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*sent by email*

30 July 2013

## **ISOMALTO-OLIGOSACCHARIDE AS A NOVEL FOOD INGREDIENT**

Dear Dr Qureshi

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 Bionutra 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.

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)*

Dr Manisha Upadhyay  
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