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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
Isomalto-oligosaccharide	<i>Specified food category</i>	<i>Maximum levels</i>	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Isomalto-oligosaccharide’.</p> <p>1. The labelling of food supplements containing isomalto-oligosaccharide shall bear a statement that they should not be consumed:</p> <ul style="list-style-type: none"> a) if foods containing added isomalto-oligosaccharide are consumed on the same day; b) by children under 10 years of age <p>2. Foods containing the novel food must be labelled as ‘a</p>		<p>Authorised on [...] [<i>OP, please insert the date dd.mm.yyyy - 20th day following its publication</i>].</p> <p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: BioNeutra North America Inc. 9608 25 Avenue NW, Edmonton, Alberta T6N 1J4, Canada.</p> <p>During the period of data protection, the novel food isomalto-oligosaccharide is authorised for placing on the market within the Union</p>
	Energy-reduced soft drinks	6,5%			
	Energy drinks	5,0%			
	Foods intended to meet the expenditure of intense muscular efforts, especially for sportsmen (including isotonic drinks)	6,5%			
	Fruit juices	5,0%			
	Processed Vegetables and Vegetable Juices	5,0%			
	Other Soft Drinks	5,0%			
	Cereals Bars	10,0%			
	Cookies, Biscuits	20,0%			

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	Breakfast cereal bars	25,0%	source of glucose'		only by BioNeutra North America Inc. unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of BioNeutra North America Inc.. End date of the data protection: [...] [<i>OP please insert the date dd.mm.yyyy – after 5 years</i>].
	Hard candies	97,0%			
	Soft Candies/Chocolate Bars	25,0%			
	Meal replacement for weight control (as bars or milk-based)	20,0%			
	Ice cream and dairy desserts	8,0%			
	Instant coffee and tea	10,0%			
	Table top sweeteners	100,0%			
	Cakes, muffins, pies	20,0%			
	Cakes and pastries	15,0%			
	Breakfast cereals	10,0%			
	Savoury sauces, pickles, gravies and condiments	10,0%			
	Gelatines, puddings, fillings	15,0%			
	Yoghurts	2,5%			
	Milk-based drinks and similar products	5,0%			
	Snacks	5,0%			
	Sweet Sauces, Toppings and Syrups	50,0%			
	Food supplements as	30 g/day			

	defined in Directive 2002/46/EC, excluding infants, and children, younger than 10 years of age				
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(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised novel food	Specification
<p>Isomalto-oligosaccharide</p>	<p>Description: Isomalto- oligosaccharide is either a light-yellow transparent syrup or a white powder produced via enzyme-catalysed hydrolysis of food grade starch from different plant-based crops.</p> <p>Characteristics/Composition: Dried solids (syrup, g/100g): $\geq 75,0$ Glucose (% dry matter): $\leq 5,0$ Isomaltose + DP3 to DP9 (% dry matter): ≥ 90 pH (syrup): 4,0 – 6,0 Moisture (powder, %): $\leq 4,0$ Solubility (powder, % in water): $\geq 99,0$ Sulfated ash (g/100): $\leq 0,3$</p> <p>Heavy metals: Arsenic (mg/kg): $\leq 0,5$ Lead (mg/kg): $\leq 0,5$</p> <p>Microbiological criteria: Total Aerobic Microbial Count: $\leq 1\ 000$ CFU/g Yeasts and moulds <i>Escherichia coli</i>: Absence in 10 g <i>Salmonella</i> spp.: Absence in 25 g</p>