

# **APPLICATION TO AMEND THE NOVEL FOOD CATEGORIES OF USE FOR ISOMALTO-OLIGOSACCHARIDES (EC 103) IN THE EUROPEAN UNION**

**Pursuant to**

***Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods***

## **NON-CONFIDENTIAL SUMMARY**

**SUBMITTED BY:**

BioNeutra North America Inc.  
9608-20 Ave NW  
Edmonton, Alberta, Canada  
T6N 1J4

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# Application to Amend the Novel Food Categories of Use for Isomalto-Oligosaccharides (EC103) in the European Union

## PART 1: ADMINISTRATIVE DATA

### 1.a Applicant/Manufacturer

Applicant: BioNeutra North America Inc.  
9608-20 Avenue NW  
Edmonton, Alberta, Canada  
T6N 1J4

### 1.c Date of Submission

11 April 2018

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## PART 2: CHARACTERISATION OF THE NOVEL FOOD, TECHNICAL AND SCIENTIFIC DATA

### Introduction

BioNeutra gained approval to market isomalto-oligosaccharides (IMO; EC 103) as both a syrup and powder called Vitasugar™ in the European Union (EU) in 2013. The initial application was filed with the United Kingdom (UK) Food Standards Agency (FSA), and the safety of the material was subsequently endorsed by all of the Member States. These products with a sweet, light taste have been incorporated into various food products and consumed throughout the community for the past 5 years, without any reported adverse effects. BioNeutra wishes now to extend the current use of IMO to include ice cream and desserts at an incorporation level of 10% while at the same time removing a number of categories including soft drinks (regular and energy reduced), fruit and vegetable juices breakfast cereal bars and milk-based meal replacements.

### 2.a Identity of the Novel Food

Common Name or Usual Name:	Isomalto-oligosaccharides
Trade Names:	Vitasugar™ (IMO-syrup); Vitasugar™ (IMO-powder)
Chemical and Physical Description:	Details are provided in the original BioNeutra submission to the UK FSA appended to this application.

### 2.b Production Process

BioNeutra does not seek to amend the production process from that which has originally been considered and approved. There are no changes to the production process and conditions of manufacture from the authorised novel food.

### 2.c Compositional Data

#### 2.c.1 Complex Mixtures and Whole Foods

The chemical, physical, and microbiological characteristics of the novel food remain identical to those filed within the original application for IMO in 2008.

### 2.d Specifications

The chemical and physical specifications for Vitasugar™ (IMO-syrup and IMO-powder) are the same as those filed within the original UK application and are presented in in Table 2.d-1. On a dry basis, the powder and syrup formulations are prepared such that the content of isomaltose and larger oligosaccharides (DP3 to DP9) is not less than 90%.

**Table 2.d-1 Physical and Chemical Specifications for Vitasugar™ (IMO-syrup and IMO-powder)**

Specification Parameter	Specification		Analytical Methods
	Syrup	Powder	
Solubility (water) (%)	N/A	≥99	-
Dried solids (g/100 g)	≥75	N/A	-
Glucose (% dry basis)	≤5 <sup>a</sup>	≤5 <sup>a</sup>	HPLC analysis

**Table 2.d-1 Physical and Chemical Specifications for Vitasugar™ (IMO-syrup and IMO-powder)**

Specification Parameter	Specification		Analytical Methods
	Syrup	Powder	
Isomaltose + DP3 to DP9 (% dry basis)	≥90 <sup>a</sup>	≥90 <sup>a</sup>	HPLC analysis
Moisture (%)	N/A	≤4	AOAC Method 925.45 (AOAC, 2000) <sup>b</sup>
pH	4 to 6	N/A	-
Sulphated ash (g/100 g)	≤0.3	≤0.3	<281> Residue on Ignition (USP, 2005) <sup>c</sup>
<i>Heavy Metals</i>			
Lead (mg/kg)	≤0.5	≤0.5	<251> Lead (USP, 2005) <sup>c</sup>
Arsenic (mg/kg)	≤0.5	≤0.5	<211> Arsenic (USP, 2005) <sup>c</sup>

AOAC = American Organization of Analytical Chemists; DP = degree of polymerisation; HPLC = high-performance liquid chromatography; IMO = isomalto-oligosaccharide; N/A = not applicable; USP = United States Pharmacopeia.

<sup>a</sup> Based upon dried solids.

<sup>b</sup> AOAC (Association of Official Analytical Chemists), 2000. Chapter 44. Sugars and sugar products. 44.1.03. AOAC Official method 925.45. Moisture in sugar. A. Vacuum Drying. In: Official methods of analysis of the Association of Official Analytical Chemists (17th Ed). Vols. 1&2. (2002, Revision 1). pp.1-2.

<sup>c</sup> USP (U.S. Pharmacopeia Convention Inc.), 2005. Test Methods <211> Arsenic, <241> Lead, <281> Residue on Ignition. In: United States Pharmacopeia, 28th edition & National Formulary, 23rd edition, pp 2297-2298, 2300-2301, and 2303.

## 2.e History of Use of the Novel Food Ingredient

Isomalto-oligosaccharides were approved for sale in the EU in 2013 following initial review by the UK's Advisory Committee on Novel Foods and Processes (ACNFP) and subsequent confirmation from the additional Member States<sup>1</sup>. IMOs have been marketed throughout the EU over the last 5 years and have been widely consumed in a number of products throughout this time. No adverse health effects have been reported. In addition to the current status within the EU, IMOs are approved and consumed within many other countries of the world including Australia/New Zealand, Canada, China, Japan, Korea, and the United States to name but a few (see approved categories below). Approvals and sales within many of these jurisdictions predate those of the EU with no adverse effects reported. The use of IMO within ice cream and desserts is currently accepted and widely consumed throughout the world.

## 2.f Proposed Uses and Use-Levels and Anticipated Intake

### 2.f.1 Target Population

Foods containing IMO are intended for use by the general population.

### 2.f.2 Proposed Uses and Use-Levels

BioNeutra wishes to extend the use of IMO to include the food categories of ice creams and desserts at a maximum use-level of 10% (**bolded** in Table 2.f.2-1). In order to ensure there is no potential increase in the total exposure of IMO, BioNeutra proposes to remove the following categories from the permitted conditions of use: soft drinks (regular and energy-reduced), fruit juices, vegetable juices breakfast cereal bars, and milk-based meal replacements (marked with ~~strike through~~ in Table 2.f.2-1).

<sup>1</sup> [http://acnfp.food.gov.uk/sites/default/files/mnt/drupal\\_data/sources/files/multimedia/pdfs/isomalto.pdf](http://acnfp.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/isomalto.pdf).

**Table 2.f.2-1 Summary of the Individual Proposed Food-Uses and Use-Levels for BioNeutra’s IMO in the EU**

<b>Food Category</b>	<b>Proposed Food-Uses<sup>a</sup></b>	<b>Serving Size<sup>b</sup> (g)</b>	<b>Maximum Use-Level (%)</b>	<b>IMO per Serving<sup>b</sup> (g/serving)</b>
Beverages	<del>Regular Soft Drinks</del>	240	5	<del>12</del>
	<del>Energy-Reduced Soft Drinks</del>	240	6.5	<del>15.6</del>
	Energy Drinks	240	5	12
	Sports & Isotonic Drinks	240	6.5	15.6
	Fruit Juices	240	5	12
	Vegetable Juices	240	5	12
Cereal products	Cereal Bars	50	10	5
	Cookies, Biscuits	40	20	8
	<del>Breakfast Cereal bars</del>	50	25	<del>12.5</del>
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
	<del>Milk-Based Meal Replacements</del>	40	20	<del>8</del>
<b>Ices and desserts</b>	<b>Ice Cream and Desserts</b>	<b>75</b>	<b>10</b>	<b>7.5</b>

EU = European Union; IMO = isomalto-oligosaccharide.

<sup>a</sup> New food-uses are **bolded**; food-uses that have been removed are marked with ~~strikethrough~~.

<sup>b</sup> Serving sizes are from Food Standards Agency Food Portion Sizes book (FSA, 2002). Servings sizes are included in this table for reference; however, for the exposure assessment, the estimated intakes of BioNeutra’s IMO were derived based on the use levels expressed on a % w/w basis, and not the g/serving basis.

### 2.f.3 Anticipated Intake of the Novel Food

The outlined changes to the food categories and use-levels were evaluated to determine the impact on human exposure using both the Food Additives Intake Model (FAIM) 2.0 and the UK National Diet and Nutrition Survey (NDNS) (NDNS 2008-2014). The FAIM tool has been established to provide a first-step screening stage for estimating chronic exposure to food additives and ingredients. Given fundamental methodological differences between surveys represented in the FAIM 2.0 template and sources of overestimation associated with this tool (notably, the use of broad food categories), a more refined assessment using raw consumption data from the UK NDNS survey dataset was conducted. A notable reduction in intakes was demonstrated upon comparing intake estimates from the current assessment (based on the proposed conditions of use) to those from the approved conditions of use, of 12 to 65%. Specifically, mean and high-level intakes from BioNeutra’s proposed extension of use were considerably lower for children/toddlers (63 to 65% lower at the mean and 39 to 44% lower at the 95<sup>th</sup> percentile, respectively), who were identified to have the highest intakes on a body weight basis, and adolescents (55 to 59% lower at the mean and 37 to 46% lower at 95<sup>th</sup> percentile, respectively), who were identified to have the highest intakes on an absolute basis, when compared to estimates from the approved conditions of use. The reduction in exposure is due to the removal of food and beverage categories from the permitted conditions of use (*i.e.*, soft drinks [regular and energy-reduced], fruit juices, vegetable juices, breakfast cereal bars and milk-based meal replacements).

### 2.f.4 Combined Intake from the Novel Food and Other Sources

Isomalto-oligosaccharides are found at low levels within honey, and soy sauce and traditional Japanese foods such as miso and sake. The consumption levels in honey and soy sauce were not considered to impact the overall exposure to IMO.

### **2.f.5 Estimate of Exposure to Undesirable Substances**

On the basis that the manufacturing process and specifications have not changed from the original evaluation and approval, the fact that the overall intakes have been reduced significantly will reduce the exposure to any undesirable substances as well.

### **2.f.6 Precautions and Restrictions of Use**

There are no precautions nor restrictions to use.

## **2.g Absorption, Distribution, Metabolism and Excretion (ADME)**

No new studies have been conducted and published that contradict the information outlined in the original novel foods application and approval for IMO.

## **2.h Nutritional Information**

There are no changes to the nutritional value from the information outlined in the original novel foods application and approval for IMO.

## **2.i Toxicological information**

No new studies have been conducted and published that contradict the information outlined in the original novel foods application and approval for IMO.

## **2.j Allergenicity**

As outlined within the most recent UK FSA Opinion<sup>2</sup>, isomalto-oligosaccharide must be labelled in accordance with requirements on food allergens if it is derived from one of the allergenic crops identified in EU labelling legislation (Annex II of Regulation (EU) No 1169/2011) (FSA, 2016).

## **2.k Overall Risk Assessment**

There is a substantial body of scientific evidence indicating that under the proposed conditions of intended use in foods, Vitasugar™, a mixture of isomalto-oligosaccharides, would not produce any adverse health effects. Vitasugar™ is produced by BioNeutra in accordance with current Good Manufacturing Practice (GMP) and meets appropriate food grade specifications. Following oral consumption, the malto-oligosaccharide fraction of the mixture, as well as the disaccharides are hydrolysed in the gastrointestinal tract to glucose, which is subsequently absorbed and utilised by the body through well characterised metabolic pathways. The remaining undigested isomalto-oligosaccharides pass through the gastrointestinal tract and are subjected to bacterial fermentation in the colon. The safety of IMO mixtures is further confirmed by a series of published animal toxicity studies, as well as human tolerance studies reporting no adverse toxicological effects relevant to the conditions of intended use in foods. Consequently, there is no risk of systemic toxicity related to the ingestion of isomalto-oligosaccharides.

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<sup>2</sup> [https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food\\_authorisation\\_2016\\_auth-letter\\_isomalto-oligosaccharide\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2016_auth-letter_isomalto-oligosaccharide_en.pdf)

## 2.1 Dietary Exposure Conclusions

BioNeutra wishes to extend the use of IMO to include ice cream and desserts while removing a number of food and beverage categories from the permitted conditions of use, including soft drinks (regular and energy-reduced), fruit juices, vegetable juices, breakfast cereal bars and milk-based meal replacements. An updated exposure analysis was conducted using both the FAIM 2.0 tool and the UK NDNS dataset. A comparison of the intakes considered by the ACNFP in the Opinion published in 2012 with those considered as part of the current assessment resulted in considerable reductions in intake, of between 12 to 65%. This is expected based on the removal of food and beverage categories from the permitted conditions of use (*i.e.*, soft drinks [regular and energy-reduced], fruit juices, vegetable juices, breakfast cereal bars and milk-based meal replacements). While the NDNS is a more accurate source of consumption data, the assessment methodology used herein is still considered worst-case based on several assumptions used (including the incorporation of the maximum proposed use level for each food category and 100% occurrence), therefore the true estimated intakes will be lower than those presented herein.

## 2.m Conclusions

The reduction in the estimated daily exposure to IMO from the consumption of BioNeutra's Vitasugar™ by 12 to 65% following the addition of the food category 'ice cream and desserts' and the removal of a number of food and beverage categories from the permitted conditions of use provides added reassurance of the safety originally outlined in the UK opinion of 2013. As such, the additional exposure of IMO to the food category 'ice cream and desserts' will be significantly offset by removing soft drinks (regular and energy reduced), fruit juices, vegetable juices, breakfast cereal bars and milk-based meal replacements. Since no data has been generated that calls in to question the safety of IMO since the original application, BioNeutra considers that the amendment to the currently available food categories provides an additional level of safety.