate)	
Hydrochloric Acid	
Sodium Hydroxide	
Activated Carbon Powder (1%)	
Ion-exchange Resins	sulphonated cross-linked polymers of styrene

Figure 3: Flow Chart for Manufacturing of IMO by COFCO

COFCO Bio-Chemical Energy (Gongzhuling) Co, LTD
中粮生化能源（公主岭）有限公司

FLOW CHART for Manufacturing of COFCO IMO (Isomalto-oligosaccharide)

- Isomalto-oligosaccharide (IMO) is enzymatically transformed from Starch, and starch is obtained from Maize
- Starch is used as a starting raw material

Following is the summarized flow diagram of the process involved in Manufacturing of COFOC IMO;

Dried Starch +Water
↓
Addition of ∂-amylases
↓
Mix to homogenous slurry
↓
Termination of Enzymatic activity
↓
Temperature >I20 OC
↓
Saccharification with Transglucosidase
↓
Termination of Enzymatic Activity
↓
Collection of crude product
↓
Discolouring
↓
(Treatment with 1 % (w/w) activated carbon powder)
↓
Filtration Step
(Removal of carbon particles)
↓
Isomalto- Oligosaccharide
Sequential ion-exchange Columns system
(Removal of protein & salt contaminants)
↓
Concentration Step
↓
Final Product (Isomalto-oligosaccharide)
(Sugar content analysis, Microbial contamination level)
QC Testing of the Final Products

7.1.6 Specification for identity and purity for a novel food ingredient

A product profile and certificate of analysis for COFCO IMO is provided in **Appendix 12.**

There are no existing specifications for IMO in the sources referenced in Standard 1.3.4. A proposed specification for IMO in this application is provided in **Appendix 13.** It is proposed that this specification is considered for inclusion in the schedule to Standard 1.3.4.

7.1.7 Analytical method for detection

A high performance liquid chromatography method (HPLC) is used to determine levels of individual oligosaccharides in the IMO mixture. All other parameters are measured using standard published methods. The method provided by COFCO is included as **Appendix 14.**

There is no published method for the detection and quantification of IMO in the Schedule 11 - Calculation of values for nutrition information panel:

Methods of analysis for dietary fibre and other fibre content[14]

(1) This section applies for the purposes of subsection 1.2.8—7(7) and section S5—6(2).

(2) The total dietary fibre, and amount of any specifically named fibre, in a food must be determined in accordance with any one or more of the methods contained in following sections of the AOAC:

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

(b) for total dietary fibre (including all resistant maltodextrins)—section 2001.03;

(c) for inulin and fructooligosaccharide—section 997.08;

(d) for inulin—section 999.03;

(e) for polydextrose—section 2000.11.

*(3) If the *dietary fibre content of a food has been determined by more than 1 method of analysis, the total dietary fibre content is calculated by:*

(a) adding together the results from each method of analysis; and

(b) subtracting any portion of dietary fibre which has been included in the results of more than one method of analysis.

(4) In this section:

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

14 https://www.comlaw.gov.au/Details/F2015L00481, accessed 05.10.2015

AOAC methods 2001.03, 985.29 and 991.43 would be suitable for determination of the level of total fibre in commercial IMO preparations and in food matrices containing IMOs.

In addition, AOAC 2009.01 (AACC International Approved Method 32-45.01) is also suitable however this method is currently not listed in the table to subclause 18(1).

The HPLC method provided under **Appendix 14** is sufficient to separate and quantify the individual oligosaccharides and distinguish them from other oligosaccharides that may be present in a food matrix. All other parameters relevant to the identity and purity of food grade IMO preparations may be analysed using standard published methods.

7.2 INFORMATION ON THE SAFETY OF IMO

(As per section 3.5.2C of the Application Handbook 1 September 2013, amended 1 June 2015)

7.2.1 History of use of IMO in other countries

IMO has been ingested by humans for hundreds of years as naturally occurring components in honey, miso, sake and soy sauce. The highest levels of consumption of natural products containing IMO have been traditionally found in Japan and other Asian countries. **Table 3** indicates the per capita consumption of IMO in Japan from four traditional food and beverage sources as determined by BioNeutra.

Table 3: History of Traditional Exposure in Japan (BioNeutra, 2008)

Product	Annual Consumption of Product	% IMO in Product	Approximate Annual per Capita Consumption of IMO (g)
Honey	0.3kg	1.0	3 g
Miso	4.6kg	1.1	50 g
Sake	8L	0.5	40 g
TOTAL			93g

BioNeutra have previously proposed that given the IMO consumption data (**Table 3**) and with the knowledge that soy sauce would also make a contribution, it would be reasonable to estimate the annual consumption in Japan of IMO from traditional sources to be 100g.

Table 4 is an updated version of Table 3 prepared by the Applicant.

Table 4: History of Traditional Exposure in Japan (updated)

Product	Annual Consumption of Product	% IMO in Product	Approximate Annual per Capita Consumption of IMO (g)
Honey	0.3kg	1.0	3.0
Miso	2.32kg	1.1	25.0
Sake	6.9L	0.5	34.5
Soy sauce	7.0L	Note 1	-
TOTAL			62.5

Note 1: the level of IMO in Soy was not available

Japan's annual per capita consumption of honey is 300 grams (BioNeutra 2008). This is considerably lower than Canadian per capita consumption which is estimated at about 1000 grams per year (CFIA, 2004) or Australia which was about 0.5kg per capita in 1998-99 (ABS 1999). The chemical composition of honey may vary with floral origin. Isomaltose is always present at a range of 0.5-1.5 % (European Commission, 2002).

Miso is soybean combined with rice and other ingredients and aged in cedar vats for up to three years. Its predecessor was known as "hisio", a seasoning made from fermenting soybeans, wheat, alcohol, salt and other ingredients. This fermented soybean paste was introduced into Japan around the 7th century. Miso is often consumed daily in soups and used in sauces and marinades. Annual per capita consumption of Miso was 2.32kg in 2008 (JFMMC, 2008). Isomaltose is produced during the miso fermentation process. Isomaltose is present in raw miso at 0.31% and increases to 1.11% by 5 days and 1.17% by day 50 (Hondo and Mochizuki, 1979).

Sake is a traditional Japanese alcoholic beverage made from rice. Annual per capita sake consumption has been declining in Japan (9.8L in 1985, 8.1 L in 2001) and is now down to 6.9L (Sake World, 2007). A study conducted on five commercial brands of sake showed varying levels of IMO including isomaltose, 2.4-4.1 mg/mL, panose 0.7-0.9 mg/mL, and isomaltotriose, 0.4-1.4 mg/mL (Hayakawa et al, 2000). On average, the sakes contained 5 mg IMO/mL.

Soy sauce is also reported to contain IMO (Tungland and Meyer, 2002). Annual per capita consumption of soy sauce in Japan was reported as 7L in 2008 (JFSSMC, 2008).

Given the updated IMO consumption data in Table 4, it would be reasonable to estimate the annual per capita consumption in Japan of IMO from traditional sources to be at least 62.5g without including the contribution from soy sauce.

Commercial IMOs are produced enzymatically and are the market leader in the dietary carbohydrate sector of functional foods in Japan (Goffin, et al, 2011; Mountzouris et al., 2002). On the basis of the safety record for IMO, FSANZ approved the use of the enzyme transglucosidase (TG) in the manufacture of isomalto oligosaccharide (FSANZ 2003, A466).

7.2.2 Potential for allergenicity of IMO

COFCO IMO is manufactured from maize and consequently no allergenicity issues are anticipated.

7.2.3 Toxicity assessment of IMO

The toxicological database primarily contains reports of tolerance studies undertaken with IMO mixtures containing a range of di-, tri and oligosaccharides. As discussed below, since the metabolic fate of all of these entities is well understood, the clinical chemistry, pathology and tolerance data from these studies provide information that is applicable to commercial IMO preparations.

The evaluation of the safety of IMO products is primarily based on well-established metabolic profiles for the simple saccharide components of the mixture (e.g., maltose, isomaltose), as well as animal and human studies assessing the digestion and elimination of the larger oligomers present in the IMO products. Additionally, in assessing the safety of IMO products, results of several short and long term animal toxicity studies conducted with similar IMO mixtures were also reviewed. Although the exact composition of the IMO preparations evaluated in the studies discussed in support of the safety of IMO products differed in the distribution of certain oligomers, these studies are considered to be nonetheless relevant to the overall assessment of the safety of IMO products and were acceptable by the GRAS Expert Panel for BioNeutra's IMO as a food ingredient, as well as by United States FDA authorities in filing Final GRAS Notification.

7.2.3.1 Absorption, Distribution, Metabolism & Excretion (ADME)

Typically, mixtures of IMO consist of both digestible and non-digestible saccharides.

Following oral ingestion, digestible (smaller) isomalto-oligosaccharides, primarily isomaltose, maltose, and panose are hydrolysed at their non-reducing ends by the sucrase-isomaltase complex in the small intestine, resulting in the release of glucose, which is rapidly absorbed from the gastrointestinal tract (Glinsmann *et al*., 1986).

Normal digestion of 1→ 4 linked carbohydrate polymers, such as amylase and amylopectin, begins in the mouth as salivary α-amylase is secreted and continues in the stomach with the release of pancreatic α-amylase. Both salivary and pancreatic α-amylase hydrolyze (α1,4)-linkages and, thus, reduce large polysaccharides into smaller oligomers. In contrast, 1→ 6 linked carbohydrate polymers are only digested in the intestine.

A number of enzymes have been identified, which are capable of hydrolyzing di- and oligosaccharides in the epithelial cells of the brush border of the mucosa of the small intestine, including the sucrase-isomaltase complex, glycoamylase, and lactase (Würsch, 1991).

Sucrase-isomaltase complex is an intestinal enzyme that consists of 2 subunits, one that cleaves (α1,4)-glycosidic linkages and the other (α1,6)-linkages, to release individual glucose molecules (Dahlqvist *et al*., 1963; Würsch, 1991; Oku and Nakamura, 2003). The sucrase-isomaltase complex accounts for approximately 80 to 90% of total intestinal maltase activity. Malto-oligosaccharides are also hydrolyzed by intestinal glucoamylase-maltase, which are not able to hydrolyse α1,6-linkages. Consequently, isomalto-oligosaccharides are less effectively digested in the gut in comparison to malto-oligosaccharides.

Larger oligosaccharides with higher degrees of polymerization greater than 3 are more resistant to hydrolysis in the small intestine and thus pass into the lower gastrointestinal tract, where they undergo microbial fermentation to yield hydrogen, carbon dioxide and methane. Approximately half of the hydrogen generated is eliminated with flatus; however, the remainder of the hydrogen is absorbed and expired (Oku and Nakamura, 2003).

In an *in vitro* batch culture study comparing the fermentation properties of several different oligosaccharides *(i.e.,* lactulose, FOS, inulin, and xylo-, galacto-, soybean-, and isomalto-oligosaccharides), incubation of human fecal bacteria in the presence of isomalto- or galacto-oligosaccharides (GOS) for 24 hours was accompanied by the lowest evolution of gas, whereas inulin and lactulose produced the largest quantities of gas (Rycroft *et al.,* 2001).

7.2.3.2 Acute Studies

The oral LD50 rats, of an IMO mixture consisting of 52.5, 25.4, and 15.2% di-, tri, and larger oligosaccharides, respectively, was > 44 g/kg body weight (Kaneko *et al*., 1990).

7.2.3.3 Sub chronic and Chronic Studies

Groups of 8 male Sprague-Dawley rats (5 weeks old) consumed diets containing 0 (corn starch control) or 20% (approximately 20 g/kg body weight/day) of sucrose or isomalto-oligosaccharides or maltose, or fructo-oligosaccharide (FOS), added in lieu of starch, *ad libitum* for 35 days (5 weeks) (Kaneko *et al.,* 1992).

The IMO product comprised 33.4% isomaltose, 11.8% panose, 14.3% isomaltotriose, 15.7% isomaltotetraose, and 10.3% other isomalto-oligosaccharides.

Rats were weighed periodically throughout the study period. At study termination, rats were killed and the liver, kidneys, stomach, small intestine, cecum, cecal contents, colon, and retro-abdominal adipose tissue removed and weighed. All rats were observed to gain weight during the feeding period; however, rats in the group receiving the IMO mixture exhibited significantly lower mean final body weights and

mean body weight gain in comparison to rats treated with 20% sucrose-supplemented diets. Otherwise, no statistically significant differences in mean final body weights or weight gain were reported between IMO- treated rats and controls or rats administered FOS or maltose in the diet.

Both the IMO and FOS groups exhibited a significantly lower food intake compared to all other groups. Food intake of IMO group was slightly greater than the FOS group, slightly lower than the control or maltose groups and significantly lower than the sucrose group.

Food utilization efficiency of IMO treated rats was significantly lower only when compared to controls and was about 96 to 97% that of the other test groups. Relative to the nutritional value provided by maltose, the body weight-to food intake ratio of the IMO group was suggestive of an 80% energy value for the IMO mixture. Relative liver weights of rats from the IMO group were significantly lower in comparison to the sucrose group; however, no significant difference in relative liver weights were observed between the IMO group and the control, maltose-, or FOS groups. The study also included evaluation of a number of serum and lipid levels. Mean serum triglyceride levels were significantly lower in the IMO group compared to the control or sucrose groups, but were significantly higher than in the FOS group, which were significantly lower than levels reported in any of the other groups. Although several other statistically significant variations were observed in various lipid parameters between different test groups, serum cholesterol, high-density lipoprotein (HDL)-cholesterol, phospholipids, and NEFA and liver cholesterol, triglyceride, and phospholipid levels of IMO group were similar to controls. Additionally, maltase and isomaltase activities of the jejunal mucosa obtained from rats in each of the treatment groups were assessed using *in vitro* digestion models (enzymes incubated with 1% maltose or isomaltose, respectively). Similar levels of enzymatic activity were observed in control and IMO groups. Conversely, the sucrose group exhibited lower maltase and isomaltase activities compared to controls, the FOS group had decreased maltase activity and the maltose group exhibited reduced isomaltase activity.

Beyond reversible metabolic adaptations to the presence of the different test carbohydrates in the diet no adverse toxicological out comes were reported.

In another study, 2-month-old male Sprague-Dawley rats consumed a diet containing 0, 5, 10, or 20% of an IMO mix, equivalent to daily doses of approximately 0, 5, 10, and 20 g IMO/kg body weight, respectively, for 6 weeks (Day and Chung, 2004). The IMO mix contained 6.9% disaccharides, 28.4% panose and 64.4% DP 4-7 oligosaccharides.

Food intake and body weight gain were recorded throughout the study period. At the end of the study period, animals were killed, and heart, spleen, kidneys, lungs, and cecum excised and weighed. Weight gain and food intake were comparable among all groups of rats; however, there was a positive trend for increased food intake in the IMO-treated groups. Apart from increased cecal weights reported at the mid- and high-dose levels *(i.e.,* 10 and 20%, respectively) no other variations were observed in organ weights between test animals and controls. The authors suggested that the increased cecal weights are likely to reflect an increase in the population of fermentation bacteria. A dose-dependent reduction in abdominal fat also was reported in all groups receiving IMO compared to control.

In a study in which a group of 9 male Sprague-Dawley rats consumed a high-cholesterol diet containing 6% of a mixture of isomalto-oligosaccharides (composition not specified) (approximately 3 g/kg body weight/day) for 5 weeks, no significant variations were observed in body weight gain, food efficiency, and relative liver weight compared to a control group fed a similar diet without IMO (Sung *et al.* 2004).

In another study, groups of 10 male Sprague-Dawley rats were fed IMO product in the diet at concentrations of 0 or 10% (composition not specified) (approximately 10 g/kg body weight/day) for a period of 4 weeks following which diabetes was induced experimentally by streptozotocin (STZ) injection (Chai and Rhee, 2001). Subsequent to the induction of diabetes, rats continued on their respective diets for another 4-week period. In addition to a diabetic control group, a normal control group of rats was also included in the study. No variations were observed in body weight, food intake, food utilization efficiency, or relative liver, kidney, and small intestine weights between IMO-treated and basal diet diabetic animals. An increase in the relative weight of the cecum was, however, observed in the IMO-test group in comparison to the diabetic control group. In comparison to the control group in which diabetes was induced, oral treatment with the IMO mixture was associated with a reduction in blood glucose levels; however, serum cholesterol and triglyceride levels of IMO-treated diabetic rats did not differ significantly from those of diabetic controls. Intestinal maltase, sucrase, and lactase activities of rats administered the IMO product in the diet were comparable to the diabetic control group, while dietary treatment of rats with other oligosaccharides *(e.g.,* xylo-oligosaccharides and FOS) resulted in a reduction in enzyme activity.

Additionally, a few other non-traditional animal toxicity studies have been performed, which included some toxicologically relevant endpoints. In a study conducted to assess potential effects of various oligosaccharides on blood lipid levels and intestinal physiology, adult male Sprague-Dawley rats received sponge cakes, with 40% of the standard sucrose content of the cakes replaced by an IMO preparation (composition not specified), mixed in the diet at 30% *(i.e.,* 12% IMO in the diet or approximately 6g/kg body weight/day) for a period of 25 days (Ly *et al.,* 1999). No significant differences were observed in the body weight gain, food intake, food utilization efficiency, levels of BUN, absolute and relative liver weight, length of the small intestine, relative cecal content weight (increase not significant), and relative weight of the cecal wall of test animals compared to the control group. Administration of the IMO preparation in the diet did, however, significantly affect the cecal content pH (decreased), dry fecal weight (increased), and fecal water content (increased).

Male Wistar rats were administered an IMO product, containing 38% di-, 25.2% tri-, and 23.7% larger oligosaccharides, in the drinking water at a concentration of 0 (control) or 3% for 1 year (Kaneko *et al.* 1990). Based on the intake of drinking water, estimated IMO consumption was between 2.7 to 5g per kg body weight per day. Body weights of IMO-treated males were comparable to those of control animals throughout the treatment period. With the exception of slight, but statistically significant reductions in hemoglobin and hematocrit levels and serum alanine aminotransferase (ALT) activity in males the IMO group, no other differences in standard hematological and biochemical parameters, including aspartate aminotransferase (AST) and alkaline phosphatase (ALP) activity and total cholesterol and triglyceride levels, were observed. Blood urea nitrogen (BUN) levels were only reduced in the IMO group during the first month of the study period compared to controls. In addition, the study

also included detailed analysis of white blood cell levels, although no changes were observed in the absolute number of white blood cells of test rats relative to levels reported in the control group, significant variations in total and individual subgroups of lymphocytes were noted *(i.e.,* elevated levels of total lymphocytes, total T cells, B cells, and helper and suppressor T cells), but only in the first treatment month. At autopsy, neither the gross nor microscopic evaluation revealed any abnormalities in treated males.

Administration of the IMO mixture in the drinking water also induced some changes in the intestinal microflora of rats *(i.e.,* significantly decreased levels of *Clostridium)*.

7.2.3.4 Reproductive and Developmental Studies

No studies intended to specifically evaluate reproduction or development following treatment with mixtures of isomalto-oligosaccharides have been reported.

7.2.3.5 Mutagenicity and Geno-toxicity Studies

An IMO mixture was not genotoxic or mutagenic in a range of *in vitro* prokaryotic and in mammalian test systems (Kaneko *et al.,* 1990). In *in vitro* mutagenicity tests with *Salmonella typhimurium (i.e.,* TA98, TA100, TA1535, and TA1537) and in *Escherichia coli* WP2uwA, with and without S9 metabolic activation, an IMO mixture was not mutagenic at concentration of up to 10% per plate. Furthermore, the IMO mixture did not significantly increase chromosome aberrations in Chinese hamster lung (CHL) cells at concentrations of up to 3% in either the absence or presence of a bio-activation system following a 24- or 48-hour incubation period.

7.2.3.6 Human Tolerance Studies

In a trial investigating the digestibility of an IMO mixture, no gastrointestinal disturbances were observed following single-dose consumption of up to 40g of an IMO product dissolved in water (Oku and Nakamura, 2003). In comparison, abdominal discomforts [*i.e.,* distension, borborygmus, and flatus (only with FOS)] were reported by all subjects following ingestion of 20g of FOS or galactosyl-sucrose. Although less severe, study participants also complained of gastrointestinal disturbances when provided 10g of FOS for oral consumption.

In a placebo-controlled double-blind study designed to assess the potential for bifidogenic properties related to the consumption of various non-digestible carbohydrates including, isomalto-oligosaccharides (Cerestar; composition not specified), an increase was observed in the severity of some gastrointestinal disturbances *(i.e.,* flatus, bloating, borborygmi, and abdominal pain) over the course of a 7-day treatment period during which subjects (n = 8) consumed daily 10g of the IMO product in 2 equal portions; however, no significant differences were observed among the different test groups *(i.e.,* placebo, FOS, GOS, soybean oligosaccharides, resistant starch, lactulose, long-chain inulin, and IMO mixture) (Bouhnik *et al.,* 2004). Moreover, none of the subjects experienced diarrhoea.

Kohmoto *et al.* (1988) conducted a study to assess the potential effects of an IMO mixture on the composition of the human microflora in 6 healthy adult men (26 to 48 years of age) and 18 elderly persons (5 males and 13 females; 50 to 93 years of age) who consumed daily 20g of an IMO product (Isomalto-900®) incorporated in either a coffee jelly or a mizuyokan jelly in alternation every 3 days. Each 20 gram-dose of the IMO product contained 13.5g of isomalto-oligosaccharides. The group of healthy males received the IMO-containing jellies for a period of 10 days, whereas the elderly group was treated for a period of 14 consecutive days. None of the subjects enrolled in this study experienced diarrhoea as a result of treatment with the IMO-supplemented food products. Conversely, an improvement in the fecal consistency was observed; however, increased flatulence was reported by 2 of the 24 participants in the first few days of the study, which subsided naturally as the study progressed. Analysis of fecal samples revealed increased levels of bifidobacteria.

A 4-week trial was conducted with a group of 20 (8 men and 12 women) hemodialysis patients (mean age 63.6 years; range 44 to 80 years) to evaluate the therapeutic efficacy of 30 g of an IMO mixture (King-Tech Chemical and Starch Co., Ltd.; 12% isomaltose, 29.1% panose, 2.6% isomaltotriose, 9.9% isomaltotetraose, 2.5% dextrin, and 43.9% monosaccharides and malto oligosaccharides), provided twice daily in equal portions of 15 g, in the treatment of chronic severe constipation and its potentially beneficial effect on the lipidemic profile (Wang *et al.,*2001). Although all study participants completed the trial, some mild gastrointestinal side effects were reported. Specifically, patients experienced diarrhoea (5%), abdominal distension (10%), tormina (10.5%), borborgymi (6.1%), and abdominal spasms (4.5%). In comparison to the pre-treatment and follow-up period, the severity of all the gastrointestinal symptoms, with the exception of diarrhoea, increased significantly with the ingestion of the IMO products; however, none of the subjects withdrew from the study as a result of the gastrointestinal symptoms. Treatment with the IMO preparation was associated with a significant increase in the number of bowel movements during the 4-weeks study period. Additionally, biochemistry and lipid parameters also were evaluated in this study. Consumption of the IMO product over the 4-week treatment period was associated with decreased levels of total cholesterol and triglycerides, as well as increases in levels of hemoglobin and hematocrit, and HDL cholesterol. No significant variations were observed between pre- and post-treatment blood glucose, BUN, creatinine, albumin, protein, calcium, and phosphorous values.

In another 5-week study evaluating the potentially beneficial effect of an IMO mixture on bowel function in a group of 7 elderly men (mean age 75.2 years), no adverse effects were reported following consumption of up to 24 g of an IMO supplement. The dose level at which the IMO product was ingested was increased gradually from 8 to 24 g over the first 10 days of the study period. The supplement contained 42.7% of isomaltose, panose, isomaltotriose, isomaltotetraose, and dextrin *(i.e.,* "active" components), such that at the highest dose level subjects received 10g of "active" components. In comparison to baseline values, daily consumption of the IMO mixture was associated with significantly elevated levels of fecal acetate, propionate, and total short-chain fatty acids, but not butyrate. Increases in short-chain fatty acid levels were not accompanied by a decrease in fecal pH. Consumption of the IMO preparation also induced a close to 2-fold significant increase in fecal bacterial mass. With the exception of a small, but statistically significant reduction in mean serum sodium levels,

no significant variations were observed in a number of other biochemical parameters *(i.e.,* glucose, total protein, albumin, calcium, phosphorus, and potassium), including no changes in several lipidemic indices *(i.e.,* triglycerides, total cholesterol, and HDL-cholesterol).

7.2.3.7 Consumption by Elderly people, Children & Infants

As discussed above, consumption of IMO (up to 30g/day) by elderly subjects for 4 weeks was safe and was not associated with any adverse effects of toxicological significance (Wang, *et al.,* 2001).

Free oligosaccharides are natural constituents of the milk of all placental mammals and are a major component of human milk, which contains between 7–12 g/L oligosaccharides. This is higher by comparison with most domestic mammals by a factor of 10 to 100 (Boehm and Stahl 2007).
The composition of human milk oligosaccharides is very complex and more than 100 different oligosaccharide-like structures are known. Oligosaccharides, like IMO, are expected to be well tolerated by infants if included in infant formulae (Vandenplas, *et al*., 2002).

7.2.3.8 Possible Adverse Effects

Individuals with a rare congenital deficiency of an enzyme (sucrase-isomaltase) are unable to utilize sucrose and isomaltose consumed in the diet. Because of the sucrase-isomaltase complex consisting of 2 subunits, one that cleaves (α1,4)-glycosidic linkages and the other (α1,6)-linkages, sucrose and isomaltose intolerance occur together. The ingestion of sucrose, maltose, isomaltose or starch typically results in stomach cramps, bloating, excess gas production, nausea, vomiting and diarrhoea. Treatment involves avoidance of all offending sugars, including sucrose, maltose and isomaltose (Dahlqvist et al, 1963, Neale, 1968).

7.2.3.9 Safety Assessment: Discussion

The scientific evidence discussed above indicates that mixtures of iso-maltooligosaccharides do not produce adverse effects on human health under the intended conditions of use relevant to this application. Although the studies have been undertaken with a range of IMO mixtures, the metabolism and fate of the different isomalto di-, tri- and oligosaccharides is well understood. Consequently, conclusions may be derived from these studies that are applicable to the wide range of commercially available IMO mixtures.

Following oral consumption, the di- and tri-saccharides in the IMO mixture are largely hydrolyzed in the gastrointestinal tract to glucose, which is subsequently absorbed and utilized by the body in well characterized metabolic pathways. The gastrointestinal tolerance of these di- and tri-saccharides is comparable to that of sucrose. The remaining undigested isomalto-oligosaccharides pass through the gastrointestinal tract and undergo bacterial fermentation in the colon.

As indicated by the available animal toxicity studies, as well as human tolerance studies, there is no risk of systemic toxicity related to the ingestion of isomalto-oligosaccharides.

A small number of individuals have a congenital deficiency in the sucrase-isomaltase complex enzymes and are unable to tolerate offending sugars, including sucrose and di and tri-isomaltoses. Management involves avoidance of these sugars.

The data and information summarized above support the conclusion that IMOs meeting appropriate food grade specifications and manufactured and used in accordance with current good manufacturing practice do not present a safety risk to the consumer.

7.2.3.10 Safety Assessment: Conclusions

In conclusion, the applicant considers there is a substantial body of evidence to support the safety of IMO (isomalto-oligosaccharide). On the basis of the available toxicology data, nutritional evaluations, and appropriate food-grade specifications and manufacturing protocols in accordance with GMP, it is concluded that IMO does not present a significant risk for human health at the intake which would result from its intended uses in food. The use of isomalto-oligosaccharides in foods at the levels proposed by the Applicant is not expected to lead to any adverse health effects.

7.2.4 Safety assessment reports prepared by international agencies or other national government agencies.

The Applicant is not aware of any safety assessments prepared by WHO however the following agencies have approved IMO as discussed under Section 6.2:

- FDA – GRAS;
- Health Canada; and
- EFSA.

7.2.4.1 Safe for Consumption: FDA agreed GRAS

The term "GRAS" stands for **G**enerally **R**ecognized **a**s **S**afe.

"Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- *Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance*

as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.

- *Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers."*[15]

Based upon its review of the GRAS Panel findings, a formal Notification was made to FDA for full GRAS, resulting in a letter of no-objection from FDA. The GRAS no objection letter is included as **Appendix 6. Appendix 5** compares the compositional parameters for BioNeutra IMO and COFCO IMO.

On March 12th, 2007, BioNeutra received a GRAS (Generally Regarded as Safe) determination for Isomalto-oligosaccharide as a food ingredient (Vitasugar™). The Expert Panel consisted of the qualified scientific experts: Dr. Joseph Borzelleca (Medical College of Virginia), Dr. John Doull (University of Kansas Medical Center), and Dr. Robert Nicolosi (University of Massachusetts, Lowell). The Panel, independently and collectively, critically examined a comprehensive package of publicly available scientific information and data compiled by Cantox Health Sciences International (Toronto) from the literature and other published sources through December of 2006. The data evaluated by the Panel included information pertaining to the method of manufacture and product specifications, analytical data, intended use levels in specified food products, and consumption estimates for IMO, as well as comprehensive literature on the safety of isomalto-oligosaccharides. Following independent, critical evaluation of such data and information, the Panel unanimously concluded that under the conditions of intended use in traditional foods described; meeting appropriate food-grade specifications; and manufactured and used in accordance with current good manufacturing practice, isomalto-oligosaccharide is GRAS up to 30g/day.

15 U.S. Food and Drug Administration, GRAS, http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm, accessed 05.10.2015

7.3 INFORMATION ON DIETARY EXPOSURE TO THE NOVEL FOOD

(As per section 3.5.2D of the Application Handbook 1 September 2013, amended 1 June 2015)

7.3.1 A list of the foods or food groups proposed to contain the novel food ingredient and the proposed level of the novel food ingredient for each food or food group

Essence Group intends to market IMO as a food ingredient in Australia and New Zealand for use as an alternative (lower calorie) sweetener and bulk filler 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 confectionary at levels up to 15g IMO/serving.

The Applicant advises that while it is proposed that foods intended for particular dietary uses are included in the proposed list of foods (formulated meal replacement and formulated supplementary food), there is no intention for formulated supplementary food for young children or foods for infants to contain IMO.

The individual proposed food-uses and use-levels of IMO are summarized in **Appendix 2**, following the categories set out in Schedule 15 of the Code - Substances that may be added as food additives.

The levels have been calculated theoretically based on replacing sucrose/sugar at 100% and 50%. The sucrose/sugar levels have been taken from NUTTAB[16] or product nutrition information panels. For organoleptic reasons (ie matching the sweetness profile of sucrose) IMO is unlikely to be used alone in high sweetness product and instead is more likely to be used as a part of a blend of sweeteners rather than alone at the theoretical max sugar replacement level.

7.3.2 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

IMO is most likely to be used in foods listed in the most recent Australian or New Zealand National Nutrition Surveys.

7.3.3 The percentage of the food group in which the novel food ingredient is proposed to be used or the percentage of the market likely to use the novel food ingredient.

This information is not provided.

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16 NUTTAB 2010 ONLINE SEARCHABLE DATABASE

7.3.4 For foods where consumption has changed in recent years, information on likely current food consumption

Existing survey data are sufficient to enable estimates of likely intake to IMOs.

7.3.5 Data to show whether the food, or the food in which the novel food ingredient is used is likely to replace another food from the diet, if applicable

IMOs are intended to be used as an alternative source of carbohydrate sweeteners. Foods containing IMOs are most likely to be similar to foods containing other carbohydrate sweeteners such as sucrose, fructose syrups or maltose syrups, inulin, fructo-oligosaccharides, polydextrose and resistant maltodextrin.

7.3.6 Information relating to the use of the novel food or novel food ingredient in other countries, if applicable

As has been discussed in previous sections, IMOs have been ingested by humans for hundreds of years as they are naturally found in honey, miso, sake and soy sauce. IMO is marketed in China, Indonesia, Korea, Canada and the USA. Information on expected exposure in the US, Canada, the EU and UK is presented in this section.

7.3.6.1 Expected exposure in the US

The BioNeutra GRAS Notice for IMO used two different approaches to calculate consumption estimates for IMO (Vitasugar™). In the first case, consumption of Vitasugar™ was based on production volume estimates. Production volume of an ingredient and the disappearance of the produced amount into the food supply of a defined population size *(e.g.,* U.S. population) over a specified period of time *(e.g.,* annually) can be used as an indicator of the consumption of the food ingredient by consumers *(ie. per capita* intake). Based on actual projected production of Vitasugar™ of 16,000 tons by 2010, the per capita intake was estimated to be approximately 0.2 g/person/day.

Alternatively, in the second scenario, intake estimates were determined based on the replacement of 2 servings per day of sucrose containing foods with Vitasugar™. Assuming daily consumption of 2 servings of food with added Vitasugar™ at the proposed use levels an intake estimate of not more than 30 g/person/day was calculated.

7.3.6.2 Expected exposure in Canada

Table 5: Estimation of Exposure of Adults to IMO in Canada (BioNeutra 2008)

Food Category	Consumption		IMO Amount Inclusive (g)	Total IMO Intake per Food Category (g)
	Sub-class	# of Servings		
Meat & Alternates	Peanut Butter	1	3	3
Dairy Products	Regular Milk	1	0	29
	Flavored Milk	1	12	
	Yogurt	1	17	
Grain Products	Bread	3	0	17
	Pasta	1	0	
	Cereal (30g)	1	7	
	Baked Good or Sports bar	1	10	
Other Foods	Sports Beverage	1	12	26
	Snack	1	2	
	Condiments	1	2	
	Candy	1	10	

IMO is proposed for use in foods at up to approximately 17 g/serving, with the majority of products less than 12.5g per serve. BioNeutra based calculations on 2006 Canadian production volume estimates of total refined sugar (sucrose), and assumed a 2% replacement of it with IMO, giving a *per capita* intake estimated at 1.38g IMO/person/day.

The ABS reported that per capita sugar consumption in Australia in 1998-99 was 43.4 kg (ABS 1998-99). Assuming that intake to be current for today, and assuming a 2% replacement of sugar by IMO; IMO intake in Australia would be 2.4g IMO/person/day. Greenpool (2012) reported that per capita sugar consumption in Australia in 2011 was 41.97 kg (Greenpool, 2012) which is lower than the 1998-99 figures. It is therefore assumed that the IMO intake in Australia would be lower than the 2.4g IMO/person/day calculated on the higher per capita sugar intake.

Alternatively, assuming that a person will consume 2 servings of food per day to which IMO has been added at levels of up to approximately 15g/serving, an upper daily level of not more than 30g IMO/person is estimated.

Based on Canada's Food Guide, if a consumer both bought and consumed all IMO-containing products in a single given time (from all four major food groups as showed in **Table 5**, then the estimated intake amount of IMO would be 75g/day. Again, this is highly unlikely for a consumer to buy all the food products containing IMO. This is looking at consumption and what would occur if all food bought contained IMO. It is unlikely that all food will contain IMO and it is also unlikely that all IMO food bought would be consumed together.

Based on Canadian market penetration, both above mentioned scenarios are highly unlikely, since the actual intake of IMO is expected to be approximately 10% (estimated market share of IMO in the market generally) of the maximum estimated percentile. Even in the case of maximum consumption, *i.e*., 75gm/day, the chances for severe gastric upset are the least, since the maximum permissible dose of IMO that does not cause diarrhoea is estimated >1.5 g/kg body wt. (*e.g*., for an average person of 50 kg weight, the tolerable range of IMO would be approximately 75 g/day) (Oku, T. & Nakamura, S., 2002).

7.3.6.3 Expected exposure in the E.U.

Estimates for the intake of IMO in the EU are based on the proposed use-levels for IMO summarized in **Table 6** and food consumption data collected as part of the United Kingdom (U.K.) Food Standards Agency's Dietary Survey Programmed (DSP).

Table 6: Summary of the individual Proposed Food-uses, use Levels and Amount per Serving of IMO in the E.U (BioNeutra 2008)

		Serving Size	Use- Level (%)	IMO per Serving (g/serving)
Beverages	Regular Soft Drinks	240	5	12
	Energy-Reduced Soft Drinks	240	6.5	15.6
	Energy Drinks	240	5.0	12
	Sports & Isotonic Drinks	240	6.5	15.6
	Fruit Juices	140	5	12
	Processed Vegetables and Vegetable Juices	100	5	12
Cereals Products	Cereals Bars	50	10	5
	Cookies, Biscuits	40	20	8
	Breakfast Cereal Bars	50	25	12.5
Sugar Confectionary	Hard Candies	10	97	9.7
	Soft Candies/Chocolate Bars	30	25	8.2
Nutritionally complete and fortified foods	Meal Replacement Bars	40	20	8
	Milk based Meal Replacement	40	20	8

Note: Additional products have been requested by BioNeutra in an Application for an Extension of Use of IMO. (May 2014).

Based upon the presented NDNS data, an estimated daily intake of IMO from all proposed food categories in the U.K. by population groups (as defined in NDNS program) are made and summarized in **Table 7**. The calculations are made based upon total intake of IMO (g/person/day) from all proposed food-uses in the E.U. by U.K. population group.

It has been indicated in 7-days survey that the percentage of users was high among all age groups evaluated in the current intake assessment; greater than 85.3% of the population groups consisted of users of those food products in which IMO is currently proposed for use (**Table 7**).

Table 7: Summary of the Estimated Daily Intake of Isomalto-oligosaccharide from All Proposed Food Categories in the U.K. by Population Group (NDNS Data) (BioNeutra 2008)

Population Groups	Age Group (years)	% Users	All-Person Consumption				All-Users Consumption			
			Mean (g)	Percentile (g)			Mean (g)	Percentile (g/kg)		
				90th	95th	97.5th		90th	95th	97.5th
Children	1½ - 4½	98.3	15.3	29.5	35.3	38.3	14.2	21.6	26.8	28.3
Young People	4-10	99.6	26.7	44.8	51.8	62.1	26.7	44.8	51.8	62.1
Female Teenagers	11-18	99.3	24.8	45.5	53.7	63.3	24.9	45.5	53.9	63.3
Male Teenagers	11-18	99.5	33.4	59.5	69.2	86.7	33.5	39.5	69.2	86.7
Female Adults	16-64	88.1	8.1	19.3	25.8	34.3	9.2	20.7	26.5	36.7
Male Adults	16-64	85.3	9.0	22.5	33.1	40.8	10.6	24.4	35	41.5

Young people had the greatest percentage of users at 99.6%. Of the individual groups, male teenagers were determined to have the greatest mean and 97.5th percentile all-user intakes of IMO on an absolute basis, at 33.5 and 86.7 g/person/day, respectively. The lowest absolute all-user intake of IMO resulting from all proposed food uses was observed to occur in female adults with a mean intake of 9.2 g/person/day.

On a body weight basis, young people (age 4-10) were identified as having the highest intakes of any population group, with mean and 97.5th percentile all-user IMO intakes of 0.9 and 2.5 g/kg body weight/day, respectively, while similar to the case observed for absolute intakes, female adults had the lowest 97.5 ^{h} percentile intakes on a body weight basis, of 0.5 g/kg body weight/day. Male and female adults had equivalent mean all-user intakes of IMO, 0.1 g/kg body weight/day (**Table 8**).

Table 8: Summary of the Estimated Daily per Kilogram Body Weight Intake of Isomalto-oligosaccharide from All Proposed Food Categories in the U.K. by Population Group (NDNS Data) (BioNeutra 2008)

Population Groups	Age Group (years)	% Users	All-Person Consumption				All-Users Consumption			
			Mean (g/kg)	Percentile (g/kg)			Mean (g/kg)	Percentile (g/kg)		
				90th	95th	97.5th		90th	95th	97.5th
Children	1½ - 4½	98.3	0.8	1.1	1.7	1.9	0.9	1.2	1.6	1.8
Young People	4-10	99.6	0.9	1.3	1.8	2.1	0.9	1.6	2.0	2.5
Female Teenagers	11-18	99.3	0.4	0.8	0.9	1.1	0.4	0.8	0.9	1.3
Male Teenagers	11-18	99.5	0.6	1.1	1.4	1.6	0.6	1.1	1.4	1.6
Female Adults	16-64	88.1	0.08	0.3	0.4	0.5	0.1	0.3	0.4	0.5
Male Adults	16-64	85.3	0.08	0.2	0.4	0.6	0.1	0.3	0.5	0.6

In summary, on an all-user basis, the highest mean and 97.5th percentile intakes of IMO by the U.K. population from all proposed food-uses in the E.U., as observed in male teenagers, were estimated to be 33.5 g/person/day (0.6 g/kg body weight/day) and 86.7 g/person/day (1.6 g/kg body weight/day), respectively. On a body weight basis, young people (age 4-10) consumed the greatest amount of IMO, with mean and 97.5th percentile all-user intakes of 0.9 and 2.5 g/kg body weight/day, respectively.

Consumption data and information pertaining to the individual proposed food-uses for IMO were used to estimate the all-person and all-user IMO intakes of specific demographic groups in the U.K. population. This type of intake methodology is generally considered to be 'worst case scenario' as a result of several conservative assumptions made in the consumption estimates. In addition, it is well established that the length of a dietary survey affects the estimated consumption of individual users.

The ACNFP did not raise any issues with this section of Bioneutra's IMO dossier.

As discussed previously in the Application, the inclusion of IMO in all proposed food groups in any single given time is highly unlikely and it is also highly unlikely for a consumer to buy, let alone, consume all the food products containing IMO at any one time.

7.4 INFORMATION ON THE NUTRITIONAL AND HEALTH IMPACT OF THE NOVEL FOOD

(As per section 3.5.2E of the Application Handbook 1 September 2013, amended 1 June 2015)

The applicant intends to market IMO as a general food ingredient for use as an alternative sweetener in conventional foods and also to provide an alternative to currently available food ingredients, such as fructose oligosaccharides (FOS), inulin, polydextrose and dextrin's, which can be added to foods as fillers to provide bulk and texture.

IMO does exhibit some similarities to other similar carbohydrates, including isomaltulose, fructo oligosaccharide (FOS) or pullanan.

7.4.1 Information to demonstrate that the use of the novel food or novel food ingredient will not cause a nutritional imbalance in the diet

The replacement of other bulk carbohydrate sweeteners with IMO and their use as fillers is not anticipated to have any impact on nutrient availability or result in nutrient imbalance.

Examined *in vitro,* mixtures of isomalto-oligosaccharides were shown to increase levels of bifidobacteria (Kohmoto *et al.,* 1988; Rycroft *et al.,* 2001), but few other human bacterial species (Kohmoto *et al.,* 1988). In rats and mice, repeat administration of IMO mixtures in the diet also was associated with increases in *Bifidobacterium* and *Lactobacillus* levels, paralleled by reductions in the growth of *Clostridium* species (Kaneko *et al.,* 1990). Although results of some linear human trials *(i.e.,* comparison of pre- and post-treatment levels of colonic bacteria) have provided evidence to suggest that the consumption of IMO mixtures increased levels of bifidobacteria in the colon (Kohmoto *et al.,* 1988, 1991; Chen *et al.,* 2001), a clinical trial performed with a placebo group did not confirm these results (Bouhnik *et al.,* 2004). Specifically, no statistically significant differences were observed in the fecal levels of bifidobacteria between subjects ingesting daily a total of 10g of an IMO mixture and the placebo group. Results of the study conducted by Bouhnik *et al.* (2004) suggest that the majority of the IMO mixture was efficiently hydrolyzed to glucose upon consumption. Although the composition of the IMO product used in this study was not identified, the results suggest that it had a higher component of di- and trisaccharides compared to the studies in which changes in colonic bacteria were reported. Consumption of non-digestible carbohydrates has been related to several nutritional effects, including increases in short-chain fatty acid production, enhanced bile acid excretion, and changes in mineral bioavailability. Levels of fecal short-chain fatty acid levels were measured in a few of the animal and human studies to determine whether ingestion of IMO products resulted in changes in short-chain fatty acid levels. While an increase was observed in lactate and acetate levels in an *in vitro* study in which fecal bacteria were incubated with isomalto-oligosaccharides, no variations were observed in propionate and butyrate levels (Rycroft *et al.,* 2001). Conversely, in a pre-clinical rat study, no changes were observed in levels of individual short-chain fatty acids or in the pH level of the cecum following

administration of 5% of an IMO mixture in the diet (unspecified period of time) (Ohta *et al.,* 1993). In human trials, results were generally more comparable to those observed in the *in vitro* assays, with increases noted in acetate, propionate, and total short-chain fatty acid levels, but not in butyrate following daily ingestion of 10 to 24g of IMO-containing mixtures for a period of 4 to 5 weeks (Chen *et al.,* 2001). Generally, the absence of a consistent effect related to the consumption of IMO mixtures on bacterial induction of the human microflora, as well as only minor variations in short-chain fatty acid levels, especially in comparison to other nondigestible carbohydrates such as FOS or galactosyl-sucrose, suggest that most components of IMO preparations tested were digested to glucose in the upper segments of the gastrointestinal tract and there was, by comparison, less fermentation of the IMO mixture in the colon. Presence of increased amounts of undigested material in the colon has been also related to greater bile acid excretion in the stool; however, in rat studies in which fecal bile acid excretion was measured directly or plasma cholesterol levels were assessed as an indirect measure of changes in bile acid secretion, no changes were observed between rats administered IMO mixtures in the diet and controls (Chai and Rhee, 2001; *BioNeutra Inc.;* Sung *et al.,* 2004). In contrast, significant reductions were observed in serum triglyceride and total cholesterol levels, in association with increased HDL-cholesterol levels following daily consumption of 30 g of an IMO mixture compared to pre-treatment values in a human trial (Wang *et al.,* 2001). Furthermore, alterations in the colonic environment *(e.g.,* decreases in pH levels) as a result of increased bacterial fermentation of non-digestible carbohydrates and secondary changes in short-chain fatty acid levels have been implicated in ensuing changes in mineral absorption. In the only study in which absorption of several minerals was assessed in rats provided diets supplemented with 5% of an IMO mixture, mineral absorption of IMO treated rats did not differ from controls (Ohta *et al.,* 1993).

Isomalto-oligosaccharides (IMO) are normal constituents of the human diet that occur naturally in a number of fermented foods, including rice miso, soy sauce, and sake (see section 7.3.1).

Following oral ingestion, digestible (smaller) isomalto-oligosaccharides, primarily isomaltose, maltose, and panose are hydrolysed at their non-reducing ends by the sucrase-isomaltase complex in the small intestine, resulting in the release of glucose, which is rapidly absorbed from the gastrointestinal tract. Larger oligosaccharides with higher degrees of polymerization greater than 3 are more resistant to hydrolysis in the small intestine and pass into the lower gastrointestinal tract, where they undergo microbial fermentation to yield hydrogen, carbon dioxide and methane. The toxicological and human clinical data indicate that IMOs are safe for consumption when included in the diet at levels consistent with their use as bulk carbohydrate sweeteners, as proposed.

7.4.2 Information to demonstrate that the addition of the novel food ingredient will not create a significant negative public health impact

No adverse public health consequences are anticipated from the use of IMOs as proposed. Literature searches have not found any reports that showed any severe adverse reactions with normal consumption of IMO by healthy individuals.

The GRAS document determination for IMO placed the intake level for IMO at 30g/d (Appendix 6). This level is expected to be well tolerated and, pending specific application areas of use, is open to future increases. Mild gastrointestinal symptoms (eg increased flatulence, bloating or soft stools) have been reported in studies with IMO consumption higher than the 30 g/day and gastric upset is anticipated with an extremely high dose (*i.e*., about 4-5 times higher than the no-effect level for laxative effects in humans), however, these symptoms are transient and reverse when excess consumption ceases.

7.5 INFORMATION RELATED TO POTENTIAL IMPACT ON CONSUMER UNDERSTANDING AND BEHAVIOUR

(As per section 3.5.2F of the Application Handbook 1 September 2013, amended 1 June 2015)

7.5.1 Information to demonstrate the level of consumer awareness and understanding of the novel food ingredient

The Applicant does not have any information to demonstrate the level of consumer awareness and understanding of the novel food ingredient.

7.5.2 Information on the actual and/or potential behaviour of consumers in responses to the novel food or novel food ingredient

The purpose for adding IMO to food does not relate to a potential beneficial physiological or health-related outcome and the applicant is not seeking to promote physiological effects in relation to IMO in food. The Applicant does not have any data that would allow substantiation of a specific food health relationship. If a manufacturer wished to make a claim in relation to such a benefit they would have to follow the requirements of Standard 1.2.7.

The indication to a consumer that the product contains IMO will be limited to the nutrition information panel (NIP) and the ingredient list. IMO will be labelled in the ingredient list as per GOS and FOS and other oligosaccharides. In the NIP IMO will be listed under dietary fibre.

7.5.3 Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups)

IMOs are well tolerated at the proposed level of use by all age and cultural groups.

The only individuals advised not to consume IMOs are those with a specific in-born sucrase-isomaltase deficiency, who are also unable to tolerate sucrose and will therefore be aware of their condition and are likely to have received targeted clinical advice about their food choices.

Since IMOs are metabolised to produce glucose, consumers with diabetes will need to be aware of their presence in manufactured foods. However, foods containing IMOs could not be labelled as "sugar free" or promoted as suitable for diabetics. IMO will be identified in the ingredient list and the carbohydrate and sugars (i.e. the mono and disaccharides) content of the food will be available from the nutrition information panel.

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LIST OF FIGURES

LIST OF TABLES

APPENDIX 1: LETTER OF SUPPORT FOR THE APPLICATION

This information is **commercial confidential information (CCI)** and has been provided separately.

Letter of support provided, indicates support for the application.

APPENDIX 2: IMO PROPOSED RANGE OF FOODS AND LEVELS OF USE FOR COFCO IMO

Separate attachment to the Application (excel spreadsheet)

APPENDIX 3: FSANZ AND ADVISORY COMMITTEE ON NOVEL FOODS (ACNF) CORRESPONDANCE IN RELATION TO IMO

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Level 6, 108 The Terrace
Wellington
PO Box 10 559
Wellington
Tel + 64 4 978 5630
Fax + 64 4 473 9855
www.foodstandards.govt.nz

[redacted]
Better Health and Wellness Solutions Pty Ltd
PO Box 326
Alexandria NSW 2015
AUSTRALIA

[redacted]

Thank you for your enquiry of 23 July 2012 regarding isomalto-oligosaccharide (IMO) as a potential novel food. You enquired whether the Advisory Committee on Novel Foods (the Committee)[1] would review its published opinion regarding IMO and whether an application to amend Standard 1.5.1 - Novel Foods of the *Australia New Zealand Food Standards Code* (the Code) should be made.

Standard 1.5.1 of the Code requires FSANZ to conduct a pre-market safety assessment of those non-traditional foods that are deemed to be novel according to the definitions in the Standard. The definitions of 'non-traditional food' and 'novel food' are provided in the Attachment to this letter.

The Committee discussed your enquiry at its meeting on 1 August 2012 and used the Guidance Tool to assist in forming a view. The Guidance Tool is divided into Part 1 – Determining whether a food is non-traditional or not; and Part 2 – Determining whether an assessment of public health and safety considerations is required for a non-traditional food.

The Committee has formed the view that IMO meets the definition of 'non-traditional food' on the basis that it does not have a history of human consumption as a food in Australia or New Zealand (Part 1 of the Guidance Tool).

Part 2 of the Guidance Tool requires the Committee to consider whether IMO is a novel food and requires an assessment of public health and safety considerations. The Committee has undertaken a preliminary hazard identification process and formed the view that an assessment of public health and safety considerations is required. Based on the information available it is likely that IMO is considered to be within the scope of the definition of novel food for the purposes of Standard 1.5.1.

[1] The Advisory Committee on Novel Foods comprises representatives from Australian State and Territory jurisdictions, the Australian Quarantine Inspection Service, the New Zealand Food Safety Authority and Food Standards Australia New Zealand. The Committee provides recommendations to the General Manager / Food Standards (Wellington) as to whether particular foods meet the definitions of 'non-traditional food' and 'novel food' in Standard 1.5.1 of the Code.

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It is the responsibility of manufacturers, suppliers or importers to ensure products comply with the requirements of the Code. FSANZ is not responsible for enforcing the requirements of the Code. Enforcement of the Code is the responsibility of the Commonwealth, State, Territory and New Zealand Governments. Accordingly, the interpretation and application of Standard 1.5.1, including decisions about the novelty of a food or food ingredient, is ultimately the responsibility of those jurisdictions. Therefore while the Committee may express a view about whether or not IMO meets the definition of a novel food for the purposes of Standard 1.5.1, it is ultimately a decision for the relevant enforcement authority.

Information regarding the application process to amend the Code is available at http://www.foodstandards.gov.au/standardsdevelopment/informationforapplicants/index.cfm.

[redacted]

Yours sincerely

[redacted]

Food Standards (Wellington)

20th August 2012

APPENDIX 4: PUBMED AND TOXLINE SEARCH RESULTS

PubMed Search (28-08-2013)

Search term: "(isomalto AND oligosaccharide) OR isomaltooligosaccharide"

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TOXLINE Search (28-08-2013)

Search term: "(isomalto AND oligosaccharide) OR isomaltooligosaccharide"

1 Isomalto oligosaccharide sulfate inhibits tumor growth and metastasis of hepatocellular carcinoma in nude mice.

Xiao CL; Tao ZH; Guo L; Li WW; Wan JL; Sun HC; Wang L; Tang ZY; Fan J; Wu WZ

BMC Cancer. 2011; 11:150. [BMC cancer] [PubMed]

PubMed Citation Link to PubMed Citation

2 Prebiotic-non-digestible oligosaccharides preference of probiotic bifidobacteria and antimicrobial activity against Clostridium difficile.

Kondepudi KK; Ambalam P; Nilsson I; Wadström T; Ljungh A

Anaerobe. 2012, Oct; 18(5):489-97. [Anaerobe] [PubMed]

PubMed Citation Link to PubMed Citation

3 Influence of isomalto-oligosaccharides on intestinal microbiota in rats.

Ketabi A; Dieleman LA; Gänzle MG

J Appl Microbiol. 2011, May; 110(5):1297-306. [Journal of applied microbiology] [PubMed]

PubMed Citation Link to PubMed Citation

4 Buffering effects of calcium salts in kimchi: lowering acidity, elevating lactic acid bacterial population and dextransucrase activity.

Chae SE; Moon JS; Jung JY; Kim JS; Eom HJ; Kim SY; Yoon HS; Han NS

J Microbiol Biotechnol. 2009, Dec; 19(12):1644-9. [Journal of microbiology and biotechnology] [PubMed]

PubMed Citation Link to PubMed Citation

5 Cloning of dextransucrase gene from Leuconostoc citreum HJ-P4 and its high-level expression in E. coli by low temperature induction.

Yi AR; Lee SR; Jang MU; Park JM; Eom HJ; Han NS; Kim TJ

J Microbiol Biotechnol. 2009, Aug; 19(8):829-35. [Journal of microbiology and biotechnology] [PubMed]

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6 Molecular determinants of substrate recognition in thermostable alpha-glucosidases belonging to glycoside hydrolase family 13.

Tsujimoto Y; Tanaka H; Takemura R; Yokogawa T; Shimonaka A; Matsui H; Kashiwabara S; Watanabe K; Suzuki Y

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PubMed Citation Link to PubMed Citation

7 Identification of catalytic amino acids of cyclodextran glucanotransferase from Bacillus circulans T-3040.

Yamamoto T; Terasawa K; Kim YM; Kimura A; Kitamura Y; Kobayashi M; Funane K

Biosci Biotechnol Biochem. 2006, Aug; 70(8):1947-53. [Bioscience, biotechnology, and biochemistry] [PubMed]

PubMed Citation Link to PubMed Citation

8 Influence of different oligosaccharides and inulin on heterocyclic aromatic amine formation and overall mutagenicity in fried ground beef patties.

Shin HS; Park H; Park D

J Agric Food Chem. 2003, Nov 5; 51(23):6726-30. [Journal of agricultural and food chemistry] [PubMed]

PubMed Citation Link to PubMed Citation

9 Mutational modulation of substrate bond-type specificity and thermostability of glucoamylase from Aspergillus awamori by replacement with short homologue active site sequences and thiol/disulfide engineering.

Fierobe HP; Stoffer BB; Frandsen TP; Svensson B

Biochemistry. 1996, Jul 2; 35(26):8696-704. [Biochemistry] [PubMed]

PubMed Citation Link to PubMed Citation

10 Effects of isomalto-oligosaccharides on bowel functions and indicators of nutritional status in constipated elderly men.

Chen HL; Lu YH; Lin JJ; Ko LY

J Am Coll Nutr. 2001, Feb; 20(1):44-9. [Journal of the American College of Nutrition] [PubDART]

PubMed Citation Link to PubMed Citation

11 Acute and chronic toxicity and mutagenicity studies on isomaltooligosaccharides, and the effects on peripheral blood lymphocytes and intestinal microflora.

KANEKO T ; KOHMOTO T ; FUKUI F ; AKIBA T ; SUZUKI S ; HIRAO A ; NAKATSURU S ; KANISAWA M

J FOOD HYG SOC JPN; 31 (5). 1990. 394-403. [Japanese] [BIOSIS]

APPENDIX 5: DESCRIPTION OF SACCARIDES IN TYPICAL IMO PRODUCTS

Separate attachment to the Application (excel spreadsheet)

APPENDIX 6: FDA IMO GRAS NO OBJECTION LETTER

Food

Agency Response Letter GRAS Notice No. GRN 000246

CFSAN/Office of Food Additive Safety
February 10, 2009

[redacted]
President
BioNeutra Inc.
9419-20th Avenue, N.W.
Edmonton Research Park
Edmonton, Alberta
CANADA T6N 1E5

Re: GRAS Notice No. GRN 000246

[redacted]

The Food and Drug Administration (FDA) is responding to the notice, dated March 17, 2008, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on April 1, 2008, filed it on April 4, 2008, and designated it as GRAS Notice No. GRN 000246.

The subject of the notice is isomalto-oligosaccharide mixture (IMOM). The notice informs FDA of the view of BioNeutra Inc. (BioNeutra) that IMOM is GRAS, through scientific procedures, for use as an ingredient in a variety of foods, including meat products, at maximum levels ranging from 1.5 to 15 grams per serving (g/serving) as detailed in Table 1 below.

Table 1: Intended food uses, maximum use levels, and amount of IMOM per serving

Food Use	Maximum Use Level (percent)	IMOM Per Serving (g)*
Baked goods and baking mixes	25	15
Beverages and beverage bases	5	12
Breakfast cereals	20	10
Condiments and relishes	20	5
Dairy product analogs	5	12
Mayonnaise and mayonnaise-type dressings	30	7
Salad dressings	30	9
Frozen dairy desserts and mixes	10	10
Gelatins, puddings, and fillings	15	15
Gravies and sauces	20	14
Hard candies	100	10
Jams and jellies	75	11
Meal replacement bars and mixes	25	10
Meat products	5	2.5
Milk and milk products	5	5.5
Nut products	10	3
Processed fruits and fruit juices	5	7
Snack foods	5	1.5
Soft candy	40	14
Sugar substitutes	100	4
Sweet sauces, toppings, and syrups	50	15
Processed vegetables and vegetable juices	15	15

*Reference amounts customarily consumed per eating occasion, 21 CFR 101.12

As part of its notice, BioNeutra includes the report of a panel of individuals (BioNeutra's GRAS panel) who evaluated the data and information that are the basis for BioNeutra's GRAS determination. BioNeutra considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food.

BioNeutra describes both syrup and powder formulations of IMOM. BioNeutra defines isomalto-oligosaccharides as relatively short glucose oligomers containing characteristic α-D-1,6 linkages[1] and indicates that the product manufactured by the firm is mainly comprised of such oligomers. BioNeutra states that approximately 77 and 73 percent of the syrup and powder formulations, respectively, are composed of oligosaccharides between three and six degrees of polymerization. Mono- and disaccharides constitute (15 to 20 percent) and larger oligomers (= seven glucose units) account for the remainder.

BioNeutra describes the method of manufacture and product specifications for IMOM. BioNeutra states that all substances used in the manufacturing process are appropriate for food use. Starch from a variety of sources (e.g., corn, wheat, rice, cassava, barley, oats, potato, peas, beans, and lentils) is mixed with water to create a slurry. Enzymes are added to hydrolyze the starch amylose and amylopectin polysaccharides and then to form isomalto-oligosaccharides. Yeast is added to consume excess glucose. The mixture is then heated to inactivate the yeast and promote evaporation of yeast-generated ethanol. The mixture is purified and the product is either spray-dried (powder formulation) or evaporated (syrup formulation). Specifications provided for IMOM include the content of isomaltose and higher oligosaccharides (three to ten glucose units) and limits on the content of glucose, sulfated ash, lead, arsenic and microbial contaminants. Specifications for the syrup formulation also include dried solids and pH; specifications for the powder formulation include solubility in water and moisture.

BioNeutra estimates that the intake of IMOM would be approximately 30 grams per person per day. This estimate is based on the assumed consumption of two servings of foods containing the highest use level identified (15 g/serving).

BioNutra discusses the safety evaluation for IMOM based on a variety of published studies and other data and information, including;

- well-established metabolic profiles of the simple saccharide components of IMOM (maltose, isomaltose).
- published studies and other information related to the absorption, digestion, metabolism, and excretion of isomalto-oligosaccharides (IMO) similar to those in the IMOM described in this notice. IMO preparations are partially hydrolyzed to glucose and absorbed; as is common with other non-digestible carbohydrates, the remainder is metabolized by gut microflora.
- published acute, subchronic, and chronic safety studies of various IMO preparations in rats. In some of these studies, IMO consumption was associated with decreased food efficiency or increased intestinal weight, which is consistent with the limited digestibility of IMO and proliferation of colon microflora. BioNeutra concluded that these observations did not raise concerns about adverse effects on human health.
- published studies and other information concerning various effects in the gut expected from or attributed to bacterial fermentation of IMO specifically, and non-digestible carbohydrates generally. BioNeutra concluded that the intended use of IMOM would not have adverse effects on human health.
- published tolerance studies of various IMO preparations in humans, in light of the potential for microbial fermentation of IMO in the lower intestine.

On the basis of all the data and information listed above, BioNeutra concludes that consumption of IMOM under the conditions of its intended use would not produce adverse effects on human health and would be well-tolerated with respect to gastrointestinal effects.

Standards of Identity

In the notice, BioNeutra states its intention to use its IMOM in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food product only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), a food is misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FFDCA lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food or that characterize the relationship of a nutrient to a disease or health-related condition. In describing the intended use of IMOM and in describing the information that BioNeutra relies on to conclude that IMOM is GRAS under the conditions of its intended use, BioNeutra raises a potential issue under these labeling provisions of the FFDCA. If products that contain IMOM bear any claims on the label or in labeling, such claims are the purview of the Office of Nutrition, Labeling and Dietary Supplements (ONLDS) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety neither consulted with ONLDS on this labeling issue nor evaluated the information in your notice to determine whether it would support any claims made about IMOM on the label or in labeling.

Use in Meat and Poultry Products

During our evaluation of GRN 000246, we consulted with the Labeling and Program Delivery Division of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS is responsible for determining the efficacy and suitability of food ingredients in meat and poultry products as well as prescribing safe conditions of use. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads consumers.

FSIS advised that BioNeutra's notice does not include any efficacy or suitability data for meat products on which FSIS could base a decision. FSIS requested that FDA advise BioNeutra to seek regulatory guidance from FSIS about the use of IMOM in meat and poultry products. Inquiries should be directed to Dr. John Hicks, Risk Management Division, Office of Policy and Program Development[2], Food Safety and Inspection Service, 1400 Independence Ave., S.W., Room 3549, South Agriculture Building, Washington, DC 20250-3700. The telephone number for that office is (202) 205-0210 and the telefax number is (202) 720-0582.

Section 301(ll) of the FFDCA

The Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amends the FFDCA to, among other things, add section 301(ll). Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of BioNeutra's notice that IMOM is GRAS for its intended uses, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing IMOM. Accordingly, this response should not be construed to be a statement that foods that contain IMOM, if introduced or delivered for introduction into interstate commerce, would not violate section 301 (ll).

Conclusions

Based on the information provided by BioNeutra, as well as other information available to FDA, the agency has no questions at this time regarding BioNeutra's conclusion that IMOM is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of IMOM. As always, it is the continuing responsibility of BioNeutra to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000246, as well as a copy of the information in this notice that conforms to the information in the proposed GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying via the FDA home page at http://www.fda.gov. To view or obtain an electronic copy of the text of the letter, follow the hyperlinks from the "Food" topic to the "Food Ingredients and Packaging" section to the "Generally Recognized as Safe (GRAS)"

page where the GRAS Inventory is listed.

Sincerely,

[redacted]
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

[redacted]
Risk Management Division
Office of Policy and Program Development
Food Safety and Inspection Service
1400 Independence Ave., SW, Room 3549 South Building
Washington, DC 20250-3700

[1] Among the isomalto-oligosaccharides identified by BioNeutra in the product it manufactures are isomaltose, panose, isomaltotetraose, isomaltopentaose, and isomaltohexaose.

[2] Effective June 1, 2008, the Office of Policy and Program Development of FSIS has transferred the review process of ingredient submissions from the Labeling and Program Delivery Division to the Risk Management Division.

Page Last Updated: 04/17/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

APPENDIX 7: HEALTH CANADA – NOVEL FOOD INFORMATION – ISOMALTOLIGOSACCHARIDE (VITASUGAR™) [17]

Health Canada Santé Canada

Canada

Home > Food & Nutrition > Genetically Modified (GM) Foods & Other Novel Foods > Approved Products

Food and Nutrition

Isomalto-oligosaccharide (Vitasugar ™)

Novel Food Information - Isomalto-oligosaccharide (Vitasugar ™)

Health Canada has notified BioNeutra Inc. that it has no objection to the use of IMO as a food ingredient. Isomalto-oligosaccharide is a food ingredient added to foods with a relative sweetness level equal to approximately 60% of sucrose. Chemically, IMO is a mixture of glucose oligomers with alpha-(1-6)-linkages.

IMO may be added to a variety of foods including, but not limited to, baked goods and baking mixes, beverages and beverage bases, condiments, salad dressings, frozen dairy deserts and mixes, gravies, sauces, hard and soft candies, jams, meat and nut products, processed fruits and vegetables, sugar substitutes, sweet sauces, and toppings. IMO is not permitted to be added to a food for which a standard exists in the *Food and Drug Regulations* unless the standard provides for the addition.

Background

The following provides a summary of the notification from BioNeutra Inc. and the evaluation by Health Canada and contains no confidential business information.

1. Introduction

Isomalto-oligosaccharide is a food ingredient that is added to various foods as either powder or a syrup. Chemically, IMO is a mixture of glucose oligomers with alpha-(1-6)-linkages such as isomaltose, panose, isomaltotriose, and isomaltopentose. The majority of glucose oligosaccharides found in IMO consist of 3-6 monosaccharide units linked together, however disaccharides as well as longer polysaccharides (up to 9 units) are also present.

2. Description of the novel process

Isomalto-oligosaccharide is formed by enzyme-catalyzed hydrolysis of starch from different cereal crops (wheat, barley, corn), pulses (lentils, peas), rice, tapioca (cassava), potato and other starch sources. Enzymes, including alpha-glucosidase, alpha-amylase, and pullulanase, hydrolyse the polysaccharides in starch to produce mono-, di-, tri-, and other smaller oligosaccharides with alpha- 1,4 and alpha-1,6 glycoside linkages. Yeast is added to remove glucose that may be formed as a result of the enzymatic hydrolysis reactions.

The final step in the starch hydrolysis is a saccharification step that yields high maltose syrup. Maltose syrup naturally contains di- and tri- oligosaccharides with alpha- 1,4 glycoside linkages. In order to convert these molecules into functional and low caloric molecules, these alpha-1,4 linkages are enzymatically converted into alpha-1,6 linkages, thus forming IMO. This step is achieved by the addition of an enzyme, transglucosidase (TG). To summarize, the TG enzyme converts malto-oligosaccharides to IMO.

3. Nutrition

The petitioner provided composition data related to the carbohydrate fractions of IMO. The content of glucose, isomaltose and other oligosaccharides was determined by high performance liquid chromatography (HPLC).

17 http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/isomalto-oligosaccharide-eng.php, accessed 08.06.14

Isomalto-oligosaccharide is composed of 15-20% of smaller saccharides and 70-80% of the larger oligosaccharides. Thus, IMO contains both digestible and non-digestible saccharides. The fractions composed of isomaltose, maltose, and panose would be digested in the small intestine and absorbed as glucose following oral administration. The non-digested oligosaccharides would pass through the small intestine and undergo microbial fermentation in the large intestine. The non-digested oligosaccharides would consist of the larger oligosaccharides.

Isomalto-oligosaccharide is completely devoid of vitamins, minerals, fats, proteins (amino acids, nucleic acids), anti-nutritional factors (phytate, tryspin inhibitors). The energy/caloric value for IMO is 2.4 kcal/g.

4. Dietary exposure

Isomalto-oligosaccharides are naturally found in honey, miso, sake, and soy sauce. In Canada these foods are generally consumed in small quantities. The levels at which IMO are present in honey, miso, sake, and soy sauce, are very low in comparison to the proposed amounts to be added to various foods.

Modelling was conducted to determine the potential exposure of the Canadian population to IMO given the different proposed levels of the foods requested for consideration. An intake of IMO higher than 30 g/day may cause possible gastrointestinal problems (flatulence, bloating, soft stool, or diarrhea). Also, according to Oku and Nakamura (Pure Appl. Chem., 2002) the maximum intake of IMO that would not cause diarrhea is 1.5 g/kg body weight. For a 70 kg person, this equals 105g per day. Based on the modelling, Health Canada considers the risk of over-exposure to IMO to be low.

5. Toxicological assessment

Based on the evidence provided, the toxicological evaluation concluded that there are no toxicological issues with IMO at the proposed maximum intake of 30 g/person/day, for the general population.

6. Chemical assessment

Physical and chemical specifications were submitted for both IMO powder and IMO syrup. The HPLC specifications indicated that the preparation (both the syrup and powder) contains less than 5% glucose and more than 90% isomaltose and oligosaccharides. The levels of the heavy metals lead and arsenic are each lower than 0.5 ppm and the petitioner has certified that there is a lack of carry-over of other chemical contaminants.

The manufacturing process shows the use of several enzymes, which are all approved for food use as per Division 16 of the *Food and Drug Regulations* except the enzyme transglucosidase. Since June 2009 the TG enzyme used in this process is considered an essential reactant, assimilated with a processing aid classification and therefore no regulatory amendment to the *Food and Drug Regulations* is necessary in order to enable its use in IMO production.

All data provided were adequate to demonstrate that the final product is safe and raises no safety concerns.

7. Microbiology

Microbiological specifications for IMO were provided. The specifications covered total aerobic plate count (no more than 10^4 CFU/g), yeast (no more than 10^2 CFU/g), E.coli (no more than 10^1 CFU/g), and Salmonella (absent). All three certificates of analysis submitted indicated compliance with these specifications.

8. Labelling

Health Canada and the Canadian Food Inspection Agency (CFIA) share responsibilities in regard to labelling requirements for foods. Health Canada is responsible for policy and standard

setting under the Food and Drugs Act and Regulations, whereas CFIA is responsible for enforcement. CFIA also administers and enforces those aspects of the Food and Drugs Act and the Consumer Packaging and Labelling Act that ensure labelling is understandable, truthful and not misleading.

Isomalto-oligosaccharide is to be included in the declared carbohydrate amount in the Nutrition Facts table and should be included in the ingredient list. BioNeutra Inc. has been notified to consult with the CFIA to determine common name and labelling requirements for food products containing IMO.

Conclusion

Health Canada's review of the information presented in support of the use of IMO as a food ingredient concluded that there are no food safety concerns. Health Canada is of the opinion that IMO can be added to a variety of foods. It is the continuing responsibility of BioNeutra Inc. to ensure that their products are in compliance with all applicable statutory and regulatory requirements.

This Novel Food Information document has been prepared to summarize the opinion regarding the subject product provided by the Food Directorate, Health Products and Food Branch, Health Canada. This opinion is based upon the comprehensive review of information submitted by the petitioner according to the *Guidelines for the Safety Assessment of Novel Foods*.

(Également disponible en français)

For further information, please contact:

Office of Food Biotechnology
Food Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario K1A 0L2

novelfoods-alimentsnouveaux@hc-sc.gc.ca

Date Modified: 2012-10-11

APPENDIX 8: UK FOOD STANDARDS AGENCY ADVICE

Food Standards Agency
food.gov.uk

[redacted]
Bioneutra Inc.
Edmonton Research Park,
Research Centre One,
9419-20th Ave.,
Edmonton,
AB T6N 1E5
Canada
sent by email

30 July 2013

ISOMALTO-OLIGOSACCHARIDE AS A NOVEL FOOD INGREDIENT

[redacted]

I am writing to inform you of the outcome of your application made to the UK for the pre-market assessment of Isomalto-oligosaccharide in accordance with Articles 4 and 6 of the Novel Food Regulation (Regulation (EC) 258/97).

1. In February 2009 an application from Bioneutra Inc. was accepted by the Food Standards Agency (the designated competent food assessment body in the UK) to place Isomalto-oligosaccharide on the EU market as a novel food ingredient.

2. On 7 December 2012 the Food Standards Agency issued its initial assessment report, having obtained advice from the Advisory Committee on Novel Foods and Processes (ACNFP), the independent Committee that advises the Agency on all novel food issues. This report concluded that Isomalto-oligosaccharide meets the criteria for acceptance as a novel food, as defined in Article 3(1) of the Regulation.

3. The Commission forwarded the initial assessment report to all member states on 31 January 2013 and no reasoned objections were presented by the Commission or the member states within the 60 day period laid down in Article 6(4) of Regulation (EC) 258/97.

Aviation House
125 Kingsway
London WC2B 6NH
T 020 7276 8574

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November 2015

4. Comments were made by Hungary, Germany, the Netherlands, Greece and Ireland and you are able to respond to these comments on a bilateral basis.

5. Therefore, on the basis of the initial assessment report, it is established that Bioneutra's Isomalto-oligosaccharide powder and syrup (Annex 1) complies with the criteria laid down in Article 3(1) of Regulation 258/97 when placed on the market in accordance with the conclusions of the initial assessment report, namely:

   I. Isomalto-oligosaccharide may be added to the foods listed in Annex 2 at up to the specified maximum levels.

   II. Foods containing Bioneutra's Isomalto-oligosaccharide must be labelled as unsuitable for diabetics.

6. Therefore, Bioneutra Inc. may place Isomalto-oligosaccharide, as defined in Annex 1, on the EU market in accordance with the conditions in this letter. This letter will be published on the Food Standards Agency website and a copy will be forwarded to the Commission for transmission to all other Member States and general publication.

7. I would remind you that Isomalto-oligosaccharide must be labelled in accordance with requirements for food allergens if it is derived from one of the allergenic crops identified in EU labelling legislation (Annex IIIa of Directive 2000/13/EC). Also, claims relating to prebiotic function may only be made for foods containing Isomalto-oligosaccharide if they have been assessed by the European Food Safety Authority (EFSA) and authorised in accordance with Regulation 1924/2006.

Yours sincerely,
(By email only)

[redacted]

Novel Foods Unit, Food Standards Agency

Annex 1

Specification for Isomalto-oligosaccharide (powder)

Specification Parameter	Specification
Solubility (water) (%)	> 99
Glucose (% dry basis)	≤ 5
Isomaltose + DP3 to DP9 (% dry basis)	≥ 90
Moisture (%)	≤ 4
Sulfated ash(g/100g)	≤ 0.3
Heavy metals:	
Lead (mg/kg)	≤ 0.5
Arsenic (mg/kg)	≤ 0.5

Specification for Isomalto-oligosaccharide (syrup)

Specification Parameter	Specification
Dried solids (g/100 g)	> 75
Glucose (% dry basis)	≤ 5
Isomaltose + DP3 to DP9 (% dry basis)	≥ 90
pH	4 to 6
Sulfated ash(g/100g)	≤ 0.3
Heavy metals:	
Lead (mg/kg)	≤ 0.5
Arsenic (mg/kg)	≤ 0.5

Annex 2

Uses of Isomalto-oligosaccharide

Food Category		Maximum Use-Level (%)
Beverages		
	Energy-Reduced Soft Drinks	6.5
	Energy Drinks	5.0
	Sports & Isotonic Drinks	6.5
	Fruit Juices	5
	Processed Vegetables and Vegetable Juices	5
	Other Soft Drinks	5
Cereal Products	Cereals Bars	10
	Cookies, Biscuits	20
	Breakfast Cereal Bars	25
Sugar Confectionery	Hard Candies	97
	Soft Candies/Chocolate Bars	25
Nutritionally complete and fortified foods	Meal Replacement Bars	20
	Milk based Meal Replacement	20

APPENDIX 9: APPROVED FOSHU PRODUCTS (JAPAN MINISTRY OF HEALTH, LABOUR AND WELFARE)

Ministry of Health, Labour and Welfare Japanese

厚生労働省 search

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Food for Specified Health Uses (FOSHU)

FOSHU refers to foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol. In order to sell a food as FOSHU, the assessment for the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the MHLW.

Seal for FOSHU Approval

Requirements for FOSHU Approval

- Effectiveness on the human body is clearly proven
- Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- Use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.)
- Guarantee of compatibility with product specifications by the time of consumption
- Established quality control methods, such as specifications of products and ingredients, processes, and methods of analysis

In addition to "regular" FOSHU, following types of FOSHU are available.: Qualified FOSHU and Standardized FOSHU were introduced to facilitate applicants for FOSHU approvals.

(1) Qualified FOSHU:
Food with health function which is not substantiated on scientific evidence that meets the level of FOSHU, or the food with certain effectiveness but without established mechanism of the effective element for the function will be approved as qualified FOSHU.

(2) Standardized FOSHU:
Standards and specifications are established for foods with sufficient FOSHU approvals and accumulation of scientific evidence. Standardized FOSHU are approved when it meets the standards and specifications.

(3) Reduction of disease risk FOSHU
Reduction of disease risk claim is permitted when reduction of disease risk is clinically and nutritionally established in an ingredient.

Approved FOSHU Products (LINK: Japanese Only)

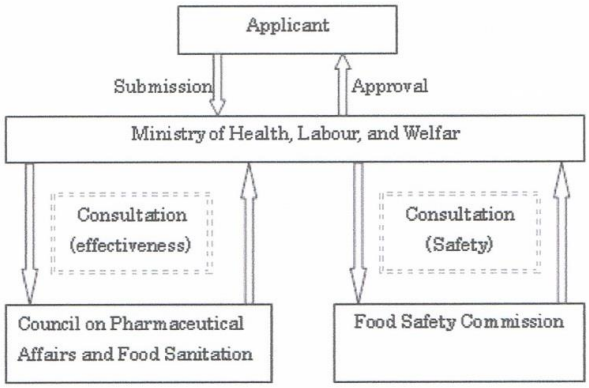
Specified Health Uses	Principal Ingredients (ingredients exhibiting health functions)
Foods to modify gastrointestinal conditions	Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber 8 ingestible dextrin, polydextrol, guar gum, psyllium seed coat, etc.)
Foods related to blood cholesterol level	Chitosan, soybean protein, degraded sodium alginate
Foods related to blood sugar levels	Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.
Foods related to blood pressure	Lactotripeptide, casein dodecaneptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.
Foods related to dental hygiene	Paratinose, maltitiose, erythrytol, etc.
Cholesterol plus gastrointestinal conditions, triacylglycerol plus cholesterol	Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.
Foods related to mineral absorption	Calcium citrated malate, casein phosphopeptide, hem iron, fracuto-oligosaccharide, etc.
Foods related to	Soybeen isoflavone, MBP (Milk basic protein),

osteogenesis	etc.
Foods related to triacylglycerol	Middle chain fatty acid, etc.

Approved Reduction of Disease Risk Claim

- Calcium and Osteoporosis: "Intake of proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones of young women and reduce the risk of osteoporosis when aged."
- Folic Acid and Neural Tube Defect: "Intake of proper amount of folic acid contained in healthy meals may support women to bear healthy baby by reducing the risk of neural tube defect, such as spondyloschisis, during fetal development.

Flow Chart of FOSHU Approval



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APPENDIX 10: CHINA NATIONAL STANDARD FOR IMO

An English translation of the Standard is provided.

IMO

11 范围range

this standard Set IMO terms and definitions, product classification, requirements, analysis, inspection inspection rules and mark, packing, transportation and storage.

This standard applies to IMO

GB /T 191 包装储运图示标志(GB/T 191-2000,eqv IS0 780:1997)/ T 191 packing storage and transportation graphic symbol (GB/T 191-2000, eqv IS0 780:1997)

GB/T 4789.2 GB/T 4789.2食品卫生微生物学检验菌落总数测定Food hygiene microbiological test colony total measurement

GB/T 4789.3 GB/T 4789.3食品卫生微生物学检验大肠菌群测定Food hygiene microbiological test coliform group determination

GB/T 4789.4 GB/T 4789.4食品卫生微生物学检验沙门氏菌检验Food hygiene microbiological test salmonella inspection

GB/T 5009. 11 GB/T 5009. 11 食品中总砷及无机砷的测定方法The total amount of arsenic in the food and inorganic arsenic determination method

GB/T 5009. 12 GB/T 5009. 12食品中铅的测定方法The determination method of lead in food

GB/T 6682-1992 GB/T 6682-1992 分析实验室用水规格和试验方法(neq IS0 3696:1987)Analysis laboratory water specifications and test methods (neq IS0 3696:1987)

GB 7718 GB 7718预包装食品标签通则Prepackaging food of the general principles of the label

GB 15203 GB 15203 淀粉糖卫生标准Starch sugar health standard

GB/T 20884-2007 GB/T 20884-2007 麦芽糊精Malt dextrin

GB/T 20885-2007 GB/T 20885-2007 葡萄糖浆Glucose syrup

33术语和定义、符号Terminology and definition, symbol

3.13.1 术语和定义Terminology and definition

下列术语和定义适用于本标准。The following terms and definitions are applicable to the standard.

3.1.13.1.1

isomaltooligosaccharide(IMO) is one kind of starch sugar, the main composition is alpha 1, 6 - glycosidic bond combination of isomaltose (IG2), panose (P), different malt trisaccharide (IG3) and four sugar (including four sugar) above (Gn) of oligosaccharides.

3.23.2符号symbol

下列符号适用于本标准。The following symbol is applicable to this standard.

IMO IMO：低聚异麦芽糖。: ismalto- oligo saccharide

IG2 IG2：异麦芽糖。: isomaltose.

P: P:潘糖。Panose

IG3 IG3：异麦芽三糖。: maltotriose

Gn Gn：四糖（含四糖）以上的低聚糖。: maltotetraose and above

44产品分类Product categories

4.14.1按形态可分为：According to the form can be divided into:

低聚异麦芽糖浆和低聚异麦芽糖粉。Oligomerization different malt syrup and oligo-ismaltose powder.

4.24.2按IMO含量可分为：According to IMO content can be divided into:

IM0-50 IM0-50型：IG2 +P+ IG3 + Gn≥50%（占干物质）的产品。Type: IG2 + P + IG3 + Gn was 50% (of dry matter) products.

IM0-90 IM0-90型：IG2 +P+ IG3 + Gn≥90%（占干物质）的产品。Type: IG2 + P + IG3 + Gn was 90% (of dry matter) products.

55要求requirements

5.15.1 感官要求Sensory requirements

Syrup colorless or pale yellow, transparent thick liquid. Sweet taste soft, no peculiar smell, no normal vision visible impurities.

Powdered sugar for white amorphous powder. Soft sweet taste, no peculiar smell, no normal vision visible impurities.

5.25.2理化要求Physical and chemical requirements

应符合表1的规定。Should comply with the provisions of the table 1.

表1 低聚异麦芽糖理化要求Table 1 oligo-ismaltose physical and chemical requirements

项目project	要求requirements			
	IMO-50IMO-50型type		IMO-90IMO-90型type	
	糖浆syrup	糖粉Powdered sugar	糖浆syrup	糖粉Powdered sugar
IMO content（%）≥	50		90	
IG2 +P+IG3（%）≥	35		45	
brix（%）≥	75	--	75	--
moisture（%）≤	--	55	--	55
pH	4.0～6.0			
Transmittance (%)≥	95	--	95	--
Solubility（%）≥	--	99	--	99
Sulfuric acid ash / (%)≤	0.3			

5.3 Hygiene requirements

Should comply with the provisions of the GB 15203.

6试验方法Test method:

The method used in the water, in does not indicate other requirements, should accord with GB/T 6682-1992 level 3 above (contain level 3) water specifications. The reagent, in does not indicate when other specifications, all the process of analyzing pure (AR).

6.1 感官检验Sensory test

6.1.1 糖浆syrup

Take sample about 30 mL in the formless, clean dry sample cup (or 50 mL small beaker), in the bright place, with the naked eye observe its color and clarity; Check whether the normal vision visible impurities, And the glass rod apply adequate amount to the sample into the mouth, taste the flavor, taste the second sample application before water gargle). Recorded.

6.1.2糖粉Powdered sugar

取适量样品，在自然光的光线下，用肉眼观察样品的颜色和形态，有无杂质；Apply proper amount of sample, in the light of natural light, with the naked eye observation sample color and form, have without impurities,取少量样品，放入口中，仔细品尝其味（品尝第二个样品前，须用清水漱口），做好记录。Take a small amount of samples, into the mouth, carefully taste the taste (tasting the second sample before, should be water gargle), recorded.

6.2 IMO含量（高效液相色谱法）Content (high performance liquid chromatograp

6.2.1 原理principle

The same time into the chromatographic column of each component, the flow and stationary phase between dissolution, adsorption, penetration or ion exchange action such as different, along with the mobile phase in the chromatographic column two phase between the distribution of repeatedly, because each component in the chromatographic column movement speed is different, after a certain length of chromatographic column, separate each other.按顺序流出色谱柱，进入信号检测器，在记录仪上或数据处理装置上显示出各组分的谱峰数值。In order outflow chromatographic column, into the signal detector, the recorder or data processing equipment is shown on the various components of the spectrum peak value.根据保留时间对照定性，依据峰面积用外标法定量。According to retention time control qualitative, on the basis of the peak area using external standard method quantitative.

6.2.2仪器nstrument

6.2.2.1. 1 High performance liquid chromatograph (with refractive index detector and column thermostatic system).

6.2.2.2. 2 Mobile phase vacuum suction filter degasser and 0.2 u m, 0. 45 μ m microporous membrane.

6.2.2.3. 3色谱柱：氨基键合柱，TSKgel Amide-80，填料粒径：5μm；Chromatographic column: amino bond column, TSKgel Amide - 80, packing size: 5 μ m;柱尺寸：φ4.6 mmXColumn size: φ 4.6 mmX 250 mm 250 mm或分析效果相类似的其他色谱柱。Or analysis effect similar to other chromatographic column.

6.2.2.4. 4分析天平：精度0.1 mg。Analytical balance: the accuracy is 0.1 mg.

6.2.2.5. 5微量进样器：10μL。Trace sampler: 10 μ L.

6.2.3试剂Reagent

6.2.3.1. 1；Water: secondary distilled water or ultrapure water;

6：2.3.2 patch notes乙腈：色谱纯：Acetonitrile: chromatography pure;

6.2.3.3.
3葡萄糖、麦芽糖、异麦芽糖、麦芽三糖、潘糖、异麦芽三糖、麦芽四糖、异麦芽四糖、麦芽五糖、麦芽六糖的标准品，纯度应为95%以上，用每种糖的标准品在0.5 mg/mL～l0 mg/mL范围内配制6个不同浓度的标准液系列。Glucose, maltose, isomaltose, malt trisaccharide, panose, different malt trisaccharide, malt sugar, four different maltooligosaccharide, malt five sugar: six malt sugar standard substance, purity should be more than 95%, with each sugar standard substance in 0.5 mg/mL ~ l0 mg/mL preparation within the scope of 6 different concentration of the standard liquid series.

6.2.46.2.4分析步骤Analysis steps

6.2.46.2.4.1. 1 样液的制备Sample solution preparation

称取糖浆或糖粉样品Say take syrup or sugar powder samples0.5 g0.5 g（以干物质计，应使各种糖组分含量在标准液系列范围内，否则可适当增加或减少取样量），称准至0. 000(in dry matter meter, should make all kinds of sugar component content in standard liquid series range, otherwise can be appropriately increase or decrease sampling quantity), says quasi to 0. 000 1 g 1 g。.加水溶解，移入50 mL容量瓶中并用水定容至刻度。Water dissolution, move into 50 mL volumetric flask and water constant volume to scale.用0.2μm 或0.45μm水相微孔膜过滤，滤液备用。With 0.2 u m or 0.45 u m water phase microporous membrane filtration, filtrate standby.

6.2.46.2.4.2. 2色谱条件Chromatographic condition

流动相为乙腈：水=67：33（体积比）。Mobile phase for acetonitrile: water = 67, 33 (volume ratio).在测定的前一天接通示差折光检测器电源，预热稳定，安上色谱柱，调节温至In the determination of the day before on refractive index detector power, preheating stability, install chromatographic column, adjustable column temperature to75℃75 ℃，以0.1 mL/min的流速通入流动相平衡过夜。To 0.1 mL/min velocity purpose of mobile phase equilibrium for the night.正式进样分析前，将所用流动相输入参比池20 min以上。Formal sample analysis ago, will use mobile phase input reference pool more than 20

min.再恢复正常流路使流动相经过样品池，调节流速至1.0 mL/min。To resume normal flow make mobile phase after sample cell, regulate the flow rate to 1.0 mL/min.走基线，待基线走稳后即可进样，进样量为5μL～l0μL。Go baseline, wait for baseline go after stability can sample, sample quantity for 5 μ L ~ l0 μ L.

6.2.46.2.4.3. 3绘制标准曲线Drawing standard curve

将每种糖的标准液系列分别进样后，以标样浓度对峰面积作标准曲线。Will each sugar standard liquid series respectively after sample, in order to guide sample concentration on peak area for standard curve.线性相关系数应为0. 9990以上。Linear correlation coefficient should be 0. 9990 above.

6.2.46.2.4.4. 4样品的测定Sample determination of

将will6.2.46.2.4.1制备好的试样进样。. 1 preparation good sample injection.根据标准品的保留时间定性样品中各种糖组分的色谱峰。According to the standard substance of retention time qualitative sample of sugar component chromatographic peak.根据样品的峰面积，以外标法计算各种糖组分的含量（质量）。According to the sample peak area, other than standard method to calculate all kinds of sugar component content (quality).

6.2.46.2.4.5. 5结果计算Results the

样品中各种糖的含量按式(1)计算，数值以%表示。Sample of sugar content according to type (1) calculation, numerical to % said.

……..... （1）(1)

式中：Type:

XiXi——样品中某种糖分的百分含量[质量分数（占干物质）]，%；Some sugar in the sample, the percentage content of [quality score (for dry matter)], %,

AiAi——样品中某种糖分的峰面积；Some sugar in the sample, the peak area;

msms——标准样品中某种糖分标准品的质量的数值，单位为克(g)- standard sample in some sugar standard product quality value, the unit is g (g)

V——V——样品的稀释体积的数值，单位为毫升(mL)；The sample dilution volume value, the unit is mL (mL);

As——As——标准样品中某种糖分标准品的峰面积；Standard sample in some sugar standard substance of peak area;

mm——样品的质量的数值，单位为克(g)；- the quality of numerical, the unit is g (g);

VsVs——标准样品稀释体积的数值，单位为毫升(mL)。- standard sample dilution volume value, the unit is mL (mL).

计算结果保留至整数。The calculation results keep to integer.

6.2.56.2.5精密度precision

在重复性条件下获得的两次独立测定结果的绝对差值应不超过算术平均值的1%。In the repeatability conditions get two independent the determination results of absolute difference value shall not exceed 1% of the arithmetic mean value.

6.36.3干物质（固形物）Dry matter (solids)

按GB/T 20885-2007中6.2测定. According to GB/T 20885-2007 in 6.2 determination.

6.46.4水分moisture

按GB/T 20884-2007中6.3测定。According to GB/T 20884-2007 in 6.3 determination.

6.5 pH 6.5 pH

按GB/T 20885-2007中6.4测定。According to GB/T 20885-2007 in 6.4 determination.

6.66.6透射比transmittance

按GB/T 20885-2007中6.5测定。According to GB/T 20885-2007 in 6.5 determination.

6.76.7溶解度solubility

按GB/T 20884-2007中6.4测定。According to GB/T 20884-2007 in 6.4 determination. . .

6.86.8硫酸灰分Sulphated ash

按GB/T 20885-2007中6.8测定。According to GB/T 20885-2007 in 6.8 determination.

6.96.9砷arsenic

按GB/T 5009.11测定。According to GB/T 5009.11 determination.

6.106.10铅lead

按GB/T 5009.12测定。According to GB/T 5009.12 determination.

6.116.11菌落总数Colony total

按GB/T 4789.2测定。According to GB/T 4789.2 determination.

6.126.12大肠菌群Coliform group

按GB/T 4789.3测定。According to GB/T 4789.3 determination.

6.136.13沙门氏菌salmonella

按GB/T 4789.4测定。According to GB/T 4789.4 determination.

77检验规则Inspection rules

7.17.1 组批Group group

同原料、同配方、同工艺生产的产品，以一次投料为一批，最大批量不得超过班产量。With raw materials, with formula, with process production products to a feeding for a batch of, the most mass may not exceed class production.每批产品应经生产厂的检验部门检验合格后出厂，并附有产品质量合格证。Every batch of products manufacturer shall be subject to the inspection department test after passing the factory, with product quality certificate.

7.27.2取样方法Sampling method

7.2.17.2.1瓶装和桶装产品，分别按表2、表3规定抽取样本。Bottled and bulk products, respectively in table 2 and table 3 provisions sample drawn.

表2低聚异麦芽糖瓶装样品抽样表Table 2 oligo-ismaltose bottled sample sampling table

批量范围／箱Batch range/box	抽取样本数／箱Extraction number of samples/box	抽取单位包装数／瓶Extraction unit packing number/bottle
<100< 100	44	11
100～250100 ~ 250	66	11
251～500251 ~ 500	1010	11
>500> 500	2020	11

表3低聚异麦芽糖桶装样品抽样表Table 3 oligo-ismaltose bulk sample sampling table

批量范围／桶Batch range/barrel	抽取样本数／桶Extraction number of samples/barrel

<50< 50	22
50 ~ 10050 ~ 100	44
>100> 100	66

7.2.27.2.2槽车装产品每车必检Tank lorry outfit product each car will check

7.2.37.2.3桶装和槽车装产品应从液面Bulk and tank lorry outfit product should be level10 cm10 cm以下处抽取样品。In the following samples.取样器应符合食品卫生标准。Sampler should comply with the food sanitation standards.

7.2.47.2.4槽车装产品每份取样量应不少于Tank lorry outfit product each sampling quantity shall be no less than2 kg2 kg；;桶装产品每份取样量应不少于lkgf瓶装产品取样总量应不少于Bulk products each sampling quantity should be not less than LKGF bottled product sampling should be not less than the total amount600 g600 g。

7.2.57.2.5抽取样品混匀后分作两份，签封。Samples after blending into two, sign the seal.粘贴标签，在标签上注明产品名称、生产厂名及地址、批号、取样日期及地点、取样人姓名。Paste label, the label product name, production factory name and address, batch number, sampling date and place, sampling names.一份送化验室进行检验，另一份封存，保留半个月备查。A send laboratory test, and the other a seal, retain half a month for future reference.需要做微生物检验时，取样器和玻璃瓶应事先灭菌（样品不得接触瓶口）。Need to do microorganism inspection, sampler and glass bottle should be prior sterilization (sample are not allowed to touch the sealing surface).

7.37.3出厂检验Delivery inspection

出厂检验项目：感官、水分、干物质（固形物）、pH、透射比、溶解度、IG2 +P+ IG3含量、IMO含量。The factory inspection item: sensory, moisture, dry matter (solids), pH and transmission ratio, solubility, IG2 + P + IG3 content, the content of IMO.

7.47.4型式检验Type test

型式检验项目为本标准要求中规定的全部项目。Type test items for the requirements of this international standard specified in the whole project.一般情况下，型式检验半年进行一次。Usually, type test half a year time.有下列情况之一时，亦应进行型式检验：One of the following conditions, also should undertake type inspection:

a)a)原辅材料有较大变化时；Raw and auxiliary materials have great changes;

b) b)更改关键工艺或设备；Change the key process or equipment;

c) c)新试制的产品或正常生产的产品停产3个月后，重新恢复生产时；New development product or normal production and products production after 3 months, restore production;

d) d)出厂检验与上次型式检验结果有较大差异时；The factory inspection and the last type test results have bigger difference;

e) e)国家质量监督检验机构按有关规定需要抽检时。The state administration of quality supervision inspection institutions in accordance with relevant provisions, need to check in.

7.57.5判定规则Decision rules

检验结果如有感官或1项~2项理化指标不合格时，应重新自同批产品中抽取两倍量样品，对不合格项目进行复检，若仍有一项不合格，则判整批产品为不合格。Inspection results if there is a sensory or a ~ two physical and chemical index is not qualified, should be redesigned with batch of products from the extraction of two times the sample quantity, unqualified project inspected, if still have a unqualified, it found the whole batch of product is not qualified.

88标志、包装、运输和贮存Mark, packing, transportation and storage

8.18.1标志mark

8.1.18.1.1供直[illegible]食用的预包装产品标签应符合GB 7718规定。For direct edible prepackaging product labels should comply with the GB 7718 regulations.

8.1.28.1.2作为原辅材料的产品，包装容器外应标注：产品名称、生产厂厂名、净含量、批号、生产日期、保质期、执行标准号。As a raw material products, packaging containers should be marked outside: product name, factory name, net content, batch number, production date, shelf-life, implement standard number.

8.1.38.1.3包装储运图示标志应符合GB/T 191的规定。Packing storage and transportation graphic symbol shall conform to the provisions of the GB/T 191.

8.28.2包装packaging

包装物和容器应整洁、卫生，无破损，并符合《中华人民共和国食品卫生法》的有关规定。Packing materials and containers should be neat, health, no damage, and accord with the law of the People's Republic of the food hygiene law "concerned regulation.

8.38.3运输和贮存Transportation and storage

8.3.18.3.1运输过程中，须防尘、防蝇，严防曝晒、雨淋，严禁与有毒、有害、有腐蚀性物质及污染物混装、混运。Transportation process, must be dustproof, fly, take strict precautions against exposure, rain, with no poisonous and harmful, corrosive materials and pollutant conventional, mix luck.装卸时应符合外包装上包装储运图示的规定。When loading and unloading on the outer package should comply with the provisions of the storage and transport packaging.

8.3.28.3.2成品应贮于干燥、通风、清洁的库房中，并掌握先进先出的原则。Product should be stored in dry and ventilated, clean warehouses, and grasp the advanced and first out principle.

附录A

（资料性附录）

Appendix A

IMO含量（高效液相色谱双柱法）

IMO Content (high-performance liquid chromatography (HPLC) double column method)

AA．1 原理 1 Principle

同一时刻进入色谱柱的各组分，由于在流动相和固定相之间溶解、吸附、渗透或离子交换等作用的不同，随流动相在色谱柱两相之间进行反复多次的分配。Because of different functions such as dissolution, adsorption, penetration or ion exchange at the flow and stationary phases, the components injecting into the chromatographic column at the same time may distribute repeatedly at the two phases in the chromatographic column along with the mobile phase.由于各组分在色谱柱中的移动速度不同，经过一定长度的色谱柱后，彼此分离开来。Because the movement speed of each component in the chromatographic column is different, after a certain length of chromatographic column, components separate to each other.按顺序流出色谱柱，进入信号检测器，在记录仪上或数据处理装置上显示出各组分的谱峰数值。Flow out of the chromatographic column in order, and go into the signal detector, the spectrum peak value of each component is shown on the recorder or data processing equipment.根据保留时间对照定性，依据峰面积用归一化法定量。Determine the quality according to the retention time, and using normalization method to determine the quantity on the basis of the peak area.

AA．2仪器 Equipment

AA．2.1 高效液相色谱仪（配有示差折光检测器和柱恒温系统）。2.1 High-performance liquid chromatograph (with refractive index detector and column thermostatic system).

AA．2.2 流动相真空抽滤脱气装置及0.2μm、0.45μm微孔膜。2.2 Mobile phase vacuum suction filter degasser and 0.2 u m, 0.45 u m microporous membrane.

A.2.3A.2.3 色谱柱Chromatographic column

a) a) 钙型阳离子交换树脂柱：Aminex HPXCalcium type cation exchange resin column: Aminex HPX-42A-42A(BIO-RAD)，填料粒径：5μm；(BIO - RAD), packing size: 5 μ m;柱尺寸：φColumn size: φ7.8 mm7.8 mm××300 mm300 mm，或分析效果相类似的其他色谱柱；, or analysis effect similar to other chromatographic column;

b)b)氨基键合柱：TSKgel Amide-80，填料粒径：5μm；Amino bond column: TSKgel Amide - 80, packing size: 5 μ m;柱尺寸：φColumn size: φ4.6 mm4.6 mm××250 mm250 mm或分析效果相类似的其他色谱柱；Or other chromatographic columns with similar analytical effect;

A.2.4A.2.4分析天平：精度0.l mg。Analytical balance: accuracy 0.l mg.

A.2.5A.2.5微量进样器：10μL。Trace sampler: 10 μ L.

A.3A.3试剂Reagent

A.3.1A.3.1 水：二次蒸馏水或超纯水。Water: twice-distilled water or ultrapure water.

A.3.2A.3.2 乙腈：色谱纯。Acetonitrile: chromatography pure.

A.3.3A.3.3葡萄糖、麦芽糖、异麦芽糖、麦芽三糖、潘糖、异麦芽三糖、麦芽四糖、异麦芽四糖、麦芽五糖、麦芽六糖的标准品，纯度应为95%以上。Standard substance of glucose, maltose, isomaltose, maltotriose, panose, isomaltotriose, maltotetraose, isomaltotetraose, maltopentaose, maltohexaose, purity should be more than 95%.分别用水配成0. 5%的水溶液。Dilute them with water into 0. 5% aqueous solution respectively.

A.4A.4分析步骤Procedure

A A．4.1样液的制备4.1 sample solution preparation

称取糖浆或糖粉样品0.5g（以干物质计），称准至0.0001g，加水溶解，移入50 mL容量瓶中并用水定容至刻度，用0.2μm或0. 45μm水相微孔膜过滤，滤液备用。Take the liquid or powder sample 0.5 g (calculating based on the dry material), with accuracy to 0.000 1 g, add water to dissolute, transfer into 50-mL volumetric flask, and add water to the scale, use 0.2 u m or 0. 45 μ m water phase microporous membrane to filter, reserve the filtrate.

A A．4.2试样的测定4.2 Sample determination

钙型阳离子交换树脂柱；流动相为纯水。Calcium type cation exchange resin column: mobile phase is pure water.在测定的前一天接通示差折光检测器电源，预热稳定，装上色谱柱，调柱温至85℃，以0.1 mL/min的流速通入流动相平衡过夜。Switch on the differential refractive index detector the day before the determination day, stabilize preheating, equip with chromatographic column, adjust column temperature to 85 ℃, flow into the mobile phase with 0.1 mL/min speed for the night.正式进样分析前，将所用流动相输入参比池20 min以上。Before sample analysis, input mobile phase to reference pool more than 20 min.再恢复正常流路使流动相经过样品池，调节流速至0．6 mL/min。Then resume to normal flow, and make mobile phase go through sample pool, adjust the flow speed to 0.6

mL/min.走基线，待基线稳定后即可进样，进样量为5μL～l0μL。Go baseline, sampling after the baseline stabilizes, sampling quantity is 5 μ L ~ l0 μ L.

将葡萄糖、麦芽糖、麦芽三糖、麦芽四糖、麦芽五糖、麦芽六糖的标准溶液和制备好的试样分别进样。Sample the standard solutions of glucose, maltose, maltotriose, maltotetraose, maltopentaose, maltohexaose and the prepared sample respectively.根据标准品的保留时间定性样品中各种糖组分的色谱峰。According to the retention time of the standard substance, determine the chromatographic peak of each sugar component in samples.根据样品的峰面积，以归一化法计算各种糖组分的百分含量。According to the peak area of the sample, calculate the percentage of each sugar component using normalization method.

氨基键合柱：流动相为乙腈：水=67：33。Amino bond column: mobile phase is acetonitrile: water = 67:33.在测定的前一天接通示差折光检测器电源，预热稳定，安上色谱柱，调柱温至75 ℃，以0.1 mL/min的流速通入流动相平衡过夜。Switch on the differential refractive index detector the day before the determination day, stabilize preheating, equip with chromatographic column, adjust column temperature to 75 ℃, flow into the mobile phase with 0.1 mL/min speed for the nigh.
正式进样分析前，将所用流相输入参比池20 min以上。Before sample analysis, input mobile phase to reference pool more than 20 min.再恢复正常流路使流动相经过样品池，调节流速至1.0 mL/min。Then resume to normal flow, and make mobile phase go through sample pool, adjust the flow speed to 1.0 mL/min.走基线，待基线稳定后即可进样，进样量为5μL～l0μL。Go baseline, sampling after the baseline stabilizes, sampling quantity is 5 μ L ~ l0 μ L.

将葡萄糖、麦芽糖、麦芽三糖、麦芽四糖、麦芽五糖、麦芽六糖的标准溶液和制备好的试样分别进样。Sample the standard solution of glucose, maltose, maltotriose, maltotetraose, maltopentaose, maltohexaose and prepared sample respectively.根据标准品的保留时间定性样品中各种糖组分的色谱峰。According to the retention time of the standard substance, determine the chromatographic peak of each sugar component in samples.根据样品的峰面积，以归一化法计算各种糖组分的百分含量。According to the peak area of the sample, calculate the percentage of each sugar component using normalization method.

A.4.3A.4.3结果计算Result calculation

A.4.3.1A.4.3.1钙型阳离子交换树脂柱，样品中组分i占总糖的百分含量按式（A.1）计算：Calcium type cation exchange resin column, component i to total sugar percentage in samples using type (A. 1) to calculate:

$$DPi = Ai/\Sigma Ai \times 100 \quad \text{.....（A.1）}$$

式中：Type:

DPi——样品中组分i占总糖的百分含量，%；- component i to total sugar percentage in the sample, %,

Ai——样品中组分i的峰面积；-the peak area of component i in the sample;

ΣAi——样品中各组分峰面积之和。ΣAi – the sum of the peak areas of all components in the sample.

A.4.3.2A.4.3.2氨基键合柱，样品中葡萄糖占总糖的百分含量按式（A.2）计算：Amino bond column, glucose to total sugar percentage in the sample using type (A. 2) to calculate:

$$G_1=DP_1 \quad \text{……（A.2）}$$

样品中异麦芽糖占总糖的百分含量按式（A.3）计算：

Isomaltose to total sugar percentage in the sample using type (A. 3) to calculate:

$$IG_2=A_{IG_2}/(A_{G_2}+A_{IG_2})\ X\ DP_2 \quad \text{.....（A.3）}$$

样品中潘糖占总糖的百分含量按式（A.4）计算：

Panose to total sugar percentage in the sample using type (A. 4) to calculate:

$$P=A_P/(A_{G_3}+A_P+A_{IG_3})\ X\ DP_3 \quad \text{.....（A.4）}$$

样品中异麦芽三糖占总糖的百分含量按式（A.5）计算：

Isomaltotriose to total sugar percentage in the sample using type (A. 5) to calculate:

$$IG_3=A_{IG_3}/(A_{G_3}+A_P+A_{IG_3})\ X\ DP_3 \quad \text{.....（A.5）}$$

样品中四糖（含四糖）以上占总糖的百分含量按式（A.6）计算：

Tetrose and other sugar to total sugar percentage in the sample using type (A. 6) to calculate:

$$G_n=100\text{-}DP1\text{-}DP2\text{-}DP3 \quad \text{……（A.6）}$$

式中：Type:

G_1（DP_1）——样品中葡萄糖占总糖的百分含量，%；G_1（DP_1）—— glucose to total sugar percentage in the sample, %,

IG_2——样品中异麦芽糖占总糖的百分含量，%；IG_2--- isomaltose to total sugar percentage in the sample, %,

A_{IG_2}-- 样品中异麦芽糖的峰面积；A_{IG_2}-- peak area of isomaltose in the sample;

A_{G2}——样品中麦芽糖的峰面积；A_{G2}- peak area of maltose in the sample;

DP2--样品二糖占总糖的百分含量,%；DP2- disaccharide to total sugar percentage in the sample, %,

P——样品中潘糖占总糖的百分含量，%；P- panose to total sugar percentage in the sample, %,

A_P——样品中潘糖的峰面积；A_P--peak area of the panose in the sample;

A_{G3}——样品中麦芽三糖的峰面积；- peak area of the maltotriose in the sample;

A_{IG3}——样品中异麦芽三糖的峰面积； peak area of the isomaltotriose in the sample,;

DP_3——样品中三糖占总糖的百分含量，%； DP_3- trisaccharide to total sugar percentage in the sample, %,

IG_3——样品中异麦芽三糖占总糖的百分含量，%； IG_3-- isomaltotriose to total sugar percentage in the sample, %,

G_Π——样品中四糖（含四糖）以上占总糖的百分含量，%；G_π-- tetrose and other sugar to the total sugar percentage in the sample, %,

计算结果保留至整数。Keep the calculation results integer.

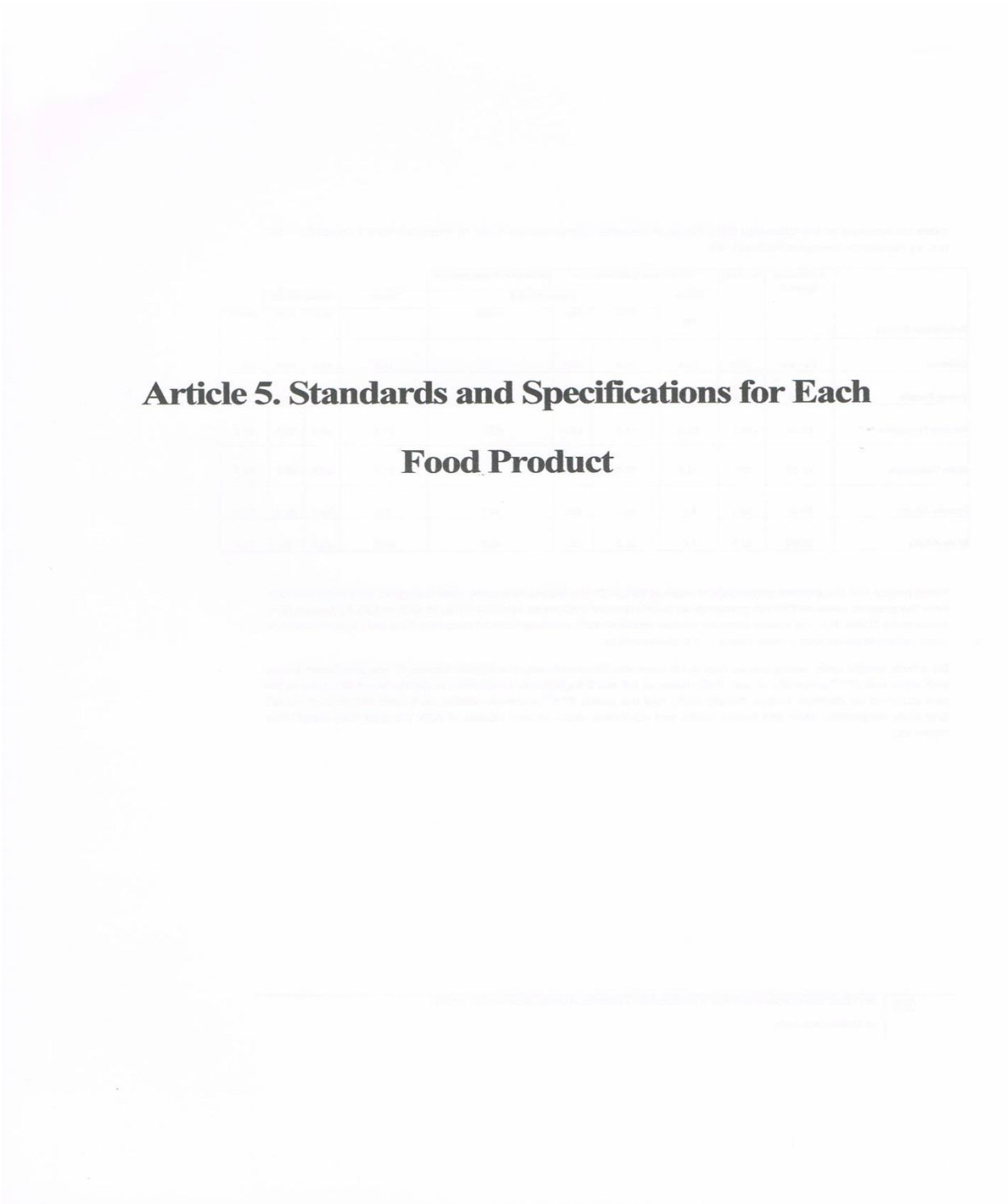
A.4.4精密度Accuracy

在重复性条件下获得的两次独立测定结果的绝对差值应不超过算术平均值的1%。

The absolute difference value of the two independent determination results obtained under repeatability shall not exceed 1% of the arithmetic mean value.

APPENDIX 11: KOREAN FOOD CODE, ARTICLE 5, SECTION 10. OLIGOSACCHARIDES

An English version of the Standard is provided.



Article 5. Standards and Specifications for Each Food Product

10. Oligosaccharides

1) Definition:

Oligosaccharides refer to products such as fructo-, isomato-, galacto-, malto-, xylo-, or gentio-oligosaccharides which are produced by the processing of sugar solutions.

2) Requirements of Raw Material

3) Manufacturing and Processing Standards

4) Food Type

(1) Fructo-Oligosaccharide

Fructo-Oligosaccharide refers to a liquid or powdery form of product that uses sugar solution that is enzymatically processed to have at least one fructose molecule binding at its structure by using sugary base materials, which is then processed by following processing steps of filtration, purification, and concentration.

(2) Isomalto-Oligosaccharide

Isomalto-Oligosaccharide refers to a liquid or powdery form of product that is processed by filtration, purification, and concentration steps by using sugar solution produced by enzymatic digestion on sugary base materials, which rearranges the molecular structures to be glucose based form.

(3) Galacto-Oligosaccharide

Galacto-Oligosaccharide refers to a liquid or powdery product that is produced by using trans-galacto-oligosaccharide sugar solution produced by enzymatic digestion of sugary base materials, or the product which is processed by filtration, purification and concentration of raffinose and stachyose sugar solution extracted from sugar beet or soybeans.

(4) Malto-Oligosaccharide

Malto-Oligosaccharide refers to a liquid and powdery form of product that is processed by using sugar solution produced by enzymatic digestion of 100% sugary base materials to produce 3~10 linearly bound glucose molecules in its structure.

(5) Xylo-Oligosaccharide

Xylo-Oligosaccharide refers to a liquid and powdery form of product that is processed by using sugar solution produced by enzymatic digestion of xylan used as a base material.

(6) Gentio-Oligosaccharide

APPENDIX 12: COFCO IMO PRODUCT PROFILE & CERTIFICATE OF ANALYSIS

To: Food Standards Australia New Zealand

In relation to: Application for approval of isomalto-oligosaccharide (IMO) as a Novel Food November 2015

Isomalto-Oligosaccharide
COFCO Bio-Chemical Energy (Gongzhuling) Co, LTD
中粮生化能源（公主岭）有限公司

Certificate of Analysis

Product's Chemical Name:	Isomalto-oligosaccharide (Powder)
Product No:	1001
Batch No:	BSC-11-003C
Source Material:	Corn Starch
Expiry Dated:	**30 July., 2014**
Country of Origin:	China

ITEMS	SPECIFICATIONS	RESULTS
Physical Appearance	a) White fine powder with no visible contaminating particles.	Pass
	b) Light-sweet in taste	Pass
Moisture	≤ 4%	4%
Carbohydrate Contents		
Isomalto-oligosaccharide	≥ 90%	90%
Glucose (% w/w)	≤ 5%	1.5%
Microbial Contents		
Total Aerobic Count (CFU/g)	$<1x10^4$	50
Yeast & Mold (CFU/g)	$<1x10^2$	< 20
E.coli (MPN/g)	negative	negative
Salmonella (CFU/g)	negative	negative
Staphylococcus aureus (CFU/g)	negative	negative
Metal Contents		
Sulphated Ash (g/100g)	≤ 0.3	0.013
As (mg.kg)	≤ 0.5	< 0.03
Pb (mg/kg)	≤ 0.5	< 0.01

Isomalto-Oligosaccharide
COFCO Bio-Chemical Energy (Gongzhuling) Co, LTD
中粮生化能源（公主岭）有限公司

Composition:

(All values are based upon % dried solids)

Total Carbohydrates	> 99.5%
IMO; DP3 through DP9	
Including Isomaltose	≥ 91%
Glucose	1.5 – 3.0%
Loss of drying	≤ 4%
pH	4.0 - 6.0
Ash (g/100g)	≤ 0.3
Heavy metals; As & Pb (each)	< 0.5 ppm
Moisture	≤ 4%

Physical Properties:

Appearance: Fine white to yellowish Powder

Taste:	~60% sweet as sucrose
pH Stability	pH 2-9
Heat Stability	~160°C (320°F)
Solubility	100%
Humectant	Yes
Solubility	100%

Microbiology:

Total Plate Count (cfu/gm)	$< 10^4$
Yeast & Mold (cfu/gm)	$\leq 10^2$
Escherichia coli	Negative
Salmonella	Negative
Staphylococcus aureas	Negative

Packing and Storage:

Packaging:	25kg poly lined bags
Storage:	Cool dry space, off floor in sealed bags
Shelf Life:	Typically stable up to 36 months from date of Manufacture
Temperature:	Ambient 68F (Min 50°F; Max 90°F)
Relative Humidity:	Ambient 55% (Min 10%; Max 90%)

Certifications:

GRAS	US-FDA-GRAS
N.O. Ltr.	Health Canada
Kosher	Certified, Star-K Kosher
Halal	Certified
None-GMO	GeneScane, USA
Sugar-Free	In-House (QC; HPLC-RI)
Gluten- Free	In-House (QC; Rida Quick)

APPENDIX 13: COFCO IMO – PROPOSED SPECIFICATION

For inclusion to the schedule to Standard 1.3.4

Proposed Specification for IMO

Chemical name	Isomalto-oligosaccharide
Description	IMO is a mixture of glucose oligomers with α-(1,6)-glucose linkages such as isomaltose, panose, isomaltotriose, isomaltopentose and higher branched oligosaccharides. The major components of IMO mixtures are disaccharide (Isomaltose, DP2) and trisaccharide (isomaltotriose, DP3).
IMO (%)	Not less than 98% on a dry weight basis
Moisture (%)	Max 4
Glucose (% dry basis)	Max 5
Degree of polymerisation	DP1 0 - 5 DP2 20 - 38 DP3 20 - 30 DP4 14 - 22 DP5 5 - 7 DP6 4 - 7 Other 3 - 4
Ash (sulphated ash (g/100g)	Max 0.3
Lead (mg/kg)/ppm	Max 0.5 on a dry weight basis
Asenic (mg/kg)/ppm	Max 0.5 on a dry weight basis

APPENDIX 14: IMO HPLC METHOD

HPLC Determination of IMO

1. Equipment

1.1 Waters high-performance liquid chromatograph equipped with a Waters 2410 differential refractive index detector.

1.2 Degasser and 0.2 μ m and 0.45 μ m micro filtration film

1.3 Column: TSKgel Amide-80

1.4 Analysis balance

1.5 Injector: 10 μ L

2. Reagents

2.1 Acetonitrile

2.2 Twice-distilled water

2.3 Reference standard: Glucose, Maltose, Isomaltose, Panose, Maltotriose, Isomaltotriose

3. Procedure:

3.1 Transfer 0.5g of IMO product powder (with accuracy to 0.0001 g) into 50-mL volumetric flask. Dilute to volume with twice-distilled water, and mix. Pass through a 0.2- μ m filter before injecting into the chromatograph.

3.2 Prepare different series of reference standard solutions.

3.3 Chromatographic System: Mobile phase is Acetonitrile and twice-distilled water = 67:33 (base on volume), Inject volume is 10 μ L, the column temperature is 75℃, the flow rate is 1.0mL/min.

3.4 Testing: According to the retention times of reference standards, define the specific peak of different components. According to peak area value, calculate the assay of different component.

Analysis: Calculate the percentage of IMO component content in sample using the following formula:

$$X_i = A_i M_s V / A_s M V_s \times 100$$

X_i = IMO sample component *i* content (Percentage)
A_i= Peak area value of IMO sample component *i*.
M_s=Weight of reference standard *i*, g
V = IMO Sample diluted volume, ml
A_s= Peak area value of reference standard *i*
M= Weight of IMO sample, g
V_s= Reference standard *i* diluted volume, ml

Note: Total fiber content % = 100-Glucose content %- Maltose content %-Maltotriose content%