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EN

# ANNEX

(1) In Table 1 (Authorised novel foods) the following entry is inserted: *[OP, please insert in the EN version in alphabetical order.]*

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
<b>Rhamnogalacturonan-I enriched carrot fibre (cRG-I)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Rhamnogalacturonan-I enriched carrot fibre (cRG-I)’.</li> <li>The labelling of food supplements containing Rhamnogalacturonan-I enriched carrot fibre (cRG-I) shall bear a statement that the food supplements should not be consumed by: <ol style="list-style-type: none"> <li>infants</li> </ol> </li> </ol>		<p>Authorised on [...]<i>[OP please insert the date dd.mm.yyyy - 20th day following its publication]</i>. 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: NutriLeads B.V., Bronland 12-N 6708 WH Wageningen, The Netherlands.</p> <p>During the period of data protection, the novel food Rhamnogalacturonan-I enriched carrot fibre (cRG-I) is authorised for placing on the market within the Union only by NutriLeads</p>
	Food supplements as defined in Directive 2002/46/EC, excluding infants	750 mg/day for young children			
		1500 mg/day for general population above 3 years of age			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	750 mg/day for young children			
		1500 mg/day for the general population above 3 years of age			
	Total diet replacement for	1500 mg/day for			

	weight control as defined in Regulation (EU) No 609/2013	adults	b) infants and children under 3 years of age depending on the age group the food supplements is intended for.	B.V., 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 NutriLeads B.V.  End date of the data protection: [...][ <i>OP please insert the date dd.mm.yyyy – after 5 years</i> ]
	Meal replacement for weight control	250 mg/meal for young children		
		500 mg/meal for the general population above 3 years of age		
	Ready-to-eat meal for infants and young children	450 mg/100 g		
	Muesli and similar mixed breakfast cereals	5000 mg/100 g		
	Cereal bars	3750 mg/100 g		
	Fruit nectars (min. 25%–50% fruit as defined in EU legislation)	500 mg/100 g		
	Mixed fruit and vegetable juices	500 mg/100 g		
	Mixed juices with added ingredients	500 mg/100 g		
	Biscuits, rusks and cookies for children	3750 mg/100 g		
	Fruit and vegetable juices and nectars specific for infants and young children	625 mg/100 g		
	Special food for children's growth	375 mg/100 g		
	Soups (ready-to-eat)	750 mg/100 g		
	Vegetable juices	500 mg/100 g		

	Soups (dry mixture uncooked)	5000 mg/100 g			
	Flavoured milks	750 mg/100 g			
	Yogurt drinks, including sweetened and/or flavoured variants	750 mg/100 g			
	Milk imitates	750 mg/100 g			
	Imitation cream	10000 mg/100 g			
	Soy yogurt	1200 mg/100 g			
	Imitation cheese	3750 mg/100 g			
	Imitation yogurt, non soy	1200 mg/100 g			

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(2) in Table 2 (Specifications), the following entry is inserted: [*OP, please insert in the EN version in alphabetical order.*]

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Authorised Novel Food	Specifications
<b>Rhamnogalacturonan-I enriched carrot fibre (cRG-I)</b>	<p><b>Description/Definition:</b>  cRG-I is an enzymatic extract of carrot pomace enriched for rhamnogalacturonan-I domains (RG-I).  Source: <i>Daucus carota</i> L., subspecies <i>Sativus</i>.</p> <p><b>Physical and chemical properties:</b>  Colour: Off-white to beige  Odour/taste: Neutral  Solubility: Soluble in water  Water activity: &lt; 0.6</p> <p><b>Composition:</b>  Moisture: ≤ 7%  Free sugars: ≤ 3%  Soluble dietary fibre: ≥ 60%  Total dietary fibre: ≥ 70%  Crude protein: ≤ 4%  Ash: ≤ 5%  Fat: ≤ 2%</p> <p><b>Contaminants</b>  Lead: ≤ 1.0 mg/kg  Cadmium: ≤ 1.0 mg/kg  Arsenic: ≤ 0.1 mg/kg  Mercury: ≤ 0.1 mg/kg</p>

	<p>Perchlorate: <math>\leq 0.05</math> mg/kg</p> <p><b>Microbiological criteria:</b></p> <p>TAMC: <math>\leq 1 \times 10^3</math> CFU/g</p> <p>TYMC: <math>\leq 1 \times 10^2</math> CFU/g</p> <p><i>Bacillus cereus</i>: <math>&lt; 1 \times 10^2</math> CFU/g</p> <p>Enterobacteriaceae: <math>&lt; 1 \times 10^2</math> CFU/g</p> <p><i>Escherichia coli</i>: <math>&lt; 10</math> CFU/g</p> <p><i>Salmonella</i> spp.; not detected in 25 g</p> <p><i>Listeria monocytogenes</i>: not detected in 25 g</p> <p>Sulphite reducing anaerobes: <math>&lt; 30</math> CFU/g</p> <p>Abbreviations: CFU, colony forming units; TAMC, total aerobic microbial count; TYMC, total yeast and mould count.</p>
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