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**AMENDED AUTHORISATION OF ISOMALTO-OLIGOSACCHARIDE AS A
NOVEL FOOD INGREDIENT**

Dear Dr Qureshi

I am writing to inform you of the outcome of your application to amend the authorisation of Isomalto-oligosaccharide as a novel food under regulation (EC) No 258/97.

In February 2009, an application from Bioneutra 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.

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.

The Commission forwarded the initial assessment report to all Member States on 31 January 2013 and no reasoned safety objections were presented by the Commission or the Member States within the 60 day period laid down in Article 6(4) of Regulation (EC) No 258/97. Comments were made by Hungary, Germany, the Netherlands, Greece and Ireland. On this basis Bioneutra's Isomalto-oligosaccharide powder and syrup (meeting the specification in Annex 1) was considered to have complied with the criteria laid down in Article 3(1) of Regulation No 258/97. Therefore it is permitted to be added to

the foods listed in Annex 2 up to the specified maximum levels, with specific labelling required on its suitability for diabetic consumers.

In June 2014, Bioneutra requested an amendment to the current labelling requirement, so that foods containing its Isomalto-oligosaccharide can be labelled as “a source of glucose”. The ACNFP evaluated the safety considerations relating to this proposed labelling amendment and was satisfied that the new proposed labelling did not pose any safety concerns for diabetics and is consistent with the way that other glycaemic carbohydrates are labelled in the EU.

On the 23 October 2015 Member States and the Commission were consulted on the proposed change and no reasoned safety objections were presented within the 60 day period laid down in Article 6(4) of Regulation (EC) No 258/97. Comments were received from Ireland, Finland, Germany, Hungary and Spain. On this basis the authorisation for Isomalto-oligosaccharide has been amended to replace the requirement to label products containing Isomalto-oligosaccharide as unsuitable for diabetics with a requirement to label the products as “a source of glucose”.

I would remind you that 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). Also, claims relating to the 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 (EC) No 1924/2006.

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.

Yours sincerely

(by email only)

Ruth Willis
Radiological and Novel Food Policy

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