Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

of 20 December 2017

establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001[(1)], and in particular Article 8 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission has to establish the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council[(2)].

(3) The Union list of novel foods is to apply without prejudice to other provisions laid down in sector specific legislation.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

[F1 Article 1

List of authorised novel foods

The list of novel foods authorised to be placed on the market within Great Britain as referred to in Article 6(1) of Regulation (EU) 2015/2283 is hereby established and set out in the Annex to this Regulation.**]**

Textual Amendments

F1 Art. 1 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **62** (as amended by S.I. 2020/1504, regs. 1(2), **15(16)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

F2 …

Textual Amendments

F2 Words in Signature omitted (31.12.2020) by virtue of The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **63**; 2020 c. 1, Sch. 5 para. 1(1)

[F3ANNEX

F4... LIST OF NOVEL FOODS

Textual Amendments

F3 Substituted by Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance).

F4 Word in Annex heading omitted (31.12.2020) by virtue of The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **64(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

Content of the list

1. The F5... list shall consist of Tables 1 and 2.

Textual Amendments

F5 Word in Annex para. 1 omitted (31.12.2020) by virtue of The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **64(b)**; 2020 c. 1, Sch. 5 para. 1(1)

2. Table 1 includes the authorised novel foods and contains the following information:

Column 1 : Authorised novel food
Column 2 : Conditions under which the novel food may be used. This column is further subdivided into two: Specified food category and Maximum levels
Column 3 : Additional specific labelling requirements
Column 4 : Other requirements

3. Table 2 includes the specifications on novel foods and contains the following information:

Column 1 : Authorised novel food
Column 2 : Specifications

TABLE 1: AUTHORISED NOVEL FOODS

Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**	**[F10Data Protection]**
***N* -Acetyl-D-neuraminic acid**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be '*N* -acetyl-D-neuraminic acid'		
	Infant and follow-on formulae as defined by Regulation (EU) No 609/2013 [a]	0,05 g/L of reconstituted formula			

Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013	0,05 g/kg for solid foods	Food supplements containing *N* -acetyl-D-neuraminic acid shall bear a statement that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added *N* -acetyl-D-neuraminic acid within the same twenty four hour period.		
Foods for special medical purposes for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than the maximum levels specified for the category mentioned in the table corresponding to the products.			
Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	0,2 g/L (drinks) 1,7 g/kg (bars)			
Foods bearing statements on the absence or reduced presence of gluten in accordance with the	1,25 g/kg			

requirements of Commission Implementing Regulation (EU) No 828/2014 [b]				
Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,05 g/L			
Unflavoured fermented milk-based products, heat treated after fermentation, flavoured fermented milk products including heat-treated products	0,05 g/L (beverages) 0,4 g/kg (solids)			
Dairy analogues, including beverage whiteners	0,05 g/L (beverages) 0,25 g/kg (solids)			
Cereal bars	0,5 g/kg			
Table top sweeteners	8,3 g/kg			
Fruit and vegetable-based drinks	0,05 g/L			
Flavoured drinks	0,05 g/L			
Speciality coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory	0,2 g/kg			

	extracts; tea, plant, fruit and cereal preparations for infusions				
	Food Supplements as defined in Directive 2002/46/EC ‘	300 mg/day for general population older than 10 years 55 mg/day for infants 130 mg/day for young children 250 mg/day for children between 3 to 10 years of age			
Adansonia digitata **(Baobab) dried fruit pulp**	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Baobab fruit pulp ’		
Ajuga reptans **extract from cell cultures**	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract of the flowering aerial parts of *Ajuga reptans*			
L-Alanyl-L-Glutamine	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC				

	Foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children				
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen				
Algal oil from the microalgae *Ulkenia* sp.	***Specified food category***	***Maximum levels of DHA***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the micro-algae *Ulkenia sp.* '		
	Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g			
	Cereal bars	500 mg/100 g			
	Non-alcoholic beverages (including milk based beverages)	60 mg/100 ml			
[F11Allanblackia **seed oil**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' *Allanblackia* seed oil'		
	Yellow fat spreads and cream based spreads	30 g/100 g			
	Mixtures of vegetable oils (*) and milk (falling under	30 g/100 g			

	the food category: Dairy analogues, including beverage whiteners)				
	(*) Except olive oils and olive pomace oils as defined in Part VIII of Annex VII of Regulation (EU) No 1308/2013.]				
***Aloe macroclada* Baker leaf extract**	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of the similar gel derived *from Aloe vera* (L.) Burm.			
Antarctic Krill oil from *Euphausia superba*	***Specified food category***	***Maximum levels of combined DHA and EPA***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)'		
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g			
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			
	Non-alcoholic beverages Milk-based drinks Dairy analogue drinks	80 mg/100 ml			

Spreadable fat and dressings	600 mg/100 g
Cooking fats	360 mg/100 ml
Breakfast cereals	500 mg/100 g
Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g
Nutrition bars/cereal bars	500 mg/100 g
Food Supplements as defined in Directive 2002/46/EC	3 000 mg/ day for the general population 450 mg/day for pregnant and lactating women
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Processed cereal-based food and baby food	200 mg/100 ml

	intended for infants and young children covered by Regulation (EU) No 609/2013				
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
Antarctic Krill oil rich in phospholipids from *Euphausia superba*	***Specified food category***	***Maximum levels of combined DHA and EPA***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)'		
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g			
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			
	Non-alcoholic beverages	80 mg/100 ml			

Milk-based drinks Dairy analogue drinks				
Spreadable fat and dressings	600 mg/100 g			
Cooking fats	360 mg/100 ml			
Breakfast cereals	500 mg/100 g			
Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g			
Nutrition bars/cereal bars	500 mg/100 g			
Food Supplements as defined in Directive 2002/46/EC	3 000 mg/ day for the general population 450 mg/day for pregnant and lactating women			
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements	250 mg/meal			

	for weight control				
	Processed cereal-based food and baby food intended for infants and young children covered by Regulation (EU) No 609/2013	200 mg/100 ml			
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
Arachidonic acid-rich oil from the fungus *Mortierella alpina*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from *Mortierella alpina* ' or ' *Mortierella alpina* oil'		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

	Foods for special medical purposes for premature infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
Argan oil from *Argania spinosa*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Argan oil ’ and if used as seasoning ‘ Vegetable oil only for seasoning ’ shall be mentioned on the label		
	As seasonings	Not specified			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of vegetable oils			
Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Astaxanthin ’		
	Food Supplements as defined in Directive 2002/46/EC	40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day			
Basil seeds (*Ocimum basilicum*)	***Specified food category***	***Maximum levels***			
	Fruit juice and fruit/ vegetable blend beverages	3 g/200 ml for addition of whole basil seeds (*Ocimum basilicum*)			
[F6Betaine	***Specified food category***	***Maximum levels*** [g]	The designation of the novel food on the labelling of		Authorised on 22 August 2019. This inclusion is based on
	Drink powders,	60 mg/100 g			

isotonic and energy drinks intended for sportsmen		the foodstuffs containing it shall be 'betaine'. The labelling of foods containing betaine shall bear a statement that the foods should not be used if food supplements containing betaine are consumed the same day.		proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: DuPont Nutrition Biosciences ApS, Langebrogade 1 Copenhagen K, DK-1411, Denmark. During the period of data protection, the novel food betaine is authorised for placing on the market within the Union only by DuPont Nutrition Biosciences ApS unless a subsequent applicant obtainsauthorisation 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
Protein and cereal bars intended for sportsmen	500 mg/100 g			
Meal replacements intended for sportsmen	20 mg/100 g			
Total diet replacement for weight control as defined under Regulation (EU) No 609/2013	500 mg/100 g (bar) 136 mg/100 g (soup) 188 mg/100 g (porridge) 60 mg/100 g (beverages)			
Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 for adults	400 mg/day]			

					or with the agreement of DuPont Nutrition Biosciences ApS, End date of the data protection: 22 August 2024.
Fermented black bean extract	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Fermented black bean (Soya) extract ’ ’ or ‘ Fermented Soya extract ’		
	Food Supplements as defined in Directive 2002/46/EC	4,5 g/day			
Bovine lactoferrin	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Lactoferrin from cows ’ milk’		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 (ready to drink)	100 mg/100 ml			
	Foods on dairy basis intended for young children (ready to eat/ drink)	200 mg/100 g			
	Processed cereal food (solid)	670 mg/100 g			
	Foods for special medical	Depending on the needs of			

	purposes as defined in Regulation (EU) No 609/2013	the individual up to 3 g/day			
	Beverages based on milk	200 mg/100 g			
	Powdered drink mixes based on milk (ready to drink)	330 mg/100 g			
	Beverages based on fermented milk (including yoghurt drinks)	50 mg/100 g			
	Non-alcoholic drinks	120 mg/100 g			
	Products based on yoghurt	80 mg/100 g			
	Products based on cheese	2 000 mg/100 g			
	Ice cream	130 mg/100 g			
	Cakes and pastries	1 000 mg/100 g			
	Candies	750 mg/100 g			
	Chewing gum	3 000 mg/100 g			
[F12Bovine milk basic whey protein isolate	**Specified food category**	**Maximum levels**	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Milk whey protein isolate’. Food supplements containing		Authorised on 20 November 2018 . This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article
	Infant formulae as defined in Regulation (EU) No 609/2013 Follow-on formulae as defined in	30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted) 30 mg/100 g (powder)			

Regulation (EU) No 609/2013 Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013 Foods for special medical purposes as defined in Regulation (EU) No 609/2013 Food Supplements as defined in Directive 2002/46/EC	4,2 mg/100 mL (reconstituted) 300 mg/day 30 mg/100 g (powder formula for infants during the first months of life until the introduction of appropriate complementary feeding) 3,9 mg/100 mL (reconstituted formula for infants during the first months of life until the introduction of appropriate complementary feeding) 30 mg/100 g (powder formula for infants when appropriate complementary feeding is introduced) 4,2 mg/100 mL (reconstituted formula for infants when appropriate complementary feeding is introduced) 58 mg/day for young children 380 mg/ day for children and adolescents from 3 to 18 years of age	bovine milk basic whey protein isolate shall bear the following statement: ‘This food supplement should not be consumed by infants/ children/ adolescents under the age of one/three/ eighteen (*) years’ (*) Depending on the age group the food supplement is intended for.		26 of Regulation (EU) 2015/2283. Applicant: Armor Protéines S.A.S., 19 bis, rue de la Libération 35460 Saint-Brice-en-Coglès, France. During the period of data protection the novel food bovine milk basic whey protein isolate is authorised for placing on the market within the Union only by Armor Protéines S.A.S. 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

		610 mg/day for adults 25 mg/day for infants 58 mg/day for young children 250 mg/ day for children and adolescents from 3 to 18 years of age 610 mg/day for adults]			of Armor Protéines S.A.S. End date of the data protection: 20 November 2023 .
Buglossoides arvensis seed oil	***Specified food category***	***Maximum levels of stearidonic acid (STA)***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Refined *Buglossoides* oil'		
	Dairy products and analogues	250 mg/100 g			
		75 mg/100 g for drinks			
	Cheese and cheese products	750 mg/100 g			
	Butter and other fat and oil emulsions including spreads (not for cooking or frying purposes)	750 mg/100 g			
	Breakfast cereals	625 mg/100 g			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	500 mg/day			
	Foods for special medical	In accordance with the particular			

	purposes as defined in Regulation (EU) No 609/2013, excluding foods for special medical purposes intended for infants and young children	nutritional requirements of the persons for whom the products are intended			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal			
***Calanus finmarchicus* oil**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from *Calanus finmarchicus* (crustacean)'		
	Food supplements as defined in Directive 2002/46/EC	2,3 g/day			
Chewing gum base (monomethoxypolyethylene glycol)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Gum base (including 1,3-butadiene, 2-methyl-		
	Chewing gum	8 %			

			homopolymer, maleated, esters with polyethylene glycol mono-Me ether) ' or ' Gum base (including CAS No: 1246080-53-4) '		
Chewing gum base (Methyl vinyl ether-maleic anhydride copolymer)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Gum base (including methyl vinyl ether-maleic anhydride copolymer) ' or ' Gum base (including CAS No 9011-16-9) '		
	Chewing gum	2 %			
Chia oil from *Salvia hispanica*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia oil (*Salvia hispanica*)'		
	Fats and oils	10 %			
	Pure chia oil	2 g/day			
	Food Supplements as defined in Directive 2002/46/EC	2 g/day			
[F13Chia seeds (*Salvia hispanica*)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia seeds (*Salvia hispanica*)'		
	Bread products	5 % (whole or ground chia seeds)			
	Baked products	10 % whole chia seeds			
	Breakfast cereals	10 % whole chia seeds			

Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses	5 % whole chia seeds			
Fruit, nut and seed mixes				
Pre-packaged Chia seed as such				
Confectionery (including chocolate and chocolate products), excluding chewing gums				
Dairy products (including yoghurt) and analogues				
Edible ices				
Fruit and vegetables products (including fruit spreads, compotes with/without cereals, fruit-preparations to underlay or to be mixed with dairy products, fruit desserts, mixed fruits with coconut milk for a twin pot)				
Non-alcoholic beverages (including				

	fruit juice and fruit/ vegetable blend beverages)				
	Puddings that do not require heat treatment at or above 120 °C in their manufacture, processing or preparation **]**				
Chitin-glucan from *Aspergillus niger*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitin-glucan from *Aspergillus niger* '		
	Food Supplements as defined in Directive 2002/46/EC	5 g/day			
Chitin-glucan complex from *Fomes fomentarius*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitin-glucan from *Fomes fomentarius* '		
	Food Supplements as defined in Directive 2002/46/EC	5 g/day			
Chitosan extract from fungi (*Agaricus bisporus* ; *Aspergillus niger*)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitosan extract from *Agaricus bisporus* ' or 'Chitosan		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of chitosan from crustaceans			

			extract from *Aspergillus niger* ’		
Chondroitin sulphate	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Chondroitin sulphate derived from microbial fermentation and sulphation ’		
	Food supplements as defined in Directive 2002/46/ EC for adult population, excluding pregnant and lactating women	1 200 mg/day			
Chromium Picolinate	***Specified food category***	***Maximum levels of total chromium***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Chromium Picolinate ’		
	Foods covered by Regulation (EU) No 609/2013	250 µg/day			
	Foods fortified in accordance with Regulation (EC) No 1925/2006 [d]				
***Cistus incanus* L. Pandalis herb**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ *Cistus incanus* L. Pandalis herb’		
	Herbal infusions	Intended daily intake: 3 g herbs/day (2 cups/day)			
Citicoline	***Specified food category***	***Maximum levels***	1. The designation of the		

	Food Supplements as defined in Directive 2002/46/EC	500 mg/day	2. The labelling of foods containing citicoline shall bear a statement that the product is not intended to be consumed by children		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	250 mg per serving and a maximum daily consumption level of 1 000 mg			
Clostridium butyricum	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ *Clostridium butyricum* MIYAIRI 588 (CBM 588)’ or ‘ *Clostridium butyricum* (CBM 588)’		
	Food Supplements as defined in Directive 2002/46/EC	$1{,}35 \times 10^{8}$ CFU/day			

<table>
<tr>
<td>[F10D-ribose</td>
<td>
<table>
<tr><th>Specified food category</th><th>Maximum levels</th></tr>
<tr><td>Cereal bars</td><td>0,20 g/100 g</td></tr>
<tr><td>Fine bakery wares</td><td>0,31 g/100 g</td></tr>
<tr><td>Chocolate confectionery (excluding chocolate bars)</td><td>0,17 g/100 g</td></tr>
<tr><td>Milk-based drinks (excluding malts and shakes)</td><td>0,08 g/100 g</td></tr>
<tr><td>Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen, isotonic and energy drinks</td><td>0,80 g/100 g</td></tr>
<tr><td>Bars intended to meet the expenditure of intense muscular effort especially for sportsmen</td><td>3,3 g/100 g</td></tr>
<tr><td>Meal replacement for weight control (as drinks)'</td><td>0,13 g/100 g</td></tr>
<tr><td>Meal replacement for weight control (as bars)</td><td>3,30 g/100 g</td></tr>
<tr><td>Confectionery</td><td>0,20 g/100 g</td></tr>
</table>
</td>
<td>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘D-ribose’.
The labelling of foods containing D-ribose shall bear a statement that the foods should not be used if food supplements containing D-ribose are consumed the same day.</td>
<td></td>
<td>Authorised on 16 April 2019. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
Applicant: Bioenergy Life Science, Inc., 13840 Johnson St. NE, Minneapolis, Minnesota, 55304, USA.
During the period of data protection, the novel food D-ribose is authorised for placing on the market within the Union only by Bioenergy Life Science, 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</td>
</tr>
</table>

	Tea and infusions (in powder form to be reconstituted)	0,23 g/100 g]			26 of Regulation (EU) 2015/2283 or with the agreement of Bioenergy Life Science, Inc. End date of the data protection: 16 April 2024 (5 years).
Extract of defatted cocoa powder	***Specified food category***	***Maximum levels***	Consumers shall be instructed not to consume more than 600 mg polyphenols corresponding to 1,1 g of extract of defatted cocoa powder per day		
	Nutrition bars	1 g/day and 300 mg polyphenols corresponding to not more than 550 mg of extract of defatted cocoa powder in one portion of food (or food supplement)			
	Milk based beverages				
	Any other foods (including food supplements as defined in Directive 2002/46/EC) which have become established vehicles for functional ingredients and which are typically positioned for consumption by health conscious adults				
Low fat cocoa extract	***Specified food category***	***Maximum levels***	Consumers shall be instructed not to consume more than 600 mg of cocoa		
	Foods including food supplements as defined	730 mg per serving and around 1,2 g/day			

	in Directive 2002/46/EC		flavanols per day		
Coriander seed oil from *Coriandrum sativum*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Coriander seed oil ’		
	Food Supplements as defined in Directive 2002/46/EC	600 mg/day			
[[F14]Cranberry extract powder	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ cranberry extract powder ’		Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Ocean Spray Cranberries Inc. One Ocean Spray Drive Lakeville-Middleboro, MA, 02349, USA. During the period of data protection the novel food, cranberry extract powder, is authorised for placing on the market within the Union only by Ocean Spray Cranberries
	Food Supplements as defined in Directive 2002/46/EC for the adult population	350 mg/day**]**			

					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 Ocean Spray Cranberries Inc. End date of the data protection: 20 November 2023.
***Crataegus pinnatifida* dried fruit**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' *Crataegus pinnatifida* dried fruit'		
	Herbal infusions	In line with normal food use of *Crataegus laevigata*			
	Jams and jellies in accordance with Directive 2001/113/EC [e]				
	Compotes				
α-cyclodextrin	Not specified		The designation of the novel food on the labelling of the foodstuffs containing		

			it shall be ‘ Alpha-cyclodextrin ’ or ‘ α-cyclodextrin ’		
γ-cyclodextrin	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Gamma-Cyclodextrin ’ or ‘ γ-Cyclodextrin ’		
[[F15]Decorticated grains of *Digitaria exilis* (Kippist) Stapf (Traditional food from a third country)	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘decorticated fonio (*Digitaria exilis*) grains’**]**		
Dextran preparation produced by *Leuconostoc mesenteroides*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Dextran ’		
	Bakery products	5 %			
Diacylglycerol oil of plant origin	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Diacylglycerol oil of plant origin (at		
	Cooking oils				
	Fat spreads				
	Salad dressings				
	Mayonnaise				

	Meal replacement for weight control (as drinks)		least 80 % diacylglycerols) ’	
	Bakery products			
	Yoghurt type products			
Dihydrocapsiate (DHC)	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Dihydrocapsiate’ 2. Food supplements containing synthetic dihydrocapsiate will be labelled as ‘not intended for children up to 4.5 years’	
	Cereal bars	9 mg/100 g		
	Biscuits, cookies and crackers	9 mg/100 g		
	Rice based snacks	12 mg/100 g		
	Carbonated drinks, dilutable drinks, fruit juice based beverages	1,5 mg/100 ml		
	Vegetable drinks	2 mg/100 ml		
	Coffee based drinks, tea based drinks	1,5 mg/100 ml		
	Flavoured water — still	1 mg/100 ml		
	Precooked oatmeal cereal	2,5 mg/100 g		
	Other cereals	4,5 mg/100 g		
	Ice cream, dairy desserts	4 mg/100 g		
	Pudding mixes (ready to eat)	2 mg/100 g		
	Products based on yoghurt	2 mg/100 g		

	Chocolate confectionery	7,5 mg/100 g			
	Hard candy	27 mg/100 g			
	Sugar-free gum	115 mg/100 g			
	Whitener/ creamer	40 mg/100 g			
	Sweeteners	200 mg/100 g			
	Soup (ready to eat)	1,1 mg/100 g			
	Salad dressing	16 mg/100 g			
	Vegetable protein	5 mg/100 g			
	Ready to eat meals	3 mg/meal			
	Meal replacements for weight control	3 mg/meal			
	Meal replacement for weight control (as drinks)	1 mg/100 ml			
	Food Supplements as defined in Directive 2002/46/EC	3 mg/single intake 9 mg/day			
	Non-alcoholic powdered drink mixes	14,5 mg/kg equivalent to 1,5 mg/100 ml			
[F16Dried aerial parts of *Hoodia parviflora*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘dried aerial parts of *Hoodia parviflora* ’		Authorised on 3 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article
	Food Supplements as defined in Directive 2002/46/ EC for adult population	9,4 mg/day**]**			

					26 of Regulation (EU) 2015/2283. Applicant: Desert Labs, Ltd Kibbutz Yotvata, 88820 Israel. During the period of data protection the novel food dried aerial parts of *Hoodia parviflora* is authorised for placing on the market within the Union only by Desert Labs, Ltd 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 Desert Labs, Ltd. End date of the data protection: 3 September 2023.

Dried extract of *Lippia citriodora* from cell cultures	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried extract of *Lippia citriodora* from cell cultures HTN ® Vb'		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from the leaves of *Lippia citriodora*			
***Echinacea angustifolia* extract from cell cultures**	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from the root of *Echinacea angustifolia*			
***[F17Echinacea purpurea* extract from cell cultures**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried extract of *Echinacea purpurea* from cell cultures EchiPure-PC™'		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from florets within the flower head of *Echinacea purpurea]*			
***Echium plantagineum* oil**	***Specified food category***	***Maximum levels of stearidonic acid (STA)***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Refined echium oil '		
	Milk-based products and drinkable yoghurt products	250 mg/100 g; 75 mg/100 g for drinks			

	delivered in a single dose				
	Cheese preparations	750 mg/100 g			
	Spreadable fat and dressings	750 mg/100 g			
	Breakfast cereals	625 mg/100 g			
	Food supplements as defined in Directive 2002/46/EC	500 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal			
***[F18Ecklonia cava* phlorotannins**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ *Ecklonia cava* Phlorotannins’. Food supplements containing		
	Food supplements as defined in Directive 2002/46/EC intended for the general population, excluding children	163 mg/ day for adolescents from 12 to 14 years of age 230 mg/ day for adolescents above 14 years of age			

under the age of 12 years	263 mg/day for adults**]**	*Ecklonia cava* phlorotannins shall bear the following statement: (a) This food supplement should not be consumed by children/ adolescents under the age of twelve/ fourteen/ eighteen (*) years. (b) This food supplement should not be consumed by persons with thyroid disease or by persons who are aware of or have been identified as being at risk of developing

			thyroid disease. (c) This food supplement should not be consumed if other food supplements containing iodine are also consumed. (*) Depending on the age group the food supplement is intended for.		
[F19Egg membrane hydrolysate	***Specified food category*** Food Supplements as defined in Directive 2002/46/EC intended for the general adult population	***Maximum levels*** 450 mg/day]	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ egg membrane hydrolysate ’ .		Authorised on 25 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Biova, LLC., 5800 Merle Hay Rd, Suite 14 PO Box 394 Johnston 50131,

					Iowa USA. During the period of data protection the novel food egg membrane hydrolysate is authorised for placing on the market within the Union only by Biova, LLC. 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 Biova, LLC. End date of the data protection: 25 November 2023
Epigallocatechin gallate as a purified extract from green tea leaves (*Camellia sinensis*)	***Specified food category***	***Maximum levels***	The labelling shall bear a statement that consumers should not consume more than 300 mg of extract per day		
	Foods including food supplements as defined in Directive 2002/46/EC	150 mg of extract in one portion of food or food supplement			

[F20L-ergothioneine	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ L-ergothioneine ’		
	Alcohol-free beverages	0,025 g/kg			
	Milk-based drinks	0,025 g/kg			
	‘ Fresh ’ milk products(*)	0,040 g/kg			
	Cereal bars	0,2 g/kg			
	Chocolate confectionery	0,25 g/kg			
	Food supplements as defined in Directive 2002/46/EC	30 mg/day for general population (excluding pregnant and lactating women) 20 mg/day for children older than 3 years			
	(*) When used in milk products L-ergothioneine may not replace in whole or in part, any milk constituent**]**				
[F18Extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai)’.		
	Food supplements as defined in Directive 2002/46/ EC for adult population	175 mg/day**]**			

			The labelling of food supplements containing the extract of mixture of the three herbal roots shall bear a statement in close proximity to the list of ingredients indicating that it should not be consumed by individuals with known celery allergy.		
Ferric Sodium EDTA	***Specified food category***	***Maximum levels (expressed as anhydrous EDTA)***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Ferric Sodium EDTA ’		
	Food supplements as defined in Directive 2002/46/EC	18 mg/day for children 75 mg/day for adults			
	Foods covered by Regulation (EU) No 609/2013	12 mg/100 g			
	Foods fortified in accordance with Regulation (EC) No 1925/2006				
Ferrous ammonium phosphate	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing		
	Food supplements as defined	To be used in compliance with			

	in Directive 2002/46/EC	Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006	it shall be ‘ Ferrous ammonium phosphate ’		
	Foods covered by Regulation (EU) No 609/2013				
	Foods fortified in accordance with Regulation (EC) No 1925/2006				
Fish peptides from *Sardinops sagax*	***Specified food category***	***Maximum levels fish peptide product***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Fish (*Sardinops sagax*) peptides’		
	Foods based on yoghurt, yoghurt drinks, fermented milk products, and powdered milk	0,48 g/100 g (ready to eat/ drink)			
	Flavoured water, and vegetable-based drinks	0,3 g/100 g (ready to drink)			
	Breakfast cereals	2 g/100 g			
	Soups, stews and soup powders	0,3 g/100 g (ready to eat)			
Flavonoids from *Glycyrrhiza glabra*	***Specified food category***	***Maximum levels of flavonoids from Glycyrrhiza glabra***	1. The designation of the novel food on the labelling of the foodstuffs containing	Beverages containing flavonoids shall be presented to the final consumer as single portions.	
	Beverages based on milk	120 mg/day			
	Beverages based on yoghurt				

Beverages based on fruit or vegetables		2.	it shall be ‘Flavonoids from *Glycyrrhiza glabra L.* ’ The labelling of the foods where the product was added as a novel food ingredient shall bear a statement that: (a) the product should not be consumed by pregnant and breast feeding women, children and young adolescents; and (b) people taking prescription drugs should only consume the
Food Supplements as defined in Directive 2002/46/EC	120 mg/day		
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	120 mg/day		
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	120 mg/day		

				(c)	product under medical supervision; a maximum of 120 mg of flavonoids per day should be consumed.	
			3.	The amount of flavonoids in the final food shall be indicated on the labelling of the food containing it.		
[F21Fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. (Traditional food from a third country)	Not specified	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'cocoa (*Theobroma cacao* L.) pulp', 'cocoa (*Theobroma cacao* L.) pulp juice' or 'cocoa (*Theobroma*				

		cacao L.) concentrated pulp juice' depending on the form used.]			
Fucoidan extract from the seaweed *Fucus vesiculosus*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fucoidan extract from seaweed *Fucus vesiculosus* '.		
	Foods including food supplements as defined in Directive 2002/46/ EC for the general population	250 mg/day			
Fucoidan extract from the seaweed *Undaria pinnatifida*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Fucoidan extract from seaweed Undaria pinnatifida '		
	Foods including food supplements as defined in Directive 2002/46/ EC for the general population	250 mg/day			
2′-Fucosyllactose	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be '2′-fucosyllactose'.		
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l			
	Unflavoured fermented milk-based products	1,2 g/l beverages			
		19,2 g/kg products other than beverages			

Flavoured fermented milk-based products including heat-treated products	1,2 g/l beverages	2.	The labelling of food supplements containing 2′-fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2′-fucosyllactose are consumed the same day.
	19,2 g/kg products other than beverages		
Dairy analogues, including beverage whiteners	1,2 g/l beverages		
	12 g/kg for products other than beverages		
	400 g/kg for whitener		
Cereal bars	12 g/kg		
Table-top sweeteners	200 g/kg		
Infant formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto- *N* -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	3.	The labelling of food supplements containing 2′-fucosyllactose intended for young children shall bear a statement that the supplements should not
Follow-on formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto- *N* -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted		

	as instructed by the manufacturer		
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	12 g/kg for products other than beverages		
	1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		
Milk-based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products added alone or in combination with up to 0,6 g/l lacto- *N* -neotetraose, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
Total diet replacement for weight control as	4,8 g/l for drinks		
	40 g/kg for bars		

be used if breast milk or other foods with added 2′-fucosyllactose are consumed the same day.

defined in Regulation (EU) No 609/2013				
Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	60 g/kg			
Flavoured drinks	1,2 g/l			
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9,6 g/l — the maximum level refers to the products ready to use			
Food supplements as defined in Directive 2002/46/EC, excluding food	3,0 g/day for general population			
	1,2 g/day for young children			

	supplements for infants				
[F22 2'-Fucosyllactose/ Difucosyllactose mixture (‘ 2'-FL/DFL ’) (microbial source)	**Specified food category**	**Maximum levels**	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘2'-Fucosyllactose/ Difucosyllactose mixture’. The labelling of food supplements containing the 2'-Fucosyllactose/ Difucosyllactose mixture shall bear a statement that they should not be used if breast milk or other foods containing added 2'-Fucosyllactose and/or Difucosyllactose are consumed the same day.		Authorised on 19.12.2019. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 2'-Fucosyllactose/ Difucosyllactose mixture is authorised for placing on the market within the Union only by Glycom A/S, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2,0 g/L			
	Unflavoured fermented milk-based products	2,0 g/L (beverages) 20 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	2,0 g/L (beverages) 20 g/kg (products other than beverages)			
	Beverages (flavoured drinks)	2,0 g/L			
	Cereal bars	20 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	1,6 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

Processed cereal-based food and baby food for infants and young children as defined under Regulation (EU) No 609/2013	1,2 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 10 g/kg for products other than beverages			with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. End date of the data protection: 19.12.2024.
Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	4,0 g/L (beverages) 40 g/kg (products other than beverages)			
Food for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food Supplements as defined in Directive 2002/46/EC intended for the general population excluding infants	4,0 g/day]			
[F23Milk-based drinks and similar products intended	[F24]1.2 g/L in the final product ready for use, marketed as such or			

	for young children**]**	reconstituted as instructed by the manufacturer**]**			
Galacto-oligosaccharide	***Specified food category***	***Maximum levels (expressed as ratio kg galacto-oligosaccharide/ kg final food)***			
	Food Supplements as defined in Directive 2002/46/EC	0,333			
	Milk	0,02			
	Milk drinks	0,03			
	Meal replacement for weight control (as drinks)	0,02			
	Dairy analogue drinks	0,02			
	Yoghurt	0,033			
	Dairy based deserts	0,043			
	Frozen dairy deserts	0,043			
	Fruit drinks and energy drinks	0,021			
	Infant meal replacement drinks	0,012			
	Baby juice	0,025			
	Baby yogurt drink	0,024			
	Baby desert	0,027			
	Baby snack	0,143			
	Baby cereals	0,027			

	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	0,013			
	Juice	0,021			
	Fruit pie fillings	0,059			
	Fruit preparations	0,125			
	Bars	0,125			
	Cereals	0,125			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	0,008			
Glucosamine HCl	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish			
	Foods covered by Regulation (EU) No 609/2013				
	Meal replacement for weight control				
	Foods intended to meet the expenditure				

	of intense muscular effort, especially for sportsmen				
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
Glucosamine sulphate KCl	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish			
Glucosamine sulphate NaCl	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish			
Guar Gum	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs		
	Fresh dairy products such as yogurts, fermented milks, fresh cheeses and other dairy-based desserts.	1,5 g/100 g			

Fruit or vegetable-based liquid foodstuffs (of the ‘ smoothie ’ variety)	1,8 g/100 g	2.	containing it shall be ‘Guar Gum’. A specific mention of the possible risks of digestive discomfort linked to the exposure of children aged under 8 to guar gum must be visible on the label of any foodstuffs containing it. For example, ‘Excessive consumption of these products may cause digestive discomfort, especially for children under
Fruit or vegetable-based compotes	3,25 g/100 g		
Cereals accompanied by a dairy product, in packaging containing two compartments	10 g/100 g in the cereals None in the accompanying dairy product 1 g/100 g in the product when ready to eat		

					8 years of age’.	
				3.	In the case of products with two compartments containing dairy and cereal products respectively, the instructions for use must clearly specify the need to mix the cereal and the dairy productbefore consumption, in order to take into account the potential risk of gastro-intestinal obstruction.	
Heat-treated milk products	***Specified food category***	***Maximum levels***				

fermented with *Bacteroides xylanisolvens*	Fermented milk products (in liquid, semi-liquid and spray-dried powder forms)				
Hydroxytyrosol	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the food products containing it shall be 'hydroxytyrosol'. The labelling of the food products containing hydroxytyrosol shall bear the following statements: (a) This food product should not be consumed by children under the age of three years, pregnant women, and lactating women; (b) This food product should not be used		
	Fish and vegetable oils, (except olive oils and olive pomace oils as defined in Part VIII of Annex VII of Regulation (EU) No 1308/2013 [f]), placed as such on the market	0,215 g/kg			
	Spreadable fats as defined in Part VII of Annex VII of Regulation (EU) No 1308/2013, placed as such on the market	0,175 g/kg			

			for cooking, baking or frying'		
Ice Structuring Protein type III HPLC 12	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Ice Structuring Protein '		
	Edible ices	0,01 %			
Aqueous extracts of dried leaves of *Ilex guayusa*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Extracts of dried leaves of *Ilex guayusa* '		
	Herbal infusions	In line with normal use in herbal infusions and food supplements of a similar aqueous extract of dried leaves of *Ilex paraguariensis*			
	Food Supplements as defined in Directive 2002/46/EC				
[F25Infusion from coffee leaves of *Coffea arabica* L. and/ or *Coffea canephora* Pierre ex A. Froehner (Traditional food from a third country)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Infusion from coffee leaves of *Coffea arabica* and/ or *Coffea canephora* '.		
	Herbal infusions]				
Isomalto-oligosaccharide	***Specified food category***	***Maximum levels***	1. The designation of the novel food		

	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 %			
	Processed Vegetables and Vegetable Juices	5 %			
	Other Soft Drinks	5 %			
	Cereals Bars	10 %			
	Cookies, Biscuits	20 %			
	Breakfast Cereal Bars	25 %			
	Hard Candies	97 %			
	Soft Candies/ Chocolate Bars	25 %			
	Meal replacement for weight control (as bars or milk based)	20 %			
			2.	Foods containing the novel ingredient must be labelled as ‘a source of glucose’.	
Isomaltulose	Not specified		1.	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Isomaltooligosaccharide’.	

			2.	the labelling of the foodstuffs containing it shall be ‘Isomaltulose’. The designation of the novel food on the labelling shall be accompanied by indication that the ‘Isomaltulose is a source of glucose and fructose’.	
[F26Lactitol	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the food supplements containing it shall be ‘ Lactitol ’		
	Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder) intended for the adult population	20 g/day**]**			
Lacto- *N* - neotetraose	***Specified food category***	***Maximum levels***	1.	The designation of the novel	

Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,6 g/l		
Unflavoured fermented milk-based products	0,6 g/l for beverages 9,6 g/kg for products other than beverages		
Flavoured fermented milk-based products including heat-treated products	0,6 g/l for beverages 9,6 g/kg for products other than beverages	2.	The labelling of food supplements containing lacto-*N*-neotetraose shall bear a statement that the supplements should not be used if other foods with added lacto-*N*-neotetraose are consumed the same day.
Dairy analogues, including beverage whiteners	0,6 g/l for beverages 6 g/kg for products other than beverages 200 g/kg for whitener		
Cereal bars	6 g/kg		
Table-top sweeteners	100 g/kg		
Infant formula as defined in Regulation (EU) No 609/2013	0,6 g/l in combination with up to 1,2 g/l of 2′-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	3.	The labelling of food
Follow-on formula as defined in	0,6 g/l in combination with up to		

food on the labelling of the foodstuffs containing it shall be ‘lacto-*N*-neotetraose’.

Regulation (EU) No 609/2013	1,2 g/l of 2′-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	supplements containing lacto-*N*-neotetraose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-*N*-neotetraose are consumed the same day.
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	6 g/kg for products other than beverages 0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Milk-based drinks and similar products intended for young children	0,6 g/l for milk-based drinks and similar products added alone or in combination with 2′-fucosyllactose, at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Foods for special medical purposes as defined in Regulation	In accordance with the particular nutritional requirements of the persons	

(EU) No 609/2013	for whom the products are intended			
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2,4 g/l for drinks 20 g/kg for bars			
Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	30 g/kg			
Flavoured drinks	0,6 g/l			
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes	4,8 g/l — the maximum level refers to the products ready to use			

	of these products				
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	1,5 g/day for general population 0,6 g/day for young children			
[[F27]Lacto-*N* -tetraose (‘LNT’) **(microbial source)**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘lacto- *N*-tetraose’. The labelling of food supplements containing lacto- *N*-tetraose shall bear a statement that they should not be used if breast milk or other foods containing added lacto-*N*- tetraose are consumed the same day.		Authorised on 23.4.2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food lacto-*N*- tetraose is authorised for placing on the market within the Union only by Glycom A/S, unless a subsequent applicant obtains authorisation for the novel food without reference
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1,0 g/l			
	Unflavoured fermented milk-based products	1,0 g/l (beverages) 10 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	1,0 g/l (beverages) 10 g/kg (products other than beverages)			
	Beverages (flavoured drinks)	1,0 g/l			
	Cereal bars	10 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,8 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

Follow-on formula as defined under Regulation (EU) No 609/2013	0,6 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. End date of the data protection: 23.4.2025.
Processed cereal-based food, baby food for infants and young children as defined under Regulation (EU) No 609/2013	0,6 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages			
Milk based drinks and similar products intended for young children	0,6 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages			
Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/l (beverages) 20 g/kg (products other than beverages)			
Food for special	In accordance			

	medical purposes as defined under Regulation (EU) No 609/2013	with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC, excluding infants	2,0 g/day for young children, children, adolescents, and adults**]**			
[F28*Lonicera caerulea* L. berries (haskap) (Traditional food from a third country)	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘haskap (*Lonicera caerulea*) berries’**]**		
Lucerne leaf extract from *Medicago sativa*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Lucerne (*Medicago sativa*) protein’ or ‘Alfalfa (*Medicago sativa*) protein’.		
	Food supplements as defined in Directive 2002/46/EC	10 g/day			
Lycopene	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing		
	Fruit/ vegetable juice-based drinks	2,5 mg/100 g			

(including concentrates)		it shall be ‘ Lycopene ’		
Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g			
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal			
Breakfast cereals	5 mg/100 g			
Fats and dressings	10 mg/100 g			
Soups other than tomato soups	1 mg/100 g			
Bread (including crispy breads)	3 mg/100 g			
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food supplements as defined in Directive 2002/46/EC	15 mg/day			

Lycopene from *Blakeslea trispora*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Lycopene ’		
	Fruit/ vegetable juice-based drinks (including concentrates)	2,5 mg/100 g			
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal			
	Breakfast cereals	5 mg/100 g			
	Fats and dressings	10 mg/100 g			
	Soups other than tomato soups	1 mg/100 g			
	Bread (including crispy breads)	3 mg/100 g			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the			

		products are intended			
	Food supplements as defined in Directive 2002/46/EC	15 mg/day			
Lycopene from tomatoes	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Lycopene ’		
	Fruit/ vegetable juice-based drinks (including concentrates)	2,5 mg/100 g			
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal			
	Breakfast cereals	5 mg/100 g			
	Fats and dressings	10 mg/100 g			
	Soups other than tomato soups	1 mg/100 g			
	Bread (including crispy breads)	3 mg/100 g			

	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in Directive 2002/46/EC	15 mg/day			
Lycopene oleoresin from tomatoes	***Specified food category***	***Maximum levels of lycopene***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Lycopene oleoresin from tomatoes ’		
	Fruit/ vegetable juice-based drinks (including concentrates)	2,5 mg/100 g			
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g			
	Total diet replacement for weight control covered by Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal			
	Breakfast cereals	5 mg/100 g			
	Fats and dressings	10 mg/100 g			

	Soups other than tomato soups	1 mg/100 g			
	Bread (including crispy breads)	3 mg/100 g			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
[F18Hen egg white lysozyme hydrolysate	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of food supplements containing it shall be ‘ Hen egg white lysozyme hydrolysate ’ .		
	Food supplements as defined in Directive 2002/46/ EC intended for adult population	1000 mg/ day**]**			
Magnesium citrate malate	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Magnesium citrate malate ’		
	Food Supplements as defined in Directive 2002/46/EC				
Magnolia Bark Extract	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Magnolia Bark Extract ’		
	Mints (confectionary products)	0,2 % for breath freshening purposes. Based on a 0,2 % maximum incorporation			
	Chewing gum				

		level and a maximum gum/mint size of 1,5 g each, each gum or mint serving will contain no more than 3 mg of magnolia bark extract.			
Maize-germ oil high in unsaponifiable matter	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Maize-germ oil extract ’		
	Food Supplements as defined in Directive 2002/46/EC	2 g/day			
	Chewing gum	2 %			
Methylcellulose	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Methylcellulose ’	Methylcellulose is not to be used in foods specially prepared for young children	
	Edible ices	2 %			
	Flavoured drinks				
	Flavoured or unflavoured fermented milk products				
	Cold desserts (dairy, fat, fruit, cereal, egg-based products)				
	Fruit preparations (pulps, purees or compotes)				
	Soups and broths				
[F29 1-Methylnicotinamide chloride	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs		Authorised on 2 September 2018. This inclusion is based on proprietary
	Food Supplements as defined	58 mg/day]			

in Directive 2002/46/EC for the adult population excluding pregnant and lactating women		containing it shall be '1-Methylnicotinamide chloride'. Food supplements containing 1-Methylnicotinamide shall bear the following statement: This food supplement should be consumed by adults only excluding pregnant and lactating women		scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Pharmena SA, Wolczanska 178, 90 530 Lodz, Poland. During the period of data protection thenovel food 1-methylnicotinamide chloride is authorised for placing on the market within the Union only by Pharmena S.A. 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 Pharmena S.A.

					End date of the data protection: 2 September 2023
(6S)-5-methyltetrahydrofolic acid, glucosamine salt	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ (6S)-5-methyltetrahydrofolic acid, glucosamine salt ’ or ‘ 5MTHF-glucosamine ’		
	Food Supplements as defined in Directive 2002/46/EC as a source of folate				
Monomethylsilanetriol (Organic Silicon)	***Specified food category***	***Maximum levels of silicon***	The designation of the novel food on the labelling of the food supplements containing it shall be ‘ Organic silicon (monomethylsilanetriol) ’		
	Food Supplements as defined in Directive 2002/46/ EC for adult population (in liquid form)	10,40 mg/day			
Mycelial extract from Shiitake mushroom (*Lentinula edodes*)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘extract from the mushroom		
	Bread products	2 ml/100 g			
	Soft drinks	0,5 ml/100 ml			
	Ready prepared meals	2,5 ml per meal			

	Foods based on yoghurt	1,5 ml/100 ml	*Lentinula edodes* ' or 'extract from Shiitake mushroom'		
	Food supplements as defined in Directive 2002/46/EC	2,5 ml per day dose			
[F30Nicotinamide riboside chloride	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Nicotinamide riboside chloride '		Authorised on 20 February 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: ChromaDex Inc., 10900 Wilshire Boulevard Suite 600, Los Angeles, CA 90024 USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by ChromaDex Inc. unless a subsequent applicant obtains authorisation for that novel food without reference
	Food Supplements as defined in Directive 2002/46/EC	300 mg/ day for the general adult population, excluding pregnant and lactating women 230 mg/day for pregnant and lactating women**]**			

					to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of ChromaDex Inc. End date of the data protection: 20 February 2025.
Noni fruit juice (*Morinda citrifolia*)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of *Morinda citrifolia* '		
	Pasteurised fruit and fruit nectar based drinks	30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per day			
Noni fruit juice powder (*Morinda citrifolia*)	Food supplements as defined in Directive 2002/46/EC	6,6 g/day (equivalent to 30 ml of noni juice)	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice powder' or 'Juice powder of *Morinda citrifolia* '		
Noni fruit puree and concentrate (*Morinda citrifolia*)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of		
		Fruit puree			

Candy/ confectionery	45 g/100 g	the foodstuffs containing it shall be: For fruit puree: ‘ *Morinda citrifolia* fruit puree’ or ‘Noni fruit puree’ For fruit concentrate: ‘ *Morinda citrifolia* fruit concentrate’ or ‘Noni fruit concentrate’		
Cereal bars	53 g/100 g			
Powdered nutritional drink mixes (dry weight)	53 g/100 g			
Carbonated beverages	11 g/100 g			
Ice cream & sorbet	31 g/100 g			
Yoghurt	12 g/100 g			
Biscuits	53 g/100 g			
Buns, cakes and pastries	53 g/100 g			
Breakfast cereals (wholegrain)	88 g/100 g			
Jams and jellies in accordance with Directive 2001/113/EC	133 g/100 g Based on pre-processing quantity to produce final 100 g product			
Sweet spreads, fillings and icings	31 g/100 g			
Savoury sauces, pickles, gravies and condiments	88 g/100 g			
Food Supplements as defined in Directive 2002/46/EC	26 g/day			
	Fruit concentrate			
Candy/ Confectionery	10 g/100 g			
Cereal bars	12 g/100 g			

	Powdered nutritional drink mixes (dry weight)	12 g/100 g			
	Carbonated beverages	3 g/100 g			
	Ice cream & sorbet	7 g/100 g			
	Yoghurt	3 g/100 g			
	Biscuits	12 g/100 g			
	Buns, cakes and pastries	12 g/100 g			
	Breakfast cereals (wholegrain)	20 g/100 g			
	Jams and jellies in accordance with Directive 2001/113/EC	30 g/100 g			
	Sweet spreads, fillings and icings	7 g/100 g			
	Savoury sauces, pickles, gravies and condiments	20 g/100 g			
	Food Supplements as defined in Directive 2002/46/EC	6 g/day			
Noni leaves (*Morinda citrifolia*)	***Specified food category***	***Maximum levels***	1.	The designation of the novel food on the labelling of the foodstuffs	
	For the preparation of infusions	A cup of infusion to be consumed shall not be prepared with more than 1 g of dried and roasted leaves			

		of *Morinda citrifolia*	containing it shall be 'Noni leaves' or 'leaves of *Morinda citrifolia*'. 2. Instructions shall be given to the consumer that a cup of infusion should not be prepared with more than 1 g of dried and roasted leaves of Morinda citrifolia.		
Noni fruit powder (*Morinda citrifolia*)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Morinda citrifolia fruit powder ' or		
	Food Supplements as defined in Directive 2002/46/EC	2,4 g per/day			

<table>
<tr><td></td><td></td><td></td><td>‘ Noni fruit powder ’</td><td></td><td></td></tr>
<tr><td rowspan="7">Odontella aurita microalgae</td><td>Specified food category</td><td>Maximum levels</td><td rowspan="7">The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Odontella aurita microalgae’</td><td rowspan="7"></td><td rowspan="7"></td></tr>
<tr><td>Flavoured pasta</td><td>1,5 %</td></tr>
<tr><td>Fish soups</td><td>1 %</td></tr>
<tr><td>Marine terrines</td><td>0,5 %</td></tr>
<tr><td>Broth preparations</td><td>1 %</td></tr>
<tr><td>Crackers</td><td>1,5 %</td></tr>
<tr><td>Frozen breaded fish</td><td>1,5 %</td></tr>
<tr><td rowspan="3">Oil enriched with phytosterols/ phytostanols</td><td>Specified food category</td><td colspan="2">Maximum levels of phytosterols/ phytostanols</td><td rowspan="3">In accordance with Annex III.5 to Regulation (EU) No 1169/2011</td><td rowspan="3"></td><td rowspan="3"></td></tr>
<tr><td>Spreadable fats as defined in Annex VII, Part VII and Appendix II, points B and C of Regulation (EU) No 1308/2013, and excluding cooking and frying fats and spreads based on butter or other animal fat</td><td colspan="2" rowspan="2">1. The products containing the novel food ingredient shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case</td></tr>
<tr><td>Milk based products, such as products based on semi-skimmed and skimmed milk products,</td></tr>
</table>

	possibly with the addition of fruits and/ or cereals, products based on fermented milk such as yoghurt and cheese based products (fat content ≤ 12 g per 100 g), where possibly the milk fat has been reduced and the fat or protein has been partly or fully replaced by vegetable fat or protein		of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/ phytostanols.		
	Soya drinks	2.	The amount of phytosterols/ phytostanols added to a container of beverages shall not exceed 3 g.		
	Salad dressings, mayonnaise and spicy sauces	3.	Salad dressings, mayonnaise and spicy sauces shall be packed as single portions.		
Oil extracted from squids	***Specified food category***	***Maximum levels of DHA and EPA combined***	The designation of the novel food on the labelling of the foodstuffs containing		
	Dairy products	200 mg/100 g or for cheese			

except milk-based beverages	products 600 mg/100 g	it shall be ‘ Squid oil ’ .		
Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			
Spreadable fat and dressings	600 mg/100 g			
Breakfast cereals	500 mg/100 g			
Bakery products (breads and bread rolls)	200 mg/100 g			
Cereal bars	500 mg/100 g			
Non-alcoholic beverages (including milk-based beverages)	60 mg/100 ml			
Food Supplements as defined in Directive 2002/46/EC	3 000 mg/day for general population 450 mg/day for pregnant and lactating women			
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products intended			
Total diet replacement for weight control defined in Regulation (EU) No	200 mg/meal			

	609/2013 and meal replacements for weight control				
[F7Partially defatted chia seed (*Salvia hispanica*) powders	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Partially defatted chia seed (*Salvia hispanica*) powder'		
	Powder with high protein content				
	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	0,7 %			
	Unflavoured fermented milk products, heat-treated after fermentation	0,7 %			
	Flavoured fermented milk products including heat-treated products	0,7 %			
	Confectionery	10 %			
	Fruit juices as defined by Directive 2001/112/EC [h] and vegetable juices	2,5 %			
	Fruit nectars as defined by Directive 2001/112/EC	2,5 %			

and vegetable nectars and similar products				
Flavoured drinks	3 %			
Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	7,5 g/day			
Powder with high fibre content				
Confectionery	4 %			
Fruit juices as defined by Directive 2001/112/EC and vegetable juices	2,5 %			
Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	4 %			
Flavoured drinks	4 %			
Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	12 g/day]			

Pasteurised fruit-based preparations produced using high-pressure treatment	***Specified food category***	***Maximum levels***	The wording ‘ pasteurised by high-pressure treatment ’ shall be displayed next to the name of the fruit preparations as such and in any product in which it is used		
	Types of fruit: apple, apricot, banana, blackberry, blueberry, cherry, coconut, fig, grape, grapefruit, mandarin, mango, melon, peach, pear, pineapple, prune, raspberry, rhubarb, strawberry				
[F31Phenylcapsaicin	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ phenylcapsaicin ’ .		Authorised on 19 December 2019. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: aXichem AB, Södergatan 26, SE 211 34, Malmö Sweden. During the period of data protection, the novel food phenylcapsaicin is authorised for placing
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants, young children and children under the age of 11 years	2,5 mg/day			
	Food supplements as defined in Directive 2002/46/EC intended for the general population, excluding children	2,5 mg/day**]**			

	under the age of 11 years				on the market within the Union only by aXichem AB, 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 aXichem AB.
Phosphated maize starch	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Phosphated maize starch ’		
	Baked bakery products	15 %			
	Pasta				
	Breakfast cereals				
	Cereal bars				
Phosphatidylserine from fish phospholipids	***Specified food category***	***Maximum levels of phosphatidylserine***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Fish phosphatidylserine ’		
	Beverages based on yoghurt	50 mg/100 ml			
	Powders based on milk powders	3 500 mg/100 g (equivalent to 40 mg/100 ml ready to drink)			
	Foods based on yoghurt	80 mg/100 g			

	Cereal bars	350 mg/100 g			
	Chocolate based confectionary	200 mg/100 g			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013			
	Food supplements as defined in Directive 2002/46/EC	300 mg/day			
Phosphatidylserine from soya phospholipids	***Specified food category***	***Maximum levels of phosphatidylserine***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Soya phosphatidylserine ’		
	Beverages based on yoghurt	50 mg/100 ml			
	Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready to drink)			
	Foods based on yoghurt	80 mg/100 g			
	Cereal bars	350 mg/100 g			
	Chocolate based confectionary	200 mg/100 g			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013			
Phospholipid product containing equal amounts of	***Specified food category***	***Maximum levels of phosphatidylserine***	The designation of the novel food on the labelling of	The product is not intended to be marketed to pregnant	
	Breakfast cereals	80 mg/100 g			

phosphatidylserine and phosphatidic acid	Cereal bars	350 mg/100 g	the foodstuffs containing shall be ‘ Soy phosphatidylserine and phosphatidic acid ’	or breast-feeding women	
	Foods based on yogurt	80 mg/100 g			
	Soy-based yogurt-like products	80 mg/100 g			
	Yogurt based-drinks	50 mg/100 g			
	Soy-based yogurt-like drinks	50 mg/100 g			
	Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready-to drink)			
	Food Supplements as defined in Directive 2002/46/EC	800 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013			
Phospholipides from egg yolk	***Specified food category***	***Maximum levels***			
	Not specified				
Phytoglycogen	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Phytoglycogen ’		
	Processed foods	25 %			
Phytosterols/ phytostanols	***Specified food category***	***Maximum levels***	In accordance with Annex III.5 of Regulation		

Rice drinks	1. They shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of 1 portion/ day) or a maximum of 1 g (in case of 3 portions/ day) of added phytosterols/ phytostanols. The amount of phytosterols/ phytostanols added to a container of beverages shall not exceed 3 g.	(EU) No 1169/2011		
Rye bread with flour containing ≥ 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and ≤ 30 % wheat; and with ≤ 4 % added sugar but no fat added.				
Salad dressings, mayonnaise and spicy sauces.				
Soya drink				
Milk type products, such as semi-skimmed and skimmed milk type products, possibly with the addition of fruits and/ or cereals, where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or fully replaced by vegetable fat and/or protein.				
Products based on fermented milk such				

	as yoghurt and cheese type products (fat content < 12 % per 100 g), where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or fully replaced by vegetable fat and/or protein	sauces shall be packed as single portions			
	Spreadable fats as defined in Annex VII, Part VII and Appendix II, points B and C of Regulation (EU) No 1308/2013, and excluding cooking and frying fats and spreads based on butter or other animal fat.				
	Food Supplements as defined in Directive 2002/46/EC	3 g/day			
Plum kernel oil	***Specified food category***	***Maximum levels***			
	For frying and as seasoning	In line with normal food use of vegetable oils			
Potato proteins (coagulated)	Not specified		The designation of the novel		

and hydrolysates thereof			food on the labelling of the foodstuffs containing it shall be ‘ Potato protein ’		
Prolyl oligopeptidase (enzyme preparation)	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Prolyl oligopeptidase ’		
	Food Supplements as defined in Directive 2002/46/EC for general adult population	120 PPU/day (2,7 g of enzyme preparation/day) (2×10^6 PPI/day) PPU – Prolyl Peptidase Units or Proline Protease Units PPI – Protease Picomole International			
[F32Protein extract from pig kidneys	***Specified food category***	***Maximum levels***			
	Food Supplements as defined in Directive 2002/46/EC	3 capsules or 3 tablets/day; equalising 12,6 mg pig kidney extract a day Diamine oxidase (DAO) content: 0,9 mg/day (3 capsules or 3 tablets with a content of DAO of 0,3 mg/capsule or 0,3 mg/tablet)			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013**]**				
[F33Pyrroloquinoline quinone disodium salt	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of		Authorised on 2 September 2018. This inclusion is based on proprietary
	Food Supplements	20 mg/day**]**			

as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women		the foodstuffs containing it shall be 'Pyrroloquinoline quinone disodium salt'. Food supplements containing Pyrroloquinoline quinone disodium salt shall bear the following statement: This food supplement should be consumed by adults only excluding pregnant and lactating women		scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Mitsubishi Gas Chemical Company, Inc., Mitsubishi Building 5-2 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8324, Japan. During the period of data protection the novel food Pyrroloquinoline quinone disodium salt is authorised for placing on the market within the Union only by Mitsubishi Gas Chemical Company, 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 Mitsubishi Gas Chemical Company, Inc. End date of the data protection: 2 september 2023
Rapeseed oil high in unsaponifiable matter	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Rapeseed oil extract ’		
	Food Supplements as defined in Directive 2002/46/EC	1,5 g per portion recommended for daily consumption			
Rapeseed Protein	As a vegetable protein source in foods except in infant formula and follow-on formula		1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Rapeseed protein’. 2. Any foodstuff containing ‘rapeseed protein’ shall bear a		

			statement that this ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof. Where relevant, this statement shall appear in close proximity to the list of ingredients.		
[[F34]Refined shrimp peptide concentrate	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ refined shrimp peptide concentrate ’ .		Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Marealis AS., Stortorget 1, Kystens
	Food Supplements as defined in Directive 2002/46/EC for the adult population	1 200 mg/ day**]**			

						Hus, 2nd floor, N-9008 Tromsø Postal address: P.O. Box 1065, 9261 Tromsø, Norway. During the period of data protection the novel food refined shrimp peptideconcentrate is authorised for placing on the market within the Union only by Marealis AS 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 Marealis AS. End date of the data protection: 20 November 2023.
Trans-resveratrol	***Specified food category***	***Maximum levels***	1.	The designation of		

	Food Supplements as defined in Directive 2002/46/ EC for adult population (capsule or tablet form)	150 mg/day	2.	the novel food on the labelling of the food supplements containing it shall be ‘ *Trans* -resveratrol’. The labelling of food supplements containing trans-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.	
Trans-resveratrol (microbial source)	***Specified food category***	***Maximum levels***	1.	The designation of the novel food on the labelling of the	
	Food supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of resveratrol extracted from Japanese			

		knotweed (*Fallopia japonica*)	2. food supplements containing it shall be ‘ *Trans* - resveratrol’. The labelling of food supplements containing trans-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.		
Rooster comb extract	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Rooster comb extract ’ or ‘ Cockerel comb extract ’		
	Milk-based drinks	40 mg/100 g or mg/100 ml			
	Milk based fermented drinks	80 mg/100 g or mg/100 ml			
	Yoghurt-type products	65 mg/100 g or mg/100 ml			
	Fromage frais	110 mg/100 g or mg/100 ml			
Sacha inchi oil from *Plukenetia volubilis*	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of		
	As for linseed oil	In line with normal food			

		use of linseed oil	the foodstuffs containing it shall be ‘ Sacha inchi oil (Plukenetia volubilis) ’	
Salatrims	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘reduced energy fat (salatrims)’. 2. There shall be a statement that excessive consumption may lead to gastro-intestinal disturbance. 3. There shall be a statement that the products are not intended for use	
	Bakery products and confectionary			

			by children.		
***Schizochytrium sp.* oil rich in DHA and EPA**	***Specified food category***	***Maximum levels of DHA and EPA combined* :**	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the microalgae *Schizochytrium* sp.'		
	Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	3 000 mg/day			
	Food Supplements as defined in Directive 2002/46/EC for pregnant and lactating women	450 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal			
	Milk-based drinks and similar	200 mg/100 g			

products intended for young children				
Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013				
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
Bakery Products (Breads, Rolls and Sweet Biscuits)	200 mg/100 g			
Breakfast Cereals	500 mg/100 g			
Cooking Fats	360 mg/100 g			

	Dairy Analogues except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)			
	Dairy Products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)			
	Non-alcoholic Beverages (including dairy analogue and milk-based drinks)	80 mg/100 g			
	Cereal/ Nutrition Bars	500 mg/100 g			
	Spreadable Fats and Dressings	600 mg/100 g			
[F35*Schizochytrium* sp. (ATCC PTA-9695) oil	***Specified food category***	***Maximum levels of DHA***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* sp.'		
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g			
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			

Spreadable fats and dressings	600 mg/100 g			
Breakfast cereals	500 mg/100 g			
Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population			
	450 mg DHA/day for pregnant and lactating women			
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal			
Milk-based drinks and similar products intended for young children	200 mg/100 g			
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
Foods bearing statements on the absence or reduced presence of gluten in				

accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Bakery products (breads, rolls, and sweet biscuits)	200 mg/100 g			
Cereal bars	500 mg/100 g			
Cooking fats	360 mg/100 g			
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml			
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
Processed cereal-based foods and baby foods for infants	200 mg/100 g			

	and young children as defined in Regulation (EU) No 609/2013				
	Fruit/ vegetable puree	100 mg/100 g**]**			
***[F36Schizochytrium sp.* strain (FCC-3204) oil**	*Specified food category*	*Maximum levels of DHA*			
	Food supplements as defined in the Food Supplements (England) Regulations 2003, excluding food supplements for infants and children under the age of 3.	1000mg/day	The designation of the novel food on the labelling of the foodstuffs containing it is 'Oil from the microalgae Schizochytrium sp.'.		
	Infant formula and follow-on formula as defined in Regulation 609/2013	In accordance with Regulation 609/2013.	The labelling of food supplements containing Schizochytrium sp. strain (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under the age of 3.**]**		
***[F37Schizochytrium sp.*(FCC-3204) oil**	*Specified food category*	*Maximum levels of DHA*			
	Food supplements as defined in the Food Supplements (Scotland)	1 g/day	The designation of the novel food on the labelling of the foodstuffs		

	Regulations 2003 excluding food supplements for infants and children under 3 years of age		containing it is “Oil from the microalgae *Schizochytrium* sp.”.		
	Infant formula and follow-on formula as defined in Regulation (EU) 609/2013	In accordance with Regulation (EU) 609/2013	The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under 3 years of age.**]**		
***[F38Schizochytrium sp.*(FCC-3204) oil**	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it is “Oil from the microalgae *Schizochytrium* sp.”. The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and children		
	Food Supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and children under 3 years of age	1g/day			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

			under 3 years of age.**]**		
[F39*Schizochytrium* sp. oil	***Specified food category***	***Maximum levels of DHA***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* sp.'		
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g			
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			
	Spreadable fat and dressings	600 mg/100 g			
	Breakfast cereals	500 mg/100 g			
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population			
		450 mg DHA/day for pregnant and lactating women			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal			
	Milk-based drinks and similar products intended	200 mg/100 g			

for young children				
Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013				
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014				
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Bakery products (breads, rolls,	200 mg/100 g			

	and, sweet biscuits)				
	Cereal bars	500 mg/100 g			
	Cooking fats	360 mg/100 g			
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml			
	Fruit/ vegetable puree	100 mg/100 g**]**			
***[F20Schizochytrium* sp. (T18) oil**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* sp.'.		
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g			
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			
	Spreadable fats and dressings	600 mg/100 g			
	Breakfast cereals	500 mg/100 g			
	Food supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population			
		450 mg DHA/day for pregnant and lactating women			
	Total diet replacement	250 mg/meal			

for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control				
Milk-based drinks and similar products intended for young children	200 mg/100 g			
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the			

		products are intended			
	Bakery products (breads, rolls and, sweet biscuits)	200 mg/100 g			
	Cereal bars	500 mg/100g			
	Cooking fats	360 mg/100 g			
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g			
	Fruit/ vegetable puree	100 mg/100 g]			
[F40*Schizochytrium* sp. (WZU477) oil	*Specified food category*	*Maximum levels of DHA*			Included in the list on 30th June 2022. This inclusion is based on proprietary scientific
	Infant formula and follow-on formula as defined in	In accordance with Regulation 609/2013.	The designation of the novel food on the labelling of the foodstuffs		

Regulation 609/2013		containing it is 'Oil from the microalgae Schizochytrium sp.'.		evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283. Applicant: Progress Biotech BV of Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, The Netherlands. During the period of data protection, Schizochytrium sp. (WZU477) oil is authorised for placing on the market within England only by Progress Biotech BV 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 2015/2283 or with the agreement

					of Progress Biotech BV. The data protection will expire at the end of 29th June 2027.**]**
[F41*Schizochytrium* sp. (WZU477) oil	Infant formula and follow-on formula as defined in Regulation (EU) 609/2013	In accordance with Regulation (EU) 609/2013	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.".		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech BV of Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands. During the period of data protection, the novel food *Schizochytrium* sp. (WZU477) oil is authorised for placing on the market within Scotland only by Progress Biotech BV 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 Progress Biotech BV.
					The data protection will expire at the end of 29 June 2027.**]**
[F42*Schizochytrium* sp. (WZU477) oil	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp."		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech BV, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands.
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

					During the period of data protection, *Schizochytrium* sp. (WZU477) oil is authorised for placing on the market within Wales only by Progress Biotech BV 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 Progress Biotech BV. The data protection ends at the end of 29 June 2027.**]**
[[F43]Syrup from *Sorghum bicolor* (L.) Moench (Traditional food from a third country)	Not specified		This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of		

			Regulation (EU) 2015/2283.		
Fermented soybean extract	***Specified food category***	***Maximum levels***	Applicant: Progress Biotech BV of Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands.		
	Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder form) intended for the adult population, excluding pregnant and lactating women	100 mg/day			
Spermidine-rich wheat germ extract (*Triticum aestivum*)	***Specified food category***	***Maximum levels***	The data protection will expire at the end of 29 June 2027.		
	Food Supplements as defined in Directive 2002/46/ EC intended for the adult population, excluding pregnant and lactating women	Equivalent of max. 6 mg/day spermidine			
Sucromalt	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs containing it shall		
	Not specified				

<table>
<tr><td></td><td colspan="2"></td><td>be ‘Sucromalt’.
2. The designation of the novel food on the labelling shall be accompanied by indication that the product is a source of glucose and fructose.</td><td></td><td></td></tr>
<tr><td>Sugar cane fibre</td><td>Specified food category</td><td>Maximum levels</td><td rowspan="10"></td><td rowspan="10"></td><td rowspan="10"></td></tr>
<tr><td></td><td>Bread</td><td>8 %</td></tr>
<tr><td></td><td>Bakery goods</td><td>5 %</td></tr>
<tr><td></td><td>Meat and muscle products</td><td>3 %</td></tr>
<tr><td></td><td>Seasonings and spices</td><td>3 %</td></tr>
<tr><td></td><td>Grated cheeses</td><td>2 %</td></tr>
<tr><td></td><td>Special diet foods</td><td>5 %</td></tr>
<tr><td></td><td>Sauces</td><td>2 %</td></tr>
<tr><td></td><td>Beverages</td><td>5 %</td></tr>
<tr><td>[F44Sugars obtained from cocoa (Theobroma cacao L.) pulp</td><td colspan="2">Not specified</td><td>The designation of the novel food on the labelling of the foodstuffs</td><td></td><td></td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>containing it shall be ‘sugars obtained from cocoa (Theobroma cacao L.) pulp’, ‘Glucose obtained from cocoa (Theobroma cacao L.) pulp’ or ‘Fructose obtained from cocoa (Theobroma cacao L.) pulp’, depending on the form used.]</td><td></td><td></td></tr>
<tr><td>Sunflower oil extract</td><td>Specified food category</td><td>Maximum levels</td><td>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Sunflower oil extract ’</td><td></td><td></td></tr>
<tr><td></td><td>Food Supplements as defined in Directive 2002/46/EC</td><td>1,1 g/day</td><td></td><td></td><td></td></tr>
<tr><td>Dried Tetraselmis chuii microalgae</td><td>Specified food category</td><td>Maximum levels</td><td>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Dried microalgae Tetraselmis chuii ’ or ‘Dried microalgae T. chuii ’ Food supplements containing dried</td><td></td><td></td></tr>
<tr><td></td><td>Sauces</td><td>20 % or 250mg/day</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Special salts</td><td>1 %</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Condiment</td><td>250 mg/day</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Food Supplements as defined in Directive 2002/46/EC</td><td>250 mg/day</td><td></td><td></td><td></td></tr>
</table>

			microalgae *Tetraselmis chuii* shall bear the following statement: 'Contains negligible amounts of iodine'		
***Therapon barcoo* / Scortum**	Intended use identical to that of the salmon, namely the preparation of culinary fish products and dishes, including cooked, raw, smoked and baked fish products				
D-Tagatose	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'D-Tagatose'. 2. The labelling of any product where the level of D-Tagatose exceeds 15 g per serving and all		
	Not specified				

			beverages containing greater than 1 % D-Tagatose (as consumed) shall bear a statement ‘excessive consumption may produce laxative effects’.		
[F20Taxifolin-rich extract	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ taxifolin-rich extract ’		
	Yogurt plain/ Yogurt with fruits (*)	0,020 g/kg			
	Kephir (*)	0,008 g/kg			
	Buttermilk (*)	0,005 g/kg			
	Milk powder (*)	0,052 g/kg			
	Cream (*)	0,070 g/kg			
	Sour cream (*)	0,050 g/kg			
	Cheese (*)	0,090 g/kg			
	Butter (*)	0,164 g/kg			
	Chocolate confectionery	0,070 g/kg			
	Non-alcoholic beverages	0,020 g/L			
	Food supplements as defined in Directive 2002/46/EC intended for	100 mg/day			

	the general population, excluding infants, young children, children and adolescents younger than 14 years				
	(*) When used in milk products Taxifolin-rich extract may not replace in whole or in part, any milk constituent**]**				
Trehalose	***Specified food category***	***Maximum levels***	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Trehalose’ and shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs		
	Not specified				

<table>
<tr><td></td><td></td><td></td><td>containing it.
2. The designation of the novel food on the labelling shall be accompanied by indication that the ‘Trehalose is a source of glucose’.</td><td></td><td></td></tr>
<tr><td>[F45UV-treated baker’s yeast (Saccharomyces cerevisiae)</td><td>Specified food category</td><td>Maximum level of vitamin D₂</td><td rowspan="4">The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D₂ yeast”.</td><td rowspan="4">The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special medical purposes.]</td><td></td></tr>
<tr><td>Yeast-leavened breads and rolls</td><td>5 µg/100 g</td><td></td></tr>
<tr><td>Yeast-leavened fine bakery wares</td><td>5 µg/100 g</td><td></td></tr>
<tr><td>Food supplements as defined in the Food Supplements (England) Regulations 2003</td><td>In accordance with any relevant requirements contained in regulations applying in relation to England and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit)</td><td></td></tr>
</table>

	Regulations 2019	
Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast, 200µg/100 g for dry yeast	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D_2 yeast”. The labelling of the novel food must bear a statement that the food is only intended for baking and it should not be eaten raw. The labelling of the novel food must bear instructions for use for the final consumer to ensure a maximum concentration of 5 µg/100 g of vitamin D_2 in the final home-baked product is not exceeded.
Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or
Soups and salads	5 µg/100 g	

Fried or extruded cereal, seed or root-based products	5 µg/100 g	"vitamin D_2 yeast".		
Infant formula and follow-on formula as defined in Regulation (EU) No. 609/2013[i]	In accordance with Regulation (EU) No. 609/2013			
Processed cereal-based food as defined in Regulation (EU) No. 609/2013	In accordance with Regulation (EU) No. 609/2013			
Processed fruit products	1.5 µg/100 g			
Processed vegetables	2 µg/100 g			
Bread and similar products	5 µg/100 g			
Breakfast cereals	4 µg/100 g			
Pasta, doughs and similar products	5 µg/100 g			
Other cereal-based products	3 µg/100 g			
Spices, seasonings, condiments, sauce ingredients, dessert sauces/ toppings	10 µg/100 g			
Protein products	10 µg/100 g			
Cheese	2 µg/100 g			

	Dairy desserts and similar products	2 µg/100 g			
	Fermented milk or fermented cream	1.5 µg/100 g			
	Dairy powders and concentrates	25 µg/100 g			
	Milk based products, whey and cream	0.5 µg/100 g			
	Meat and dairy analogues	2.5 µg/100 g			
	Total diet replacement for weight control as defined in Regulation (EU) No. 609/2013	5 µg/100 g			
	Meal replacement for weight control	5 µg/100 g			
	Food for special medical purposes as defined in Regulation (EU) No. 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended.			
[F46UV-treated baker's yeast (*Saccharomyces cerevisiae*)	*Specified food category*	*Maximum levels of Vitamin D#*	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or	The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based	
	Yeast-leavened breads and rolls	5 µg/100 g			

Yeast-leavened fine bakery wares	5 µg/100 g	"vitamin D# yeast".	food and food for special medical purposes.]
Food supplements as defined in the Food Supplements (Scotland) Regulations 2003	In accordance with any relevant requirements contained in regulations applying in relation to Scotland and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019		
Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dry yeast	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D# yeast". The labelling of the novel food must bear a statement that the food is only intended for baking and it should not be eaten raw. The labelling of the novel food must bear instructions for use for the final consumer	

		to ensure a maximum concentration of 5µg/100g of vitamin D# in the final home-baked product is not exceeded.		
Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D# yeast”.		
Soups and salads	5 µg/100 g			
Fried or extruded cereal, seed or root-based products	5 µg/100 g			
Infant formula and follow-on formula as defined in Regulation (EU) No. 609/2013	In accordance with Regulation (EU) No. 609/2013			
Processed cereal-based food as defined in Regulation (EU) No. 609/2013	In accordance with Regulation (EU) No. 609/2013			
Processed fruit products	1.5 µg/100 g			
Processed vegetables	2 µg/100 g			
Bread and similar products	5 µg/100 g			
Breakfast cereals	4 µg/100 g			

Pasta, doughs and similar products	5 µg/100 g
Other cereal-based products	3 µg/100 g
Spices, seasonings, condiments, sauce ingredients, dessert sauces/ toppings	10 µg/100 g
Protein products	10 µg/100 g
Cheese	2 µg/100 g
Dairy desserts and similar products	2 µg/100 g
Fermented milk or fermented cream	1.5 µg/100 g
Dairy powders and concentrates	25 µg/100 g
Milk-based products, whey and cream	0.5 µg/100 g
Meat and dairy analogues	2.5 µg/100 g
Total diet replacement for weight control as defined by Regulation (EU) No. 609/2013	5 µg/100 g
Meal replacement for weight control	5 µg/100 g

	Food for special medical purposes as defined by Regulation (EU) No. 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
[F47UV-treated baker's yeast (*Saccharomyces cerevisiae*)	***Specified food category***	***Maximum levels of vitamin D_2***	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D_2 yeast".	The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special medical purposes.**]**	
	Yeast-leavened breads and rolls	5 µg/100 g			
	Yeast-leavened fine bakery wares	5 µg/100 g			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003	In accordance with any relevant requirements contained in regulations applying in relation to Wales and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019			
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dry yeast	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D_2 yeast". The labelling of the novel		

			food must bear a statement that the food is only intended for baking and should not be eaten raw. The labelling of the novel food must bear instructions for use for the final consumer to ensure a maximum concentration of 5µg/100g of vitamin D_2 in the final home-baked product is not exceeded.		
UV-treated bread	**Dishes, including ready-to-eat meals (excluding soups and salads)**	**3 µg/100 g**	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D_2 yeast”.		
	Soups and salads	**5 µg/100 g**			
	Fried or extruded cereal, seed or root-based products	**5 µg/100 g**			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	**In accordance with Regulation (EU) No 609/2013**			
	Processed cereal-	**In accordance**			

based food as defined in Regulation (EU) No 609/2013	**with Regulation (EU) No 609/2013**
Processed fruit products	**1.5 µg/100 g**
Processed vegetables	**2 µg/100 g**
Bread and similar products	**5 µg/100 g**
Breakfast cereals	**4 µg/100 g**
Pasta, doughs and similar products	**5 µg/100 g**
Other cereal-based products	**3 µg/100 g**
Spices, seasonings, condiments, sauce ingredients, dessert sauces/ toppings	**10 µg/100 g**
Protein products	**10 µg/100 g**
Cheese	**2 µg/100 g**
Dairy desserts and similar products	**2 µg/100 g**
Fermented milk or fermented cream	**1.5 µg/100 g**
Dairy powders and concentrates	**25 µg/100 g**
Milk-based products, whey and cream	**0.5 µg/100 g**

	Meat and dairy analogues	**2.5 µg/100 g**			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	**5 µg/100 g**			
	Meal replacement for weight control	**5 µg/100 g**			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
UV-treated milk	***Specified food category***	***Maximum levels of vitamin D*** $_3$	1. The designation on the label of the novel food shall be 'UV-treated'. Where UV-treated milk contains an amount of vitamin D that is considered significant in		
	Pasteurised whole milk as defined in Regulation (EU) No 1308/2013 to be consumed as such	5-32 µg/kg for general population excluding infants			
	Pasteurised semi-skimmed milk as defined in Regulation (EU) No 1308/2013 to be consumed as such	1-15 µg/kg for general population excluding infants	2.		

			accordance with Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council, the designation for the labelling shall be accompanied by 'contains vitamin D produced by UV-treatment' or 'milk containing vitamin D resulting from UV-treatment'.		
[F9Vitamin D_2 mushroom powder	***Specified food category***	***Maximum levels of vitamin D_2*** [k]	The designation of the novel food on the labelling of the foodstuffs		Authorised on 27 August 2020. This inclusion is based on proprietary

Breakfast cereals	2,25 µg of vitamin D_2 /100 g	containing it shall be 'UV-treated mushroom powder containing vitamin D' or 'UV-treated mushroom powder containing vitamin D_2' The labelling of food supplements containing vitamin D_2 mushroom powder shall bear a statement that they should not be consumed by infants		scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Oakshire Naturals, LP., PO Box 388 Kennett Square, Pennsylvania 19348, United States. During the period of data protection, the novel food vitamin D_2 mushroom powder is authorised for placing on the market within the Union only by Oakshire Naturals, LP., 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
Yeast-leavened bread and pastries	2,25 µg of vitamin D_2 /100 g			
Grain products and pastas	2,25 µg of vitamin D_2 /100 g			
Fruit juice and fruit/ vegetable blend beverages	1,125 µg of vitamin D_2 /100 mL			
Milk and dairy products (excluding fluid milks)	2,25 µg of vitamin D_2 /100 g/1,125 µg of vitamin D_2 /100 mL (beverages)			
Cheese (excluding cottage cheese, ricotta cheese, and hard-grating cheeses)	2,25 µg of vitamin D_2 /100 g			
Meal replacement bars and beverages	2,25 µg of vitamin D_2 /100 g/1,125 µg of vitamin D_2 /100 mL (beverages)			
Dairy analogues	2,25 µg of vitamin D_2 /100 g/1,125 µg of vitamin D_2 /100 mL (beverages)			
Meat analogues	2,25 µg of vitamin D_2 /100 g			
Soups and broths	2,25 µg of vitamin D_2 /100 g			

	Extruded vegetable snacks	2,25 µg of vitamin D_2 /100 g			Regulation (EU) 2015/2283 or with the agreement of Oakshire Naturals, LP. End date of the data protection: 27 August 2025.
	Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 excluding those intended for infants	15 µg/day			
	Food supplements as defined in Directive 2002/46/EC intended for the general population excluding infants	15 µg/day]			
[F48Vitamin D_2 mushroom powder	***Specified food category***	***Maximum levels of vitamin D_2***	The designation of the novel food on the labelling of food containing it is "UV-treated mushroom powder containing vitamin D_2". The labelling of food supplements, as defined in the Food Supplements (England) Regulations 2003, containing vitamin D_2 mushroom powder		Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283. Applicant: MBio, Monaghan Mushrooms of Tullygony, Tyholland Co Monaghan, Ireland, H18 FW95. During the period of data
	Breakfast cereals	2.1 µg/100 g			
	Yeast leavened bread and similar pastries	2.1 µg/100 g			
	Grain products and pasta and similar products	2.1 µg/100 g			
	Fruit/ vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			

Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)	must bear a statement that they should not be consumed by infants and children under 3 years of age.]		protection, Vitamin D_2 mushroom powder is authorised for placing on the market, within England, only by MBio, Monaghan Mushrooms 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 2015/2283 or with the agreement of MBio, Monaghan Mushrooms.
Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
Meat analogues	2.1 µg/100 g			
Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
Extruded vegetable snacks	2.1 µg/100 g			
Meal replacement for weight control	2.1 µg/100 g			
Food for special medical purposes as defined in Regulation (EU) No. 609/2013 excluding those	In accordance with the particular nutritional requirements of the persons for whom the products are intended.			

	intended for infants				
	Food supplements as defined in the Food Supplements (England) Regulations 2003 excluding food supplements for infants and children under 3 years of age.	15 µg of vitamin D_2/ day			
[F49Vitamin D# mushroom powder	*Specified food category*	*Maximum levels of vitamin D#*	The designation of the novel food on the labelling of food containing it is "UV-treated mushroom powder containing vitamin D#". The labelling of food supplements, as defined by the Food Supplements (Scotland) Regulations 2003, containing vitamin D# mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.		Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D# mushroom powder is authorised for placing on the market,
	Breakfast cereals	2.1 µg/100 g			
	Yeast leavened bread and similar pastries	2.1 µg/100 g			
	Grain products and pasta and similar products	2.1 µg/100 g			
	Fruit/ vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and	1.1 µg/100 ml (marketed			

analogues as beverages	as such or reconstituted as instructed by the manufacturer)			within Scotland, only by MBio, Monaghan Mushrooms 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 MBio, Monaghan Mushrooms. The data protection will expire at the end of 14 May 2028.**]**
Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
Meat analogues	2.1 µg/100 g			
Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
Extruded vegetable snack	2.1 µg/100 g			
Meal replacement for weight control	2.1 µg/100 g			
Food for special medical purposes as defined in Regulation (EU) 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 excluding	15 µg of vitamin D#/ day			

	food supplements for infants and children under 3 years of age				
[F50Vitamin D_2 mushroom powder	*Specified food category*	*Maximum levels of vitamin D_2*	The designation of the novel food on the labelling of food containing it is "UV-treated mushroom powder containing vitamin D_2". The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D_2 mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.		Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D_2 mushroom powder is authorised for placing on the market, within Wales, only by MBio, Monaghan Mushrooms unless a subsequent applicant obtains authorisation for the novel
	Breakfast cereals	2.1 µg/100 g			
	Yeast-leavened bread and similar pastries	2.1 µg/100 g			
	Grain products and pasta and similar products	2.1 µg/100 g			
	Fruit / vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed			

		by the manufacturer)			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 MBio, Monaghan Mushrooms. The data protection will expire at the end of 14 May 2028.]
	Meat analogues	2.1 µg/100 g			
	Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Extruded vegetable snack	2.1 µg/100 g			
	Meal replacement for weight control	2.1 µg/100 g			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and children under 3 years of age	15 µg of vitamin D_2/ day			
Vitamin K_2 (menaquinone)	To be used in compliance with Directive 2002/46/ EC, Regulation (EU) No		The designation of the novel food on the		

	609/2013 and/or Regulation (EC) No 1925/2006		labelling of the foodstuffs containing it shall be 'Menaquinone' or 'Vitamin K_2'		
Wheat bran extract	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Wheat bran extract '	The ' Wheat Bran Extract ' may not be introduced onto the market as a food supplement or food supplement ingredient. Nor may it be added to infant formula.	
	Beer and substitutes	0,4 g/100 g			
	Ready to eat cereals	9 g/100 g			
	Dairy products	2,4 g/100 g			
	Fruit and vegetable juices	0,6 g/100 g			
	Soft drinks	0,6 g/100 g			
	Meat preparations	2 g/100 g			
[F51Xylo-oligosaccharides	***Specified food category***	***Maximum levels*** [i]	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' Xylo-oligosaccharides '		
	White bread	14 g/kg			
	Wholemeal bread	14 g/kg			
	Breakfast cereals	14 g/kg			
	Biscuits	14 g/kg			
	Soy drink	3,5 g/kg			
	Yoghurt [i]	3,5 g/kg			
	Fruit spreads	30 g/kg			
	Chocolate confectionery	30 g/kg			
	Food supplements as defined in Directive 2002/46/ EC for the general adult population	2 g/day]			

⌈[F52] *Yarrowia lipolytica* yeast biomass	**Specified food category**	**Maximum levels**	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' *Yarrowia lipolytica* yeast heat-killed biomass'		
	Food Supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	6 g/day for children from 10 years of age, adolescents and general adult population 3 g/day for children from 3 to 9 years of age⌋			
⌈[F53]3'-Sialyllactose (3'-SL) sodium salt (microbial source)	**Specified food category**	**Maximum levels (expressed as 3'-Sialyllactose)**	The designation of the novel food on the labelling of the foodstuffs containing it is '3'-Sialyllactose sodium salt'. The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed: (a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day (b) by infants and young children.		Included in the list on 30th June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283. Applicant: Glycom A/S of Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, 3'-Sialyllactose sodium salt is authorised for placing on the market within England only by Glycom A/S unless a subsequent applicant obtains authorisation
	Unflavoured pasteurised and sterilised (including UHT) milk products	0.25 g/L unflavoured			
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L			
	Cereal bars	2.5g/kg			
	Infant formula as	0.2 g/L in the final product			

defined in Regulation 609/2013	ready for use, marketed as such or reconstituted as instructed by the manufacturer			for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation 2015/2283 or with the agreement of Glycom A/S. The data protection will expire at the end of 29th June 2027.]
Follow-on formula as defined in Regulation 609/2013	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Processed cereal-based food and baby food for infants and young children as defined in Regulation 609/2013	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer. 1.25 g/kg for products other than beverages			
Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Total diet replacement food for weight control as defined in Regulation 609/2013	0.5 g/L (beverages) 5g/kg (products other than beverages)			

	Food for special medical purposes as defined in Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined the Food Supplements (England) Regulations 2003, excluding food supplements for infants and young children	0.5 g/day			
[F54 3'-Sialyllactose (3'-SL) sodium salt (microbial source)	*Specified food category*	*Maximum levels (expressed as 3'-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it is "3'-Sialyllactose sodium salt". The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day, b) by infants and young children.		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 3'-sialyllactose sodium salt is authorised for
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/L			
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages)			
	Unflavoured fermented milk-based products	2.5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding	0.25 g/L (beverages)			

drinks with a pH less than 5)				
Cereal bars	0.5 g/kg (products other than beverages)			
Infant formula as defined in Regulation (EU) 609/2013	0.25 g/L			
Follow-on formula as defined in Regulation (EU) 609/2013	2.5 g/kg			
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) 609/2013	0.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Total diet replacement foods for weight control as defined in Regulation (EU) 609/2013	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed			placing on the market within Scotland only by Glycom A/S, 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 Glycom A/S. The data protection will expire at the end of 29 June 2027.**]**

		by the manufacturer			
	Food for special medical purposes as defined in Regulation (EU) 609/2013	1.25 g/kg for products other than beverages			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003, excluding food supplements for infants and young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
[F55 3'-Sialyllactose (3'-SL) sodium salt (microbial source)	*Specified food category*	*Maximum levels (expressed as 3'-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it is "3'-Sialyllactose sodium salt". The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark. During the period of data protection, 3'-Sialyllactose sodium salt is
	Unflavoured pasteurised and sterilised (including UHT) milk products	0.25 g/L unflavoured			
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5 g/kg (products other than beverages)			

Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L	consumed the same day; b) by infants and young children.		authorised for placing on the market within Wales only by Glycom A/S 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 Glycom A/S. The data protection ends at the end of 29 June 2027.]
Cereal bars	2.5 g/kg			
Infant formula as defined in Regulation (EU) No 609/2013	0.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Follow-on formula as defined in Regulation (EU) No 609/2013	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer. 1.25 g/kg (products other than beverages)			
Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed			

		by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	0.5 g/L (beverages) 5g/kg (products other than beverages)			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	0.5 g/day			
[F53 6'-Sialyllactose (6'-SL) sodium salt (microbial source)	**Specified food category**	***Maximum levels (expressed as 6'-Sialyllactose)***	The designation of the novel food on the labelling of the foodstuffs containing it is '6'-Sialyllactose sodium salt'. The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear		Included in the list on 30th June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L			
	Unflavoured fermented	0.5 g/L (beverages)			

milk-based products	2.5g/ kg (products other than beverages)	a statement that they should not be consumed: (a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day (b) by infants and young children.		Applicant: Glycom A/S of Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within England only by Glycom A/S 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 2015/2283 or with the agreement of Glycom A/S. The data protection will expire at the end of 29th June 2027.]
Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/ kg (products other than beverages)			
Beverages (flavoured drinks, excluding drinks with a PH less than 5)	0.5 g/L			
Cereal bars	5.0 g/kg			
Infant formula as defined in Regulation 609/2013	0.4 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Follow-on formula as defined in Regulation 609/2013	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Processed cereal-based food and baby food for infants and young children as defined in Regulation 609/2013	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 2.5 g/ kg for products			

		other than beverages			
	Milk based drinks and similar products intended for young children	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation 609/2013	1.0 g/L (beverages) 10.0 g/kg (products other than beverages)			
	Food for special medical purposes as defined in Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in the Food Supplements (England) Regulations 2003, excluding food supplements for infants and young children	1.0 g/day			
[F56 6'-Sialyllactose (6'-SL) sodium salt (microbial source)	*Specified food category*	*Maximum levels (expressed as 6'-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs		Included in the list on 30 June 2022. This inclusion is based on proprietary

Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L	containing it is '6'-Sialyllactose sodium salt'. The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt must bear a statement that they should not be consumed: (a) if foods containing added 6'-Sialyllactose sodium salt are consumed on the same day, (b) by infants and young children.		scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 6'-sialyllactose sodium salt is authorised for placing on the market within Scotland only by Glycom A/S, 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 Glycom A/S.
Unflavoured fermented milk-based products	0.5 g/L (beverages)			
Flavoured fermented milk-based products including heat-treated products	2.5 g/kg (products other than beverages)			
Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.5 g/L (beverages)			
Cereal bars	5.0 g/kg (products other than beverages)			
Infant formula as defined in Regulation (EU) 609/2013	0.5 g/L			
Follow-on formula as defined in Regulation (EU) 609/2013	5.0 g/kg			
Processed cereal-based food and baby food for infants and young children as	0.4 g/L in the final product ready for use, marketed as such or reconstituted as instructed			

	defined in Regulation (EU) 609/2013	by the manufacturer			The data protection will expire at the end of 29June 2027.**]**
	Milk based drinks and similar products intended for young children	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) 609/2013	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Food for special medical purposes as defined in Regulation (EU) 609/2013	2.5 g/kg for products other than beverages			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003, excluding food supplements for infants and young children	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
[F57"6'-Sialyllactose (6'-SL) sodium salt	*Specified food category*	*Maximum levels (expressed*	The designation of the novel food on the		Included in the list on 30 June 2022.

(microbial source)		*as 6'-Sialyllactose)*	labelling of the foodstuffs containing it is "6'-Sialyllactose sodium salt". The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		This inclusion is authorised based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark. During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S 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 Glycom A/S.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L			
	Unflavoured fermented milk-based products	0.5 g/L (beverages) 2.5 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a PH less than 5)	0.5 g/L			
	Cereal bars	5.0 g/kg			
	Infant formula as defined in Regulation (EU) No 609/2013	0.4 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined in Regulation (EU) No 609/2013	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 2.5 g/kg (products other than beverages)			The data protection ends at the end of 29 June 2027.]
Milk based drinks and similar products intended for young children	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	1.0 g/L (beverages) 10.0 g/kg (products other than beverages)			
Food for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food supplements as defined in the Food Supplements (Wales) Regulations 2003,	1.0 g/day			

	excluding food supplements for infants and young children				
Yeast beta-glucans	***Specified food category***	**1.0 g/L (beverages)**	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Yeast (*Saccharomyces cerevisiae*) beta-glucans'		
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	10.0 g/kg (products other than beverages)			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013, excluding food for special medical purposes intended for infants and young children	1.0 g/day.			
	Beverages based on fruit and/or vegetable juices	1,3 g/kg			

including concentrate and dehydrated juices				
Fruit-flavoured drinks	0,8 g/kg			
Cocoa beverages preparation powder	38,3 g/kg (powder)			
Other beverages	0,8 g/kg (ready to drink)			
	7 g/kg (powder)			
Cereal bars	6 g/kg			
Breakfast cereals	15,3 g/kg			
Wholegrain and high fibre instant hot breakfast cereals	1,5 g/kg			
Cookie-type biscuits	6,7 g/kg			
Cracker-type biscuits	6,7 g/kg			
Milk based beverages	3,8 g/kg			
Fermented milk products	3,8 g/kg			
Milk product analogues	3,8 g/kg			
Dried milk/ milk powder	25,5 g/kg			
Soups and soup mixes	0,9 g/kg (ready to eat)			
	1,8 g/kg (condensed)			
	6,3 g/kg (powder)			

	Chocolate and confectionery	4 g/kg			
	Protein bars and powders	19,1 g/kg			
	Jam, marmalade and other fruit spreads	11,3 g/kg			
[F58Zeaxanthin	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Zeaxanthin ’ .		
	Food Supplements as defined in Directive 2002/46/EC	2 mg/day**]**			
Zinc L-pidolate	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘ Zinc L-pidolate ’		
	Foods covered by Regulation (EU) No 609/2013	3 g/day			
	Milk based drinks and similar products intended for young children				
	Meal replacement for weight control				
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
	Food bearing statement on				

	the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
	Food Supplements as defined in Directive 2002/46/EC]				

a	Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).
b	Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).
c	Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
d	Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).
e	Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67).
f	Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulation (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) 1234/2007 (OJ L 347, 20.12.2013, p. 671).
g	**[**F6Maximum use levels in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.**]**
h	**[**F7Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).**]**
i	**[**F8When used in milk products xylo-oligosaccharides shall not replace, in whole or in part, any milk constituent.
j	Maximum levels calculated on the basis of the specifications of Powder form 1.**]**
k	**[**F9The minimum specification for vitamin D content in vitamin D_2 mushroom powder of 1 000 µg vitamin D_2/gram of mushroom powder is used.**]**

Textual Amendments

F6 Inserted by Commission Implementing Regulation (EU) 2019/1294 of 1 August 2019 authorising the placing on the market of betaine as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F7 Inserted by Commission Implementing Regulation (EU) 2020/500 of 6 April 2020 authorising the placing on the market of partially defatted chia seed (Salvia hispanica) powders as novel foods under

Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F8 Inserted by Commission Implementing Regulation (EU) 2020/916 of 1 July 2020 authorising the extension of use of xylo-oligosaccharides as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F9 Inserted by Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020 authorising the placing on the market of vitamin D2 mushroom powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F10 Inserted by Commission Implementing Regulation (EU) 2019/506 of 26 March 2019 authorising the placing on the market of D-ribose as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F11 Substituted by Commission Implementing Regulation (EU) 2019/110 of 24 January 2019 authorising an extension of use of Allanblackia seed oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F12 Substituted by Commission Implementing Regulation (EU) 2019/1686 of 8 October 2019 authorising the extension of use of bovine milk basic whey protein isolate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F13 Substituted by Commission Implementing Regulation (EU) 2020/24 of 13 January 2020 authorising an extension of use of chia seeds (Salvia hispanica) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (Salvia hispanica) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F14 Inserted by Commission Implementing Regulation (EU) 2018/1631 of 30 October 2018 authorising the placing on the market of cranberry extract powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F15 Inserted by Commission Implementing Regulation (EU) 2018/2016 of 18 December 2018 authorising the placing on the market of decorticated grains of Digitaria exilis as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F16 Inserted by Commission Implementing Regulation (EU) 2018/1133 of 13 August 2018 authorising the placing on the market of dried aerial parts of Hoodia parviflora as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F17 Substituted by Commission Implementing Regulation (EU) 2019/1272 of 29 July 2019 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods and Implementing Decision (EU) 2017/2078 authorising an extension of use of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (Text with EEA relevance).

F18 Inserted by Commission Implementing Regulation (EU) 2020/1559 of 26 October 2020 amending Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance).

F19 Inserted by Commission Implementing Regulation (EU) 2018/1647 of 31 October 2018 authorising the placing on the market of egg membrane hydrolysate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F20 Substituted by Commission Implementing Regulation (EU) 2020/1559 of 26 October 2020 amending Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance).

F21 Inserted by Commission Implementing Regulation (EU) 2020/206 of 14 February 2020 authorising the placing on the market of fruit pulp, pulp juice, concentrated pulp juice from Theobroma cacao L. as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F22 Inserted by Commission implementing Regulation (EU) 2019/1979 of 26 November 2019 authorising the placing on the market of 2'-Fucosyllactose/Difucosyllactose mixture as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F23 Words in Annex Table 1 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **2(2)(a)(i)**; words inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 1 para. 1**; and words inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 1 para. 1**

F24 Words in Annex Table 1 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **2(2)(a)(ii)**; words inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 1 para. 1**; and words inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 1 para. 1**

F25 Inserted by Commission Implementing Regulation (EU) 2020/917 of 1 July 2020 authorising the placing on the market of infusion from coffee leaves of Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F26 Substituted by Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food lactitol (Text with EEA relevance).

F27 Inserted by Commission Implementing Regulation (EU) 2020/484 of 2 April 2020 authorising the placing on the market of lacto-N-tetraose as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F28 Inserted by Commission Implementing Regulation (EU) 2018/1991 of 13 December 2018 authorising the placing on the market of berries of Lonicera caerulea L. as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F29 Inserted by Commission Implementing Regulation (EU) 2018/1123 of 10 August 2018 authorising the placing on the market of 1-methylnicotinamide chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F30 Inserted by Commission Implementing Regulation (EU) 2020/16 of 10 January 2020 authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F31 Inserted by Commission Implementing Regulation (EU) 2019/1976 of 25 November 2019 authorising the placing on the market of Phenylcapsaicin as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F32 Substituted by Commission Implementing Regulation (EU) 2020/973 of 6 July 2020 authorising a change of the conditions of use of the novel food 'protein extract from pig kidneys' and amending Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F33 Inserted by Commission Implementing Regulation (EU) 2018/1122 of 10 August 2018 authorising the placing on the market of pyrroloquinoline quinone disodium salt as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F34 Inserted by Commission Implementing Regulation (EU) 2018/1633 of 30 October 2018 authorising the placing on the market of refined shrimp peptide concentrate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F35 Substituted by Commission Implementing Regulation (EU) 2019/387 of 11 March 2019 authorising an extension of use of Schizochytrium sp. (ATCC PTA-9695) oil as a novel food and the change of the designation and of the specific labelling requirement of Schizochytrium sp. (ATCC PTA-9695) oil under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F36 Words in Annex Table 1 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), reg. 1(3), **Sch. 1**

F37 Words in Annex Table 1 inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 2 para. 1**

F38 Words in Annex Table 1 inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 2 para. 1**

F39 Substituted by Commission Implementing Regulation (EU) 2019/109 of 24 January 2019 authorising an extension of use of Schizochytrium sp. oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F40 Words in Annex Table 1 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), reg. 1(3), **Sch. 2**

F41 Words in Annex Table 1 inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 3 para. 1**

F42 Words in Annex Table 1 inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 3 para. 1**

F43 Inserted by Commission Implementing Regulation (EU) 2018/2017 of 18 December 2018 authorising the placing on the market of syrup from Sorghum bicolor (L.) Moench as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F44 Inserted by Commission Implementing Regulation (EU) 2020/1634 of 4 November 2020 authorising the placing on the market of sugars obtained from cocoa (Theobroma cacao L.) pulp as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F45 Words in Annex Table 1 substituted (E.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (England) Regulations 2023 (S.I. 2023/334), reg. 1(1), **Sch. 4** (with reg. 4)

F46 Words in Annex Table 1 substituted (S.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023 (S.S.I. 2023/78), reg. 1(1), **sch. 4 para. 1** (with reg. 5)

F47 Words in Annex Table 1 substituted (W.) (15.5.2023) by The Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023 (S.I. 2023/343), reg. 1(4), **Sch. 4 para. 2** (with reg. 4)

F48 Words in Annex Table 1 inserted (E.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (England) Regulations 2023 (S.I. 2023/334), reg. 1(1), **Sch. 5** (with reg. 4)

F49 Words in Annex Table 1 inserted (S.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023 (S.S.I. 2023/78), reg. 1(1), **sch. 5 para. 1** (with reg. 5)

F50 Words in Annex Table 1 inserted (W.) (15.5.2023) by The Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023 (S.I. 2023/343), reg. 1(4), **Sch. 5 para. 2** (with reg. 4)

F51 Substituted by Commission Implementing Regulation (EU) 2020/916 of 1 July 2020 authorising the extension of use of xylo-oligosaccharides as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F52 Inserted by Commission Implementing Regulation (EU) 2019/760 of 13 May 2019 authorising the placing on the market of Yarrowia lipolytica yeast biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F53 Words in Annex Table 1 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), reg. 1(3), **Sch. 3** (as amended by S.I. 2022/619, regs. 1(1), **2(2)**)

F54 Words in Annex Table 1 inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 4 para. 1**

F55 Words in Annex Table 1 inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 4 para. 1**

F56 Words in Annex Table 1 inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 5 para. 1**

F57 Words in Annex Table 1 inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 5 para. 1**

F58 Substituted by Commission Implementing Regulation (EU) 2018/1132 of 13 August 2018 authorising the change of the designation and specific labelling requirement of the novel food synthetic zeaxanthin under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

TABLE 2: SPECIFICATIONS

Authorised Novel Food	**Specifications**
N **-Acetyl-D-neuraminic acid**	**Description:** *N* -Acetyl-D-neuraminic acid is a white to off-white crystalline powder **Definition:** **Chemical name:** IUPAC names: *N* -Acetyl-D-neuraminic acid (dihydrate) 5-Acetamido-3,5-dideoxy-D-glycero-D-galacto-non-2-ulopyranosonic acid (dihydrate) Synonyms:

	Sialic acid (dihydrate) **Chemical formula:** $C_{11}H_{19}NO_9$ (acid) $C_{11}H_{23}NO_{11}$ ($C_{11}H_{19}NO_9$ * $2H_2O$) (dihydrate) **Molecular mass:** 309,3 Da (acid) 345,3 (309,3 + 36,0) (dihydrate) **CAS No.:** 131-48-6 (free acid) 50795-27-2 (dihydrate) **Specifications:** Description: white to off-white crystalline powder pH (20 °C, 5 % solution): 1,7 – 2,5 *N* -Acetyl-D-neuraminic acid (dihydrate): > 97,0 % Water (dihydrate calculates to 10,4 %): ≤ 12,5 % (w/w) Ash, sulphated: < 0,2 % (w/w) Acetic acid (as free acid and/or sodium acetate): < 0,5 % (w/w) **Heavy Metals:** Iron: < 20,0 mg/kg Lead: < 0,1 mg/kg Residual proteins: < 0,01 % (w/w) **Residual solvents:** 2-Propanol: < 0,1 % (w/w) Acetone: < 0,1 % (w/w) Ethyl acetate: < 0,1 % (w/w) **Microbiological criteria:** *Salmonella:* Absence in 25 g Aerobic mesophilic total count:< 500 CFU/g Enterobacteriaceae: Absence in 10 g *Cronobacter (Enterobacter) sakazakii:* Absence in 10 g *Listeria monocytogenes:* Absence in 25 g *Bacillus cereus:* < 50 CFU/g Yeasts: < 10 CFU/g Moulds: < 10 CFU/g Residual endotoxins: < 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.
***Adansonia digitata* (Baobab) dried fruit pulp**	**Description/Definition:** The Baobab (*Adansonia digitata*) fruits are harvested from trees. The hard shells are cracked open and the pulp is separated from the seeds and the shell. This is milled, separated into coarse and fine lots (particle size 3 to 600 μ) and then packaged. **Typical nutritional components:** Moisture (loss on drying) (g/100 g): 4,5-13,7 Protein (g/100 g): 1,8-9,3 Fat (g/100 g): 0-1,6 Total carbohydrate (g/100 g): 76,3-89,5 Total sugars (as glucose): 15,2-36,5 Sodium (mg/100 g): 0,1-25,2 **Analytical specifications:** Foreign matter: Not more than 0,2 % Moisture (loss on drying) (g/100 g): 4,5-13,7 Ash (g/100 g): 3,8-6,6

***Ajuga reptans* extract from cell cultures**	**Description/Definition:** Hydroalcoholic extract from *Ajuga reptans* L. tissue cultures which is substantially equivalent to extracts from flowering aerial parts of *Ajuga reptans* obtained by traditional cultures.
L-Alanyl-L-Glutamine	**Description/Definition:** L-Alanyl-L-Glutamine is produced by fermentation with a genetically modified strain of *Escherichia coli* . During the fermentation process, the ingredient is secreted into the growth medium from which it is subsequently separated and purified to a concentration of > 98 %. Appearance: White crystalline powder Purity: > 98 % Infrared spectroscopy: Conformity with ref. standard Appearance of solution: Colourless and clear Assay (dry basis): 98-102 % Related substances (each): ≤ 0,2 % Residue on ignition: ≤ 0,1 % Loss on drying: ≤ 0,5 % Optical rotation: +9,0 - +11,0 ° pH (1 %; H_2O): 5,0-6,0 Ammonium (NH_4): ≤ 0,020 % Chloride (Cl): ≤ 0,020 % Sulphate (SO_4): ≤ 0,020 % **Microbiological criteria:** *Escherichia coli* : Absence/g
Algal oil from the microalgae *Ulkenia* sp.	**Description/Definition:** Oil from the micro-algae *Ulkenia* sp. Acid value: ≤ 0,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % DHA content: ≥ 32 %
[F11*Allanblackia* seed oil	**Description/Definition:** *Allanblackia* seed oil is obtained from the seeds of the allanblackia species: *A. floribunda* (synonymous with *A. parviflora*) and *A. stuhlmannii* . **Composition of fatty acids (as a % of the total fatty acids):** Lauric acid — Myristic acid — Palmitic acid (C12:0 – C14:0 – C16:0): sum of these acids < 4,0 % Stearic acid (C18:0): 45-58 % Oleic acid (C18:1): 40-51 % Poly unsaturated fatty acids (PUFA): < 2 % **Characteristics:** Free fatty acids: max 0,1 % of total fatty acids Trans fatty acids: max 1,0 % of total fatty acids Peroxide value: max 1,0 meq/kg Unsaponifiable matter: max 1,0 % (w/w) of the oil Saponification value: 185-198 mg KOH/g]
Aloe macroclada	**Description/Definition:**

Baker leaf extract	Powdered gel extract derived from the leaves of *Aloe macroclada* Baker which is substantially equivalent to the same gel derived from *Aloe vera* (L.) Burm.f. leaves. Ash: 25 % Dietary fibres: 28,6 % Fat: 2,7 % Moisture: 4,7 % Polysaccharides: 9,5 % Protein: 1,63 % Glucose: 8,9 %
[F60Antarctic Krill oil from *Euphausia superba*	**Description/Definition:** To produce lipid extract from Antarctic Krill (*Euphausia superba*) deep-frozen crushed krill or dried krill meal is subjected to lipid extraction with an approved extraction solvent (under Directive 2009/32/EC). Proteins and krill material are removed from the lipid extract by filtration. The extraction solvents and residual water are removed by evaporation. Saponification value: ≤ 230 mg KOH/g Peroxide value (PV): ≤ 3 meq O_2 /kg oil Oxidative stability: All food products containing Antarctic Krill oil from *Euphausia superba* should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC). Moisture and volatiles: ≤ 3 % or 0,6 expressed as water activity at 25 °C Phospholipids: ≥ 35 % to < 60 % Trans-fatty acids: ≤ 1 % EPA (eicosapentaenoic acid): ≥ 9 % DHA (docosahexaenoic acid): ≥ 5 %**]**
Antarctic Krill oil rich in phospholipids from *Euphausia superba*	**Description/Definition:** Oil rich in phospholipids is produced from Antarctic krill (*Euphausia superba*) by repeated solvent washings with an approved solvent (under Directive 2009/32/EC) to increase phospholipid content of the oil. Solvents are removed from the final product by evaporation. Saponification value: ≤ 230 mg KOH/g Peroxide value (PV): ≤ 3 meq O_2 /kg oil Moisture and volatiles: ≤ 3 % or 0,6 expressed as water activity at 25 °C Phospholipids: ≥ 60 % Trans-fatty acids: ≤ 1 % EPA (eicosapentaenoic acid): ≥ 9 % DHA (docosahexaenoic acid): ≥ 5 %
Arachidonic acid-rich oil from the fungus *Mortierella alpina*	**Description/Definition:** The clear yellow arachidonic acid-rich oil is obtained by fermentation of the non-genetically modified strains IS-4, I49-N18, FJRK-MA01 and CBS 210.32 of the fungus *Mortierella alpina* using a suitable liquid. The oil is then extracted from the biomass and purified. Arachidonic acid: ≥ 40 % by weight of the total fatty acid content Free fatty acids: ≤ 0,45 % of the total fatty acid content Trans fatty acids: ≤ 0,5 % of the total fatty acid content Unsaponifiable matter: ≤ 1,5 % Peroxide value (PV): ≤ 5 meq/kg Anisidin value: ≤ 20 Acid value: ≤ 1,0 KOH/g Moisture: ≤ 0,5 %

Argan oil from *Argania spinosa*	**Description/Definition:** Argan oil is the oil obtained by cold pressing of the almond like kernels of the fruits of *Argania spinosa* (L.) Skeels. Kernels may be roasted prior to pressing, but with no direct contact with a flame. **Composition:** Palmitic acid (C16:0): 12-15 % Stearic acid (C18:0): 5-7 % Oleic acid (C18:1): 43-50 % Linoleic acid (C18:2): 29-36 % Unsaponifiable matter: 0,3-2 % Total sterols: 100-500 mg/100 g Total tocopherols: 16-90 mg/100 g Oleic acidity: 0,2-1,5 % Peroxide value (PV): < 10 meq O_2 /kg
Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	**Description/Definition:** Astaxanthin is a carotenoid produced by *Haematococcus pluvialis* algae. Production methods for the growth of the algae are variable; using either closed systems exposed to sunlight or strictly controlled illuminated light; alternatively open ponds may be used. The algal cells are harvested and dried; the oleoresin is extracted using either super critical CO_2 or a solvent (ethyl acetate). The Astaxanthin is diluted and standardized to 2,5 %, 5,0 %, 7,0 %, 10 %, 15 % or 20 % using olive oil, safflower oil, Sunflower oil or MCT (Medium Chain Triglycerides). **Composition of the Oleoresin:** Fat: 42,2- 99 % Protein: 0,3-4,4 % Carbohydrate: 0-52,8 % Fibre: < 1,0 % Ash: 0,0-4,2 % Specification of Carotenoids w/w% Total Astaxanthins: 2,9-11,1 % 9-cis-astaxanthin: 0,3-17,3 % 13-cis-astaxanthin: 0,2-7,0 % Astaxanthin monoesters: 79,8-91,5 % Astaxanthin diesters: 0,16-19,0 % B-Carotene: 0,01-0,3 % Lutein: 0-1,8 % Canthaxanthin: 0-1,30 % **Microbiological criteria:** Total aerobic bacteria: < 3 000 CFU/g Yeast and Moulds: < 100 CFU/g Coliforms: < 10 CFU/g *E. coli* : Negative *Salmonella* : Negative *Staphylococcus* : Negative
Basil seeds (*Ocimum basilicum*)	**Description/Definition:** Basil (*Ocimum basilicum* L.) belongs to the family ‘ *Lamiaceae* ’ within the order ‘Lamiales’. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed. Highest level of purity of Basil seeds has to be ensured by filtering (optical, mechanical). Production process of fruit juice and fruit/vegetable blend beverages containing Basil seeds (*Ocimum basilicum* L.) includes seed

	pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place. Dry Matter: 94,1 % Protein: 20,7 % Fat: 24,4 % Carbohydrate: 1,7 % Dietary Fibre: 40,5 % (Method: AOAC 958,29) Ash: 6,78 %
[F6Betaine	**Description/Definition:** Betaine (N,N,N-trimethylglycine or carboxy-N,N,N-trimethylmethanaminium), in anhydrous $(CH_3)_3N^+CH_2COO^-$ (CAS No: 107-43-7) and monohydrate $(CH_3)3N^+CH_2COO^-.H_2O$ (CAS No: 590-47-6) forms is obtained from processing of sugar beets (i.e. molasses, vinasses or betaine-glycerol). **Characteristics/Composition** Appearance: Free-flowing white crystals Betaine: ≥ 99,0 % (w/w on dry weight basis) Moisture: ≤ 2,0 % (anhydrous); ≤ 15,0 % (monohydrate) Ash: ≤ 0,1 % pH: 5,0-7,0 Residual protein: ≤ 1,0 mg/g **Heavy metals:** Arsenic: < 0,1 mg/kg Mercury: < 0,005 mg/kg Cadmium: < 0,01 mg/kg Lead: < 0,05 mg/kg **Microbiological criteria:** Total viable count: ≤ 100 CFU/g Coliforms: Negative/10 g *Salmonella* sp.: Negative/25 g Yeast: ≤ 10 CFU/g Mould: ≤ 10 CFU/g CFU: Colony Forming Units.**]**
Fermented black bean extract	**Description/Definition:** Fermented black bean extract (Touchi extract) is a fine light-brown protein-rich powder obtained by water extraction of small soybeans (*Glycine max (L.) Merr.*) fermented with *Aspergillus oryzae* . The extract contains an α-glucosidase inhibitor. **Characteristics:** Fat: ≤ 1,0 % Protein: ≥ 55 % Water: ≤ 7,0 % Ash: ≤ 10 % Carbohydrate: ≥ 20 % α-glucosidase inhibitory activity: IC50 min 0,025 mg/ml Soy isoflavone: ≤ 0,3 g/100 g
Bovine lactoferrin	**Description/Definition:** Bovine lactoferrin is a protein that occurs naturally in cows' milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids. Production process: Bovine lactoferrin is isolated from skimmed milk or cheese whey via ion exchange and subsequent ultra-filtration steps.

	Finally, it is dried by freeze drying or spraying and the large particles are sieved out. It is a virtually odourless, light pinkish powder. **Physical-Chemical properties of Bovine lactoferrin:** Moisture: < 4,5 % Ash: < 1,5 % Arsenic: < 2,0 mg/kg Iron: < 350 mg/kg Protein: > 93 % of which bovine lactoferrin: > 95 % of which other proteins: < 5,0 % pH (2 % solution, 20 °C): 5,2-7,2 Solubility (2 % solution, 20 °C): complete
[F12Bovine milk basic whey protein isolate	**Description** Bovine milk basic whey protein isolate is a yellowish grey powder obtained from bovine skimmed milk via a series of isolation and purification steps. **Characteristics/Composition** Total protein (w/weight of product): ≥ 90 % Lactoferrin (w/weight of product): 25-75 % Lactoperoxidase (w/weight of product): 10-40 % Other proteins (w/weight of product): ≤ 30 % TGF-β2: 12-18 mg/100 g Moisture: ≤ 6,0 % pH (5 % solution w/v): 5,5 – 7,6 Lactose: ≤ 3,0 % Fat: ≤ 4,5 % Ash: ≤ 3,5 % Iron: ≤ 25 mg/100 g **Heavy Metals** Lead: < 0,1 mg/kg Cadmium: < 0,2 mg/kg Mercury: < 0,6 mg/kg Arsenic: < 0,1 mg/kg **Microbiological criteria:** Aerobic mesophilic count: ≤ 10 000 CFU/g *Enterobacteriaceae* : ≤ 10 CFU/g *Escherichia coli* : Negative/g Coagulase positive *Staphylococci:* Negative/g *Salmonella* : Negative/25 g *Listeria* : Negative/25 g *Cronobacter* spp.: Negative/25 g Moulds: ≤ 50 CFU/g Yeasts: ≤ 50 CFU/g CFU: Colony Forming Units**]**
***Buglossoides arvensis* seed oil**	**Description/Definition:** Refined Buglossoides oil is extracted from the seeds of *Buglossoides arvensis* (L.) I.M.Johnst Alpha-linolenic acid: ≥ 35 % w/w of total fatty acids Stearidonic acid: ≥ 15 % w/w of total fatty acids Linoleic acid: ≥ 8,0 % w/w of total fatty acids Trans fatty acids: ≤ 2,0 % w/w of total fatty acids Acid value: ≤ 0,6 mg KOH/g

	Peroxide value (PV): ≤ 5,0 meq O_2/kg Unsaponifiable content: ≤ 2,0 % Protein content (total nitrogen): ≤ 10 µg/ml Pyrrolizidine alkaloids: Not detectable with a detection limit of 4,0 µg/kg
***Calanus finmarchicus* oil**	**Description/Definition:** The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton) *Calanus finmarchicus* . The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids. **Specifications:** Water: < 1,0 % Wax esters: > 85 % Total fatty acids: > 46 % Eicosapentaenoic acid (EPA): > 3,0 % Docosahexaenoic acid (DHA): > 4,0 % Total fatty alcohols: > 28 % C20:1 n-9 fatty alcohol: > 9,0 % C22:1 n-11 fatty alcohol: > 12 % Trans fatty acids: < 1,0 % Astaxanthinesters: < 0,1 % Peroxide value (PV): < 3,0 meq. O_2/kg
Chewing gum base (monomethoxypolyethylene glycol)	**Description/Definition:** The novel food ingredient is a synthetic polymer (Patent synthesis WO2006016179). It consists of branched polymers of monomethoxypolyethylene glycol (MPEG) grafted onto polyisoprene-graft-maleic anhydride (PIP-g-MA), and unreacted MPEG (less than 35 % by weight). White to off-white colour. CAS No.: 1246080-53-4 **Characteristics:** Moisture: < 5,0 % Aluminium: < 3,0 mg/kg Lithium: < 0,5 mg/kg Nickel: < 0,5 mg/kg Residual anhydride: < 15 µmol/g Polydispersity index: < 1,4 Isoprene: < 0,05 mg/kg Ethylene oxide: < 0,2 mg/kg Free maleic anhydride: < 0,1 %Total oligomeres (less than 1 000 Dalton): ≤ 50 mg/kg Ethylene glycol: < 200 mg/kg Diethylene glycol: < 30 mg/kg Monoethylene glycol methyl ether: < 3,0 mg/kg Diethylene glycol methyl ether: < 4,0 mg/kg Triethylene glycol methyl ether: < 7,0 mg/kg 1,4-Dioxane: < 2,0 mg/kg Formaldehyde: < 10 mg/kg
Chewing gum base (Methyl vinyl ether-maleic	**Description/Definition:** Methyl vinyl ether-maleic anhydride copolymer is an anhydrous copolymer of methyl vinyl ether and maleic anhydride. Free-flowing, white to white-off powder

anhydride copolymer)	CAS No: 9011-16-9 **Purity:** Assay value: At least 99,5 % in dry matter Specific viscosity (1 % MEK): 2-10 Residual methyl vinyl ether: ≤ 150 ppm Residual maleic anhydride: ≤ 250 ppm Acetaldehyde: ≤ 500 ppm Methanol: ≤ 500 ppm Dilauroyl peroxide: ≤ 15 ppm Total heavy metals: ≤ 10 ppm **Microbiological criteria:** Total aerobic plate count: ≤ 500 CFU/g Mould/yeast: ≤ 500 CFU/g *Escherichia coli* : Negative to test *Salmonella* : Negative to test *Staphylococcus aureus:* Negative to test *Pseudomonas aeruginosa* : Negative to test
Chia oil from *Salvia hispanica*	**Description/Definition:** Chia oil is produced from Chia (*Salvia hispanica* L.) seeds (99,9 % pure) by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities. It can also be produced by extraction with supercritical CO_2. **Production process:** Produced by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities. Acidity expressed as oleic acid: ≤ 2,0 % Peroxide value (PV): ≤ 10 meq/kg Insoluble impurities: ≤ 0,05 % Alpha linolenic acid: ≥ 60 % Linoleic acid: 15-20 %
Chia seeds (*Salvia hispanica*)	**Description/Definition:** Chia (*Salvia hispanica* L.) is a summer annual herbaceous plant belonging to the *Labiatae* family. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed. Dry matter: 90-97 % Protein: 15-26 % Fat: 18-39 % Carbohydrate (*): 18-43 % Crude Fibre(**): 18-43 % Ash: 3-7 % (*) Carbohydrates include the fibre value (**) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin **Production process:** Production process of fruit juices and fruit juice blends beverages, containing Chia seeds, includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.
Chitin-glucan from	**Description/Definition:**

Aspergillus niger	Chitin-glucan is obtained from the mycelium of *Aspergillus niger* ; it is a slightly yellow, odourless, free-flowing powder. It has a dry matter content of 90 % or more. Chitin-glucan is composed largely of two polysaccharides: — chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4), — beta (1, 3)-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9). Loss on drying: ≤ 10 % Chitin-glucan: ≥ 90 % Ratio of chitin to glucan: 30:70 to 60:40 Ash: ≤ 3,0 % Lipids: ≤ 1,0 % Proteins: ≤ 6,0 %
Chitin-glucan complex from *Fomes fomentarius*	**Description/Definition:** Chitin-glucan complex is obtained from the cell walls of the fruit bodies of the fungus *Fomes fomentarius* . It consists primarily of two polysaccharides: — Chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4); — Beta-(1,3)(1,6)-D-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9). The production process consists of several steps, including: cleaning, reduction in size and grinding, softening in water and heating in an alkaline solution, washing, drying. No hydrolysis is applied during the production process. Appearance: Powder, odourless, flavourless, brown **Purity:** Moisture: ≤ 15 % Ash: ≤ 3,0 % Chitin-glucan: ≥ 90 % Ratio of chitin to glucan: 70:20 Total carbohydrates, excluding glucans: ≤ 0,1 % Proteins: ≤ 2,0 % Lipids: ≤ 1,0 % Melanins: ≤ 8,3 % Additives: None pH: 6,7-7,5 **Heavy metals:** Lead (ppm): ≤ 1,00 Cadmium (ppm): ≤ 1,00 Mercury (ppm): ≤ 0,03 Arsenic (ppm): ≤ 0,20 **Microbiological criteria:** Total mesophilic bacteria: ≤ 10^3 /g Yeast and moulds: ≤ 10^3 /g Coliforms at 30 °C: ≤ 10^3 /g *E. coli* : ≤ 10/g *Salmonella* and other pathogenic bacteria: Absence/25 g
Chitosan extract from fungi	**Description/Definition:**

(*Agaricus bisporus* ; *Aspergillus niger*)	The chitosan extract (containing mainly poly(D-glucosamine)) is obtained from stems of *Agaricus bisporus* or from the mycelium of *Aspergillus niger* . The patented production process consists of several steps, including: extraction and deacetylation (hydrolysis) in alkaline medium, solubilisation in acidic medium, precipitation in alkaline medium, washing and drying. Synonym: Poly(D-glucosamine) Chitosan CAS number: 9012-76-4 Chitosan formula: $(C_6H_{11}NO_4)_n$ Appearance: fine free-flowing powder Aspect: Off –white to slightly brownish Odour: Odourless **Purity:** Chitosan content (% w/w dry weight):≥ 85 Glucan content (% w/w dry weight): ≤ 15 Loss on drying (% w/w dry weight): ≤ 10 Viscosity (1 % in 1 % acetic acid): 1-15 Degree of acetylation (in % mol/wet weight): 0-30 Viscosity (1 % in 1 % acetic acid) (mPa.s): 1-14 for chitosan from Aspergillus niger; 12-25 for chitin from *Agaricus bisporus* Ash (% w/w dry weight): ≤ 3,0 Proteins (% w/w dry weight): ≤ 2,0 Particle size: > 100 nm Tapped density (g/cm ^{3}): 0,7-1,0 Fat binding capacity 800 × (w/w wet weight): pass **Heavy metals:** Mercury (ppm): ≤ 0,1 Lead (ppm): ≤ 1,0 Arsenic (ppm): ≤ 1,0 Cadmium (ppm): ≤ 0,5 **Microbiological criteria:** Aerobic count (CFU/g): ≤ 10^3 Yeast and mould count (CFU/g): ≤ 10^3 *Escherichia coli* (CFU/g): ≤ 10 Enterobacteriaceae (CFU/g): ≤ 10 *Salmonella* : Absence/25g *Listeria monocytogenes* : Absence/25g
Chondroitin sulphate	**Description/Definition:** Chondroitin sulphate (sodium salt) is a biosynthetic product. It is obtained by chemical sulphation of chondroitin derived from fermentation by the bacterium *Escherichia coli* O5:K4:H4 strain U1-41 (ATCC 23502). Chondroitin sulphate (sodium salt) (% dry basis): 95-105 MWw (weight avg.) (kDa): 5-12 MWn (number avg.) (kDa): 4-11 Dispersity ($w_h/w_{0,05}$): ≤ 0,7 Sulphation pattern (ΔDi-6S) (%): ≤ 85 Loss on drying (%) (105 °C to constant weight): ≤ 10,0 Residue on ignition (% dry basis): 20-30 Protein (% dry basis): ≤ 0,5 Endotoxins (EU/mg): ≤ 100

	Total organic impurities (mg/kg): ≤ 50
Chromium Picolinate	**Description/Definition:** Chromium picolinate is a reddish free-flowing powder, slightly soluble in water at pH 7. The salt is also soluble in polar organic solvents. Chemical name: tris(2pyridinecarboxylato-N,O)chromium(III) or 2-pyridinecarboxylic acid chromium(III) salt CAS No.: 14639-25-9Chemical formula: $Cr(C_6H_4NO_2)_3$ Chemical characteristics: Chromium Picolinate: ≥ 95 % Chromium (III): 12-13 % Chromium (VI): not detected Water: ≤ 4,0 %
***Cistus incanus* L. Pandalis herb**	**Description:** *Cistus incanus* L. Pandalis herb; species belonging to the *Cistaceae* family and native to the Mediterranean region, Chalkidiki Peninsula. **Composition:** Moisture: 9–10 g/100 g herbs Protein: 6,1 g/100 g herbs Fat: 1,6 g/100 g herbs Carbohydrates: 50,1 g/100 g herbs Fiber: 27,1 g/100 g herbs Minerals: 4,4 g/100 g herbs Sodium: 0,18 g Potassium: 0,75 g Magnesium: 0,24 g Calcium: 1,0 g Iron: 65 mg Vitamin B_1: 3,0 µg Vitamin B_2: 30 µg Vitamin B_6: 54 µg Vitamin C: 28 mg Vitamin A: less than 0,1 mg Vitamin E: 40–50 mg Alpha-Tocopherol: 20–50 mg Beta and Gamma-Tocopherols: 2–15 mg Delta-Tocopherol: 0,1–2 mg
Citicoline	**Description/Definition:** Citicoline is produced by a microbial process. Citicoline is composed of cytosine, ribose, pyrophosphate and choline. White crystalline powder Chemical name: Choline cytidine 5′-pyrophosphate, Cytidine 5′-(trihydrogen diphosphate) P'-[2-(trimethylammonio)ethyl]ester inner salt Chemical formula: $C_{14}H_{26}N_4O_{11}P_2$ Molecular weight: 488,32 g/mol CAS No.: 987-78-0 pH (sample solution of 1 %): 2,5-3,5 **Purity:** Assay value: ≥ 98 % of dry matter Loss on drying (100 °C for 4 hours): ≤ 5,0 % Ammonium: ≤ 0,05 % Arsenic: Not more than 2 ppm

	Free phosphoric acids: ≤ 0,1 % 5′-Cytidylic acid: ≤ 1,0 % **Microbiological criteria:** Total plate count: ≤ 10^3 CFU/g Yeast and moulds: ≤ 10^2 CFU/g *Escherichia coli* : Absence in 1 g
Clostridium butyricum	**Description/Definition:** *Clostridium butyricum* (CBM-588) is a Gram-positive, spore-forming, obligate anaerobic, non-pathogenic, non-genetically modified bacterium. Depository number FERM BP-2789 **Microbiological criteria:** Total viable aerobic count: ≤ 10^3 CFU/g *Escherichia coli* : Not detected in 1 g *Staphylococcus aureus* : Not detected in 1 g *Pseudomonas aeruginosa* : Not detected in 1 g Yeast and moulds: ≤ 10^2 CFU/g
[F10D-ribose	**Description** D-ribose is an aldopentose monosaccharide which is produced by fermentation using a transketolase-deficient strain of *Bacillus subtilis* . Chemical formula: $C_5H_{10}O_5$ CAS No: 50-69-1 Molecular mass: 150,13 Da **Characteristics/Composition** Appearance: Dry with powdery texture, white to slightly yellow in colour Specific rotation $[\alpha]_D^{25}$: – 19,0° to – 21,0° D-ribose purity (% dry basis): -HPLC/RI[h] Method 98,0–102,0 % Ash: < 0,2 % Loss on drying (moisture): < 0,5 % Clarity on solution: ≥ 95 % transmittance **Heavy metals** Lead: ≤ 0,1 mg/kg Arsenic: ≤ 0,1 mg/kg Cadmium: ≤ 0,1 mg/kg Mercury: ≤ 0,1 mg/kg **Microbiological criteria** Total plate count: ≤ 100 CFU[i]/g Yeast: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Coliforms: ≤ 10 CFU/g *Salmonella* sp: Negative/25 g]
Extract of defatted cocoa powder	Cocoa (*Theobroma cacao* L.) Extract Appearance: Dark brown powder free of visible impurities Physical and chemical properties: Polyphenol content: Min 55,0 % GAE Theobromine content: Max 10,0 % Ash content: Max 5,0 % Moisture content: Max 8,0 % Bulk density: 0,40-0,55 g/cm^3

	pH: 5,0-6,5 Residual solvent: Max 500 ppm
Low fat cocoa extract	Low fat Cocoa (*Theobroma cacao* L.) extract Appearance: Dark red to purple powder Cocoa extract, concentrate: Min 99 % Silicon dioxide (technological aid): Max 1,0 % Cocoa flavanols: Min. 300 mg/g — Epicatechin: Min. 45 mg/g Loss on drying: Max. 5,0 %
[F61Coriander seed oil from *Coriandrum sativum*	**Description/Definition:** Coriander seed oil is an oil containing glycerides of fatty acids that is produced from the seeds of the coriander plant *Coriandrum sativum* L. Slight yellow colour, bland taste CAS No: 8008-52-4 Composition of fatty acids: Palmitic acid (C16:0): 2-5 % Stearic acid (C18:0): < 1,5 % Petroselinic acid (cis-C18:1(n-12)): 60-75 % Oleic acid (cis-C18:1 (n-9)): 7-15 % Linoleic acid (C18:2): 12-19 % α-Linolenic acid (C18:3): < 1,0 % Trans fatty acids: ≤ 1,0 % **Purity:** Refractive index (20 °C): 1,466-1,474 Acid value: ≤ 2,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg Iodine value: 88-110 units Saponification value: 179-200 mg KOH/g Unsaponifiable matter: ≤ 15 g/kg**]**
[F14 Cranberry extract powder	**Description/Definition:** Cranberry extract powder is a water-soluble phenolic-rich powder extract prepared through an ethanolic extraction from the juice concentrate of sound, mature berries of the cranberry cultivar *Vaccinium macrocarpon* . **Characteristics/Composition** Moisture (% w/w): ≤ 4 Proanthocyanidins — PACs (% w/w dry weight) — OSC-DMAC method[ce]: 55.0-60.0 or — BL-DMAC method[de]: 15.0-18.0 Total phenolics (GAE[f], % w/w dry weight)[e] — Folin-Ciocalteau method: > 46.2 Solubility (water): 100 %, with no visible insoluble particles Ethanol Content (mg/kg): ≤ 100 Screen Analysis: 100 % through 30 mesh screen Appearance and aroma, as powder: Free-flowing, deep red colour. Earthy aroma with no burnt character. **Heavy metals:** Arsenic (ppm): < 3 **Microbiological criteria:** Yeast: < 100 CFU[g]/g Mould: < 100 CFU/g Aerobic plate count: < 1 000 CFU/g

	Coliforms: < 10 CFU/g *Escherichia coli* : < 10 CFU/g *Salmonella* : Absent in 375 g]
***Crataegus pinnatifida* dried fruit**	**Description/Definition:** Dried fruits of *Crataegus pinnatifida* species belonging to the *Rosaceae* family and native to north China and Korea. **Composition:** Dry matter: 80 % Carbohydrates: 55 g/kg fresh weight Fructose: 26,5–29,3 g/100 g Glucose: 25,5–28,1 g/100 g Vitamin C: 29,1 mg/100 g fresh weight Sodium: 2,9 g/100 g fresh weight Compotes are products obtained by thermal processing of the edible part of one or several species of fruits, whole or in pieces, sieved or not, without significant concentration. Sugars, water, cider, spices and lemon juice may be used.
α-cyclodextrin	**Description/Definition:** A non-reducing cyclic saccharide consisting of six α-1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolyzed starch. Recovery and purification of α-cyclodextrin may be carried out using one of the following procedures: precipitation of a complex of α-cyclodextrin with 1-decanol, dissolution in water at elevated temperature and re-precipitation, steam-stripping of thecomplexant, and crystallisation of α-cyclodextrin from the solution; or chromatography with ion-exchange or gel filtration followed by crystallisation of α-cyclodextrin from the purified mother liquor; or membrane separation methods such as ultra-filtration and reverse osmosis: Description: Virtually odourless, white or almost white crystalline solid. Synonyms: α-cyclodextrin, α-dextrin, cyclohexaamylose, cyclomaltohexaose, α-cycloamylase Chemical name: CyclohexaamyloseCAS No.: 10016-20-3 Chemical formula: $(C_6H_{10}O_5)_6$ Formula weight: 972,85 Assay: ≥ 98 % (dry basis) **Identification:** Melting range: Decomposes above 278 °C Solubility: Freely soluble in water; very slightly soluble in ethanol Specific rotation: $[\alpha]_D^{25}$: Between +145 ° and +151 ° (1 % solution) Chromatography: The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for α-cyclodextrin in a chromatogram of reference α-cyclodextrin (available from *Consortium für Elektrochemische Industrie GmbH, München, Germany or Wacker Biochem Group, Adrian, MI, USA*) using the conditions described in the METHOD OF ASSAY **Purity:** Water: ≤ 11 % (Karl Fischer Method) Residual complexant: ≤ 20 mg/kg (1-decanol) Reducing substances: ≤ 0,5 % (as glucose)

	Sulphated ash: ≤ 0,1 % Lead: ≤ 0,5 mg/kg **Method of assay:** Determine by liquid chromatography using the following conditions: Sample solution: Weigh accurately about 100 mg of test sample into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath (10-15 min) and dilute to the mark with purified deionised water. Filter through a 0,45-micrometer filter Reference solution: Weigh accurately about 100 mg of α-cyclodextrin into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath and dilute to the mark with purified deionised water. Chromatography: Liquid chromatograph equipped with a refractive index detector and an integrating recorder. Column and packing: Nucleosil-100-NH_2 (10 μm) (*Macherey & Nagel Co. Düren* , Germany) or similar Length: 250 mm Diameter: 4 mm Temperature: 40 °C Mobile phase: acetonitrile/water (67/33, v/v) Flow rate: 2,0 ml/min Injection volume: 10 μlProcedure: Inject the sample solution into the chromatograph, record the chromatogram, and measure the area of the α-CD peak. Calculate the percentage of α-cyclodextrin in the test sample as follows: % α-cyclodextrin (dry basis) = $100 \times (A_S/A_R)(W_R/W_S)$ where A_S and A_R are the areas of the peaks due to α-cyclodextrin for the sample solution and reference solution, respectively. W_S and W_R are the weights (mg) of the test sample and reference α-cyclodextrin, respectively, after correcting for water content.
γ-cyclodextrin	**Description/Definition:** A non-reducing cyclic saccharide consisting of eight α-1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolysed starch. Recovery and purification of γ-cyclodextrin may be carried out by precipitation of a complex of γ-cyclodextrin with 8-cyclohexadecen-1-one, dissolution of the complex with water and n-decane, steam-stripping of the aqueous phase and recovery of gamma-CD from the solution by crystallisation. Virtually odourless, white or almost white crystalline solid Synonyms: γ-cyclodextrin, γ-dextrin, cyclooctaamylose, cyclomaltooctaose, γ-cycloamylase Chemical name: Cyclooctaamylose CAS number: 17465-86-0 Chemical formula: $(C_6H_{10}O_5)_8$ Assay: ≥ 98 % (dry basis) **Identification:** Melting range: Decomposes above 285 °C Solubility: Freely soluble in water; very slightly soluble in ethanol Specific rotation: $[\alpha]_D^{25}$: between + 174 ° and + 180 ° (1 % solution)

	Purity: Water: ≤ 11 % Residual complexant (8-cyclohexadecen-1-one (CHDC)): ≤ 4 mg/kg Residual solvent (n-decane): ≤ 6mg/kg Reducing substances: ≤ 0,5 % (as glucose) Sulphated ash: ≤ 0,1 %
[F15Decorticated grains of *Digitaria exilis* (Kippist) Stapf (fonio) (Traditional food from a third country)	**Description/Definition** The traditional food is the decorticated grain (bran removed) of *Digitaria exilis* (Kippist) Stapf. *Digitaria exilis* (Kippist) Stapf) is an annual herbaceous plant belonging to the *Poaceae* family. **Typical nutritional components of decorticated grain of fonio** Carbohydrates: 76,1 g/100 g of fonio Water: 12,4 g/100 g of fonio Protein: 6,9 g/100 g of fonio Fat: 1,2 g/100 g of fonio Fibre: 2,2 g/100 g of fonio Ash: 1,2 g/100 g of fonio Phytate content: ≤ 2,1 mg/g]
Dextran preparation produced by *Leuconostoc mesenteroides*	1. **Powdered form:** Carbohydrates: 60 % with: (Dextran: 50 %, Mannitol: 0,5 %, Fructose: 0,3 %, Leucrose: 9,2 %) Protein: 6,5 % Lipid: 0,5 % Lactic acid: 10 % Ethanol: traces Ash: 13 % Moisture: 10 % 2. **Liquid form:** Carbohydrates: 12 % with: (Dextran: 6,9 %, Mannitol: 1,1 %, Fructose: 1,9 %, Leucrose: 2,2 %) Protein: 2,0 % Lipid: 0,1 % Lactic acid: 2,0 % Ethanol: 0,5 % Ash: 3,4 % Moisture: 80 %
Diacylglycerol oil of plant origin	**Description/Definition:** Manufactured from glycerol and fatty acids derived from edible vegetable oils, in particular from soybean oil (*Glycine max*) or rapeseed oil (*Brassica campestris, Brassica napus*) using a specific enzyme. **Acylglycerol Distribution:** Diacylglycerols (DAG): ≥ 80 % 1,3-Diacylglycerols (1,3-DAG): ≥ 50 % Triacylglycerols (TAG): ≤ 20 % Monoacylglycerols (MAG): ≤ 5,0 % **Fatty Acid Composition (MAG, DAG, TAG):** Oleic acid (C18:1): 20-65 % Linoleic acid (C18:2): 15-65 % Linolenic acid (C18:3): ≤ 15 % Saturated fatty acids: ≤ 10 %

	Others: Acid value: ≤ 0,5 mg KOH/g Moisture and volatile: ≤ 0,1 % Peroxide value (PV): ≤ 1,0 meq/kg Unsaponifiables: ≤ 2,0 % Trans fatty acids≤ 1,0 % MAG = monoacylglycerols, DAG = diacylglycerols, TAG = triacylglycerols
Dihydrocapsiate (DHC)	**Description/Definition:** Dihydrocapsiate is synthesised by enzyme-catalysed esterification of vanillyl alcohol and 8-methylnonanoic acid. Following the esterification dihydrocapsiate is extracted with n-hexane. Viscous to colourless to yellow liquid Chemical formula: C_{18} H_{28} O_4 CAS No: 205687-03-2 **Physical-chemical properties:** Dihydrocapsiate: > 94 % 8-Methylnonanoic acid: < 6,0 % Vanillyl acohol: < 1,0 % Other synthesis related substances: < 2,0 %
[F16Dried aerial parts of *Hoodia parviflora*	**Description/Definition:** It is the whole dried aerial parts of *Hoodia parviflora* N.E.Br., (family *Apocynaceae*) **Characteristics/Composition** Plant material: Aerial parts of at least 3-year-old plants Appearance: Light green to tan fine powder Solubility (water): > 25 mg/mL Moisture: < 5,5 % A_w : < 0,3 pH: < 5,0 Protein: < 4,5 g/100 g Fat: < 3 g/100 g Carbohydrate (including dietary fibre): < 80 g/100 g Dietary fibre: < 55 g/100 g Total sugars: < 10,5 g/100 g Ash: < 20 % **Hoodigosides** P57: 5–50 mg/kg L: 1 000–6 000 mg/kg O: 500–5 000 mg/kg Total: 1 500–11 000 mg/kg **Heavy metals:** Arsenic: < 1,00 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 0,1 mg/kg Lead: < 0,5 mg/kg **Microbiological criteria:** Aerobic plate count: < 10^5 CFU/g *Escherichia coli* : < 10 CFU/g *Staphylococcus aureus* : < 50 CFU/g Total coliforms: < 10 CFU/g

	Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g *Salmonella* species: Negative/25 g *Listeria monocytogenes* : Negative/25 g CFU: Colony Forming Units**]**
Dried extract of *Lippia citriodora* from cell cultures	**Description/Definition:** Dried extract of *Lippia citriodora* (Palau) Kunth from cell cultures HTN ® Vb.
***Echinacea angustifolia* extract from cell cultures**	**Description/Definition:** Extract of the roots of *Echinacea angustifolia* obtained from plant tissue culture which is substantially equivalent to a root extract from *Echinacea angustifolia* obtained in ethanol-water titrated to 4 % echinacoside.
***[F17Echinacea purpurea* extract from cell cultures**	**Description/Definition:** Dried extract of *Echinacea purpurea* from cell cultures EchiPure-PC™**]**
***Echium plantagineum* oil**	**Description/Definition:** Echium oil is the pale yellow product obtained by refining oil extracted from the seeds of *Echium plantagineum* L. Stearidonic acid: ≥ 10 % w/w of total fatty acids Trans fatty acids: ≤ 2,0 % (w/w of total fatty acids) Acid value: ≤ 0,6 mg KOH/g Peroxide value (PV): ≤ 5,0 meq O_2 /kg Unsaponifiable content: ≤ 2,0 % Protein content (total nitrogen): ≤ 20 µg/ml Pyrrolizidine alkaloids: Not detectable with a detection limit 4,0 µg/kg
***[F18Ecklonia cava* phlorotannins**	**Description/Definition** *Ecklonia cava* phlorotannins are obtained via alcohol extraction from the edible marine alga *Ecklonia cava.* The extract is a dark brown powder, rich in phlorotannins, polyphenolic compounds found as secondary metabolites in certain brown algae species. **Characteristics/Composition** Phlorotannin content: 90 ± 5 % Antioxidant activity: > 85 % Moisture: < 5 % Ash: < 5 % **Microbiological criteria** Total viable cell count: < 3 000 CFU/g Mould/yeast: < 300 CFU/g Coliforms: Negative to test *Salmonella* spp.: Negative to test *Staphylococcus aureus:* Negative to test **Heavy metals and Halogens** Lead: < 3,0 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 3,0 mg/kg Arsenic: < 25,0 mg/kg Inorganic Arsenic: < 0,5 mg/kg Iodine: 150,0 – 650,0 mg/kg

<table>
<tr><td></td><td>CFU: Colony Forming Units]</td></tr>
<tr><td>[^{F19}Egg membrane hydrolysate</td><td>Description
The egg membrane hydrolysate is derived from the eggshell membranes of chicken eggs. The eggshells undergo hydro-mechanical separation in order to obtain the egg membranes, which are then further processed using a patented solubilisation method. Following the solubilisation process, the solution is filtered, concentrated, spray-dried and packaged.
Characteristics/Composition
<table>
<tr><th>Chemical parameters</th><th>Methods</th></tr>
<tr><td>Total nitrogen-containing compounds (% w/w): ≥ 88</td><td>Combustion according to AOAC 990.03 and AOAC 992.15</td></tr>
<tr><td>Collagen (% w/w): ≥ 15</td><td>Sircol ™ Soluble Collagen Assay</td></tr>
<tr><td>Elastin (% w/w): ≥ 20</td><td>Fastin ™ Elastin Assay</td></tr>
<tr><td>Total glycosaminoglycans (% w/w): ≥ 5</td><td>USP26 (chondroitin sulphate K0032 method)</td></tr>
<tr><td>Calcium: ≤ 1 %</td><td></td></tr>
</table>
Physical parameters
pH: 6,5 – 7,6
Ash (% w/w): ≤ 8
Moisture (% w/w): ≤ 9
Water activity: ≤ 0,3
Solubility (in water): soluble
Bulk density: ≥ 0,6 g/cc
Heavy metals
Arsenic ≤ 0,5 mg/kg
Microbiological criteria
Aerobic plate count: ≤ 2 500 CFU/g
Escherichia coli : ≤ 5 MPN/g
Salmonella : Negative (in 25 g)
Coliforms: ≤ 10 MPN/g
Staphylococcus aureus : ≤ 10 CFU/g
Mesophilic spore count: ≤ 25 CFU/g
Thermophilic spore count: ≤ 10 CFU/10 g
Yeast: ≤ 10 CFU/g
Mould: ≤ 200 CFU/g
CFU: Colony Forming Units; MPN = Most Probable Number; USP: United States Pharmacopeia.]</td></tr>
<tr><td>Epigallocatechin gallate as a purified extract from green tea leaves</td><td>Description/Definition:
A highly purified extract from the leaves of green tea (Camellia sinensis (L.) Kuntze) in the form of a fine, off-white to pale pink powder. It is composed of a minimum of 90 % epigallo-catechin gallate (EGCG), and has a melting point between approx. 210 and 215 °C</td></tr>
</table>

(*Camellia sinensis*)	Appearance: off-white to pale pink powder Chemical name: polyphenol (-) epigallocatechin-3-gallate Synonyms: epigallocatechin gallate (EGCG) CAS No.: 989-51-5 INCI name: epigallocatechin gallate Molecular mass: 458,4 g/mol Loss on drying: max 5,0 % **Heavy metals:** Arsenic: max 3,0 ppm Lead: max 5,0 ppm **Assay:** Min. 94 % EGCG (on dry material) max. 0,1 % caffeine Solubility: EGCG is fairly soluble in water, ethanol, methanol and acetone
L-ergothioneine	**Definition** Chemical name (IUPAC): (2S)-3-(2-thioxo-2,3-dihydro-1 *H* -imidazol-4-yl)-2-(trimethylammonio)-Propanoate Chemical formula: $C_9H_{15}N_3O_2S$ Molecular mass: 229,3 Da CAS No.: 497-30-3

Parameter	***Specification***	***Method***
Appearance	White powder	Visual
Optical rotation	$[\alpha]_D \geq (+)\ 122°$ (c = 1, H_2O) [a]	Polarimetry
Chemical purity	≥ 99,5 % ≥ 99,0 %	HPLC [Eur. Ph. 2,2.29] 1H-NMR
Identification	Compliant with the structure C: 47,14 ± 0,4 % H: 6,59 ± 0,4 % N: 18,32 ± 0,4 %	1H-NMR Elemental analysis
Total residual solvents (methanol, ethyl acetate, isopropanol, ethanol)	[Eur. Ph. 01/2008:50400] < 1 000 ppm	Gas chromatography [Eur. Ph. 01/2008:20424]
Loss on drying	Internal standard < 0,5 %	[Eur. Ph. 01/2008:20232]
Impurities	< 0,8 %	HPLC/GPC or 1H-NMR
Heavy metals [b) c)]		
Lead	< 3,0 ppm	ICP/AES
Cadmium	< 1,0 ppm	(Pb, Cd)
Mercury	< 0,1 ppm	Atomic fluorescence (Hg)

	Microbiological specifications [b]		
	Total viable aerobic count (TVAC)	$\leq 1 \times 10^3$ CFU/g	[Eur. Ph. 01/2011:50104]
	Total yeast and mould count (TYMC)	$\leq 1 \times 10^2$ CFU/g	
	Escherichia coli	Absence in 1 g	
	Eur. Ph.: European Pharmacopoeia; 1H-NMR: proton nuclear magnetic resonance; HPLC: high-performance liquid chromatography; GPC: gel permeation chromatography; ICP/AES: Inductively coupled plasma atomic emission spectroscopy; CFU: colony-forming units. a) Lit. $[\alpha]_D = (+)\ 126{,}6^{\circ}$ (c = 1, H_2O) b) Analyses conducted on each batch c) Maximum levels in accordance with Regulation (EC) No 1881/2006		
[F18Extract of three herbal roots *(Cynanchum wilfordii Hemsley, Phlomis umbrosa Turcz. and Angelica gigas Nakai)*	**Description/Definition** The mixture of the three herbal roots is yellowish brown fine powder produced by hot-water extraction, concentration by evaporation, and spray drying **Composition of the extract of mixture of the 3 herbal roots** *Cynanchum wilfordii* root: 32,5 % (w/w) *Phlomis umbrosa* root: 32,5 % (w/w) *Angelica gigas* root: 35,0 % (w/w) **Specifications** Loss on drying: NMT 100 mg/g **Assay** Cinnamic acid: 0,012 – 0,039 mg/g Shanzhiside methyl ester: 0,20 – 1,55 mg/g Nodakenin: 3,35 – 10,61 mg/g Methoxsalen: < 3 mg/g Phenols: 13,0 – 40,0 mg/g Coumarins: 13,0 – 40,0 mg/g Iridoids: 13,0 – 39,0 mg/g Saponins: 5,0 – 15,5 mg/g **Nutritive components** Carbohydrates: 600 – 880 mg/g Proteins: 70 – 170 mg/g Fats: < 4 mg/g **Microbiological parameters** Total viable plate count: < 5000 CFU/g Total mold and yeast: < 100 CFU/g Coliform bacteria: < 10 CFU/g *Salmonella* : Negative/25 g *Escherichia coli* : Negative/25 g *Staphylococcus aureus* : Negative/25 g **Heavy metals** Lead: < 0,65 mg/kg		

	Arsenic: < 3,0 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 1,0 mg/kg CFU: Colony Forming Units**]**
Ferric Sodium EDTA	**Description/Definition:** Ferric Sodium EDTA (ethylenediaminetetraacetic acid) is an odourless free-flowing, yellow to brown powder with a chemical purity of more than 99 % (w/w). It is freely soluble in water. Chemical formula: $C_{10}H_{12}FeN_2NaO_8 * 3H_2O$ Chemical characteristics: pH of 1 % solution: 3,5-5,5 Iron: 12,5-13,5 % Sodium: 5,5 % Water: 12,8 % Organic matter (CHNO): 68,4 % EDTA: 65,5-70,5 % Water insoluble matter: ≤ 0,1 % Nitrilo-triacetic acid: ≤ 0,1 %
Ferrous ammonium phosphate	**Description/Definition:** Ferrous ammonium phosphate is a grey/green fine powder, practically insoluble in water and soluble in dilute mineral acids. CAS No.: 10101-60-7 Chemical formula: $FeNH_4PO_4$ Chemical characteristics: pH of 5 % suspension in water: 6,8-7,8 Iron (total): ≥ 28 % Iron (II): 22-30 % (w/w) Iron (III): ≤ 7,0 % (w/w) Ammonia: 5-9 % (w/w) Water: ≤ 3,0 %
Fish peptides from *Sardinops sagax*	**Description/Definition:** The novel food ingredient is a peptide mixture, which is obtained by an alkaline protease-catalysed hydrolysis of fish (*Sardinops sagax*) muscle, subsequent isolation of the peptide fraction by column chromatography, concentration under vacuum and spray drying. Yellowish white powderPeptides ([1]) (short chain peptides, dipeptides and tripeptides with a molecular weight of less than 2 kDa): ≥ 85 g/100 g Val-Tyr (dipeptide): 0,1-0,16 g/100 g Ash: ≤ 10 g/100 g Moisture: ≤ 8 g/100 g ([1]) Kjeldahl method
Flavonoids from *Glycyrrhiza glabra*	**Description/Definition:** Flavonoids derived from the roots or rootstock of *Glycyrrhiza glabra* L. are extracted with ethanol followed by further extraction of this ethanolic extract with medium-chain triglycerides. It is a dark-brown coloured liquid, containing 2,5 % to 3,5 % of glabridin. Moisture: < 0,5 % Ash: < 0,1 % Peroxide value (PV): < 0,5 meq/kg

	Glabridin: 2,5-3,5 % of fat Glycyrrhizinic acid: < 0,005 % Fat including polyphenol-type substances: ≥ 99 % Protein: < 0,1 % Carbohydrates: not detectable
[[F21]Fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. (Traditional food from a third country)	**Description/Definition** The traditional food is the fruit pulp from the cocoa (*Theobroma cacao* L) plant, which is the 'aqueous, mucilaginous and acidic substance in which the seeds are embedded'. Cocoa fruit pulp is obtained by splitting cocoa pods followed by separation from husks and beans; the pulp is then subject to pasteurisation and freezing. Cocoa pulp juice and/or cocoa concentrated pulp juice are produced following processing (enzymatic treatment, pasteurization, filtration, and concentration). **Typical compositional data of cocoa fruit pulp, pulp juice, concentrated pulp juice** Protein (g/100 g): 0,0 to 2,0 Total fat (g/100 g): 0,0 to 0,2 Total sugars (g/100 g): > 11,0 Brix level (° Brix): ≥ 14 pH: 3,3 to 4,0 **Microbiological criteria** Total Plate Count (aerobic): < 10 000 cfu[i]/g Enterobacteriaceae: ≤ 10 cfu/g *Salmonella* : Absence in 25 g**]**
Fucoidan extract from the seaweed *Fucus vesiculosus*	**Description/Definition:** Fucoidan from the seaweed *Fucus vesiculosus* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications: Off-white to brown powder Odour and Taste: Bland odour and taste Moisture: < 10 % (105 °C for 2 hours) pH value: 4,0-7,0 (1 % suspension at 25 °C) **Heavy metals:** Arsenic (inorganic): < 1,0 ppm Cadmium: < 3,0 ppm Lead: < 2,0 ppm Mercury: < 1,0 ppm **Microbiological criteria:** Total aerobic microbial count: < 10 000 CFU/g Yeast and mould count: < 100 CFU/g Total enterobacteria count: Absence/g *Escherichia coli* : Absence/g *Salmonella* : Absence/10 g *Staphylococcus aureus* : Absence/g Composition of the two permitted types of extracts, based on the level of fucoidan: *Extract 1:* Fucoidan: 75-95 % Alginate: 2,0-5,5 % Polyphloroglucinol: 0,5-15 % Mannitol: 1-5 %

	Natural salts/Free Minerals: 0,5-2,5 % Other carbohydrates: 0,5-1,0 % Protein: 2,0-2,5 % *Extract 2:* Fucoidan: 60-65 % Alginate: 3,0-6,0 % Polyphloroglucinol: 20-30 % Mannitol: < 1,0 % Natural salts/Free Minerals: 0,5-2,0 % Other carbohydrates: 0,5-2,0 % Protein: 2,0-2,5 %
Fucoidan extract from the seaweed *Undaria pinnatifida*	**Description/Definition:** Fucoidan from seaweed *Undaria pinnatifida* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications: Off-white to brown powder Odour and Taste: Bland odour and tasteMoisture: < 10 % (105 °C for 2 hours) pH value: 4,0-7,0 (1 % suspension at 25 °C) **Heavy metals:** Arsenic (inorganic): < 1,0 ppm Cadmium: < 3,0 ppm Lead: < 2,0 ppm Mercury: < 1,0 ppm **Microbiology:** Total aerobic microbial count: < 10 000 CFU/g Yeast and mould count: < 100 CFU/g Total enterobacteria count: Absence/g *Escherichia coli* : Absence/g *Salmonella* : Absence/10 g *Staphylococcus aureus* : Absence/g Composition of the two permitted types of extracts, based on the level of fucoidan: *Extract 1:* Fucoidan: 75-95 % Alginate: 2,0-6,5 % Polyphloroglucinol: 0,5-3,0 % Mannitol: 1-10 % Natural salts/Free Minerals: 0,5-1,0 % Other carbohydrates: 0,5-2,0 % Protein: 2,0-2,5 % *Extract 2:* Fucoidan: 50-55 % Alginate: 2,0-4,0 % Polyphloroglucinol: 1,0-3,0 % Mannitol: 25-35 % Natural salts/Free Minerals: 8-10 % Other carbohydrates: 0,5-2,0 % Protein: 1,0-1,5 %
2′-Fucosyllactose	**Definition:**

<table>
<tr><td>(synthetic)</td><td colspan="2">Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)- D-glucopyranose
Chemical formula: $C_{18}H_{32}O_{15}$
CAS No: 41263-94-9
Molecular weight: 488,44 g/mol
Description:
2′-fucosyllactose is a white to off-white powder that is produced by a chemical synthesis process.
Purity:
2'-Fucosyllactose: ≥ 95 %
D-Lactose: ≤ 1,0 w/w %
L-Fucose: ≤ 1,0 w/w %
Difucosyl- D-lactose isomers: ≤ 1,0 w/w %
2′-Fucosyl- D-lactulose: ≤ 0,6 w/w %
pH (20 °C, 5 % solution): 3,2-7,0
Water (%): ≤ 9,0 %
Ash, sulphated: ≤ 0,2 %
Acetic acid: ≤ 0,3 %
Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50,0 mg/kg singly, ≤ 200,0 mg/kg in combination
Residual proteins: ≤ 0,01 %
Heavy Metals:
Palladium: ≤ 0,1 mg/kg
Nickel: ≤ 3,0 mg/kg
Microbiological criteria:
Aerobic mesophilic bacteria total count: ≤ 500 CFU/g
Yeasts and Moulds: ≤ 10 CFU/g
Residual endotoxins: ≤ 10 EU/mg</td></tr>
<tr><td>2'-Fucosyllactose (microbial source)</td><td colspan="2">[F62Definition:
Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose
Chemical formula: $C_{18}H_{32}O_{15}$
CAS No: 41263-94-9
Molecular weight: 488,44 g/mol</td></tr>
<tr><td></td><td>Source:
Genetically modified strain of Escherichia coli K-12</td><td>Source:
Genetically modified strain of Escherichia coli BL21</td></tr>
<tr><td></td><td>Description:
2′-Fucosyllactose is a white to off-white powder that is produced by a microbial process.
Purity:
2′-Fucosyllactose: ≥ 83 %
D-Lactose: ≤ 10,0 %
L-Fucose: ≤ 2,0 %
Difucosyl-D-lactose: ≤ 5,0 %
2′-Fucosyl-D-lactulose: ≤ 1,5 %
Sum of saccharides (2′-Fucosyllactose, D-Lactose, L-Fucose, Difucosyl-D-lactose, 2′-Fucosyl-D-lactulose): ≥ 90 %</td><td>Description:
2′-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % ± 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2′-Fucosyllactose is produced by a microbiological process.
Purity:
2′-Fucosyllactose: ≥ 90 %
Lactose: ≤ 5,0 %
Fucose: ≤ 3,0 %
3-Fucosyllactose: ≤ 5,0 %</td></tr>
</table>

	pH (20 C, 5 % solution): 3,0-7,5 Water: ≤ 9,0 % Sulphated ash: ≤ 2,0 % Acetic acid: ≤ 1,0 % Residual proteins: ≤ 0,01 % **Microbiological criteria:** Aerobic mesophilic bacteria total count: ≤ 3 000 CFU/g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Endotoxins: ≤ 10 EU/mg	Fucosylgalactose: ≤ 3,0 % Difucosyllactose: ≤ 5,0 % Glucose: ≤ 3,0 % Galactose: ≤ 3,0 % Water: ≤ 9,0 % (powder) Ash, sulphated: ≤ 0,5 % (powder and liquid) Residual proteins: ≤ 0,01 % (powder and liquid) **Heavy Metals:** Lead: ≤ 0,02 mg/kg (powder and liquid) Arsenic: ≤ 0,2 mg/kg (powder and liquid) Cadmium: ≤ 0,1 mg/kg (powder and liquid) Mercury: ≤ 0,5 mg/kg (powder and liquid) **Microbiological criteria:** Total plate count: ≤ 10^4 CFU/g (powder), ≤ 5 000 CFU/g (liquid) Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid) Enterobacteriaceae/Coliforms: absence in 11 g (powder and liquid) *Salmonella* : negative/100 g (powder), negative/200 ml (liquid) *Cronobacter* : negative/100 g (powder), negative/200 ml (liquid) Endotoxins: ≤ 100 EU/g (powder), ≤ 100 EU/ml (liquid) Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid)**]**
[F63 2’-Fucosyllactose/ Difucosyllactose mixture (‘2’-FL/DFL’) **(microbial source)**	**Description /Definition:** 2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white **[**F64 powder or agglomerates thereof that is produced by a microbial process**]**. **Source:** Genetically modified strain of Escherichia coli strain K-12 DH1 **Characteristics/Composition** Appearance: White to off white powder or agglomerates Sum of 2'-Fucosyllactose, Difucosyllactose, **[**F65 D-Lactose, L-Fucose, and 3-Fucosyllactose**]** (% of dry matter): ≥ 92,0 % (w/w) Sum of 2'-fucosyllactose and difucosyllactose (% of dry matter): ≥ 85,0 % (w/w) 2'-Fucosyllactose (% of dry matter): ≥ 75,0 % (w/w) Difucosyllactose (% of dry matter): ≥ 5,0 % (w/w) D-Lactose: ≤ 10,0 % (w/w) L-Fucose: ≤ 1,0 % (w/w) 2'-Fucosyl-D-lactulose: ≤ 2,0 % (w/w) Sum of other carbohydratesl: ≤ 6,0 % (w/w) Moisture: ≤ 6,0 % (w/w) Ash, sulfated: ≤ 0,8 % (w/w)	

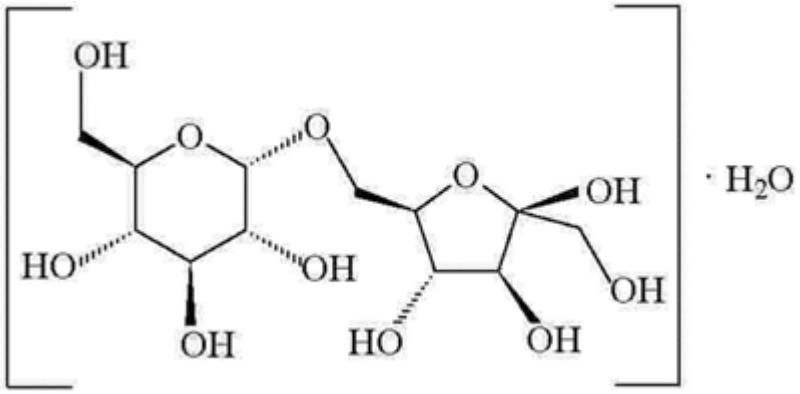
	pH (20 °C, 5 % solution): 4,0-6,0 Residual protein: ≤ 0,01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g Enterobacteriaceae : ≤ 10 CFU/g Salmonella sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units**]**
[F66 2'-Fucosyllactose/ Difucosyllactose mixture ('2'-FL/DFL') **(microbial source)**	**Description:** 2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white powder or agglomerate thereof that is produced by a microbial process. **Source:** Genetically modified strain of Escherichia coli K-12 DH1 **Characteristics/Composition:** Appearance: White to off white powder or agglomerates Sum of 2′-Fucosyllactose, Difucosyllactose, D-Lactose, L-Fucose, and 3-Fucosyllactose (% of dry matter): ≥ 92.0 % (w/w) Sum of 2′-Fucosyllactose and Difucosyllactose (% of dry matter): ≥ 85.0 % (w/w) 2′-Fucosyllactose (% of dry matter): ≥ 75.0 % (w/w) Difucosyllactose (% of dry matter): ≥ 5.0 % (w/w) D-Lactose: ≤ 10.0 % (w/w) L-Fucose: ≤ 1.0 % (w/w) 2′-Fucosyl-D-lactulose: ≤ 2.0 (w/w) Sum of other carbohydrates (11): ≤ 6.0 % (w/w) Moisture: ≤ 6.0 % (w/w) Ash, sulfated: ≤ 0.8 % (w/w) pH (20 °C, 5 % solution): 4.0 -6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g Salmonella sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units**]**
[F67 **2'-Fucosyllactose / Difucosyllactose mixture ('2'-FL/DFL') (microbial source)**	**Description/Definition:**
	2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white powder or agglomerates thereof that is produced by a microbial process.
	Source: Genetically modified strain of *Escherichia coli* strain K-12 DH1
	Characteristics/Composition:
	Appearance: White to off-white powder or agglomerates Sum of 2'-Fucosyllactose, Difucosyllactose, D-Lactose, L-Fucose, and 3-Fucosyllactose (% of dry matter): ≥ 92.0 % (w/w) Sum of 2'-fucosyllactose and difucosyllactose (% of dry matter): ≥ 85.0 % (w/w)

	2'-Fucosyllactose (% of dry matter): ≥ 75.0 % (w/w) Difucosyllactose (% of dry matter): ≥ 5.0 % (w/w) D-Lactose: ≤ 10.0 % (w/w) L-Fucose: ≤ 1.0 % (w/w) 2'-Fucosyl-D-lactulose: ≤ 2.0 % (w/w) Sum of other carbohydrates : ≤ 6.0 % (w/w) Moisture: ≤ 6.0 % (w/w) Ash, sulfated: ≤ 0.8 % (w/w) pH (20 °C, 5 % solution): 4.0-6.0 Residual protein: ≤ 0.01 % (w/w)
	Microbiological criteria:
	Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units**]**
Galacto-oligosaccharide	**Description/Definition:** **Galacto-oligosaccharide is produced from milk lactose by an enzymatic process using β-galactosidases from *Aspergillus oryzae* , *Bifidobacterium bifidum, Pichia pastoris, Sporobolomyces singularis, Kluyveromyces lactis, Bacillus circulans, and Papiliotrema terrestris* .** GOS: min 46 % Dry Matter (DM) Lactose: max 40 % DM Glucose: max 27 % DM Galactose: min 0,8 % DM Ash: max 4,0 % DM Protein: max 4,5 % DM Nitrite: max. 2 mg/kg
Glucosamine HCl from *Aspergillus niger* and genetically modified strain of *E. coli* K-12	White crystalline odourless powder Molecular formula: $C_6H_{13}NO_5 \cdot HCl$ Relative molecular mass: 215,63 g/mol D-Glucosamine HCl 98,0-102,0 % of reference standard (HPLC) Specific rotation + 70,0 ° - + 73,0 °
Glucosamine sulphate KCl from *Aspergillus niger* and genetically modified strain of *E. coli* K-12	White crystalline odourless powder Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$ Relative molecular mass: 605,52 g/mol D-Glucosamine Sulphate 2KCl 98,0-102,0 % of reference standard (HPLC) Specific Rotation +50,0 ° to +52,0 °
Glucosamine sulphate NaCl from *Aspergillus niger* and	White crystalline odourless powder Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl$ Relative molecular mass: 573,31 g/mol D-Glucosamine HCl: 98-102 % of reference standard (HPLC)

genetically modified strain of *E. coli* K-12	Specific Optical Rotation: +52 ° - +54 °
Guar Gum	**Description/Definition:** Native guar gum is the ground endosperm of seeds from natural strains of guar *Cyamopsis tetragonolobus* L. Taub. (*Leguminosae* family). It consists of a high molecular weight polysaccharide, primarily composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as a galactomannan (galactomannan content not less than 75 %). Appearance: White to yellowish powder Molecular weight: Between 50 000 – 8 000 000 Daltons CAS number: 9000-30-0 Einecs Number: 232-536-8 Purity: As specified by Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council[a] & by Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins[b]. **Physico-chemical properties:** **Powder** Shelf-life: 2 years Colour: White Odour: Light Average diameter of particles: 60-70µm Moisture: Max 15 % Viscosity * at 1 hour —Viscosity * at 2 hours: Min 3 600 mPa.s Viscosity * at 24 hours: Min 4 000 mPa.s Solubility: Soluble in hot and cold water pH for 10g/L, at 25 °C - 6-7,5 **Flakes** Useful life: 1 year Colour: White/off white with absence or minimal presence of black spots Odour: Light Average diameter of particles: 1-10 mm Moisture: Max 15 % Viscosity * at 1 hour: Min 3 000 mPa.s Viscosity * at 2 hours — Viscosity * at 24 hours — Solubility — Soluble in hot and cold water pH for 10g/L, at 25 °C - 5-7,5 (*) The measurements of viscosity are carried out under the following conditions: 1 %, 25 °C, 20 rpm
Heat-treated milk products fermented with *Bacteroides xylanisolvens*	**Description/Definition:** Heat-treated fermented milk products are produced with *Bacteroides xylanisolvens* (DSM 23964) as starter culture. Semi-skimmed milk (between 1,5 % and 1,8 % fat) or skimmed milk (0,5 % fat or less) is pasteurised or ultra-heat-treated before starting the fermentation with *Bacteroides xylanisolvens* (DSM 23964). The

	resulting fermented milk product is homogenised and then heat-treated to inactivate *Bacteroides xylanisolvens* (DSM 23964). The final product does not contain viable cells of *Bacteroides xylanisolvens* (DSM 23964) ([1]). ([1]) Modified DIN EN ISO 21528-2.
Hydroxytyrosol	**Description/Definition:** Hydroxytyrosol is a pale yellow viscous liquid obtained by chemical synthesis Molecular formula: $C_8H_{10}O_3$ Molecular weight: 154,6 g/mol CAS No: 10597-60-1 Moisture ≤ 0,4 % Odour: CharacteristicTaste: Slightly bitter Solubility (water): Miscible with water pH: 3,5-4,5 Refractive Index: 1,571-1,575 **Purity:** Hydroxytyrosol: ≥ 99 % Acetic acid: ≤ 0,4 % Hydroxytyrosol acetate: ≤ 0,3 % Sum of homovanillic acid, iso-homovanilic acid, and 3-methoxy-4hydroxyphenylglycol: ≤ 0,3 % **Heavy Metals** Lead: ≤ 0,03 mg/kg Cadmium: ≤ 0,01 mg/kg Mercury: ≤ 0,01 mg/kg **Residual Solvents** Ethyl acetate: ≤ 25,0 mg/kg Isopropanol: ≤ 2,50 mg/kg Methanol: ≤ 2,00 mg/kg Tetrahydrofuran: ≤ 0,01 mg/kg
Ice Structuring Protein type III HPLC 12	**Description/Definition:** The Ice Structuring Protein (ISP) preparation is a light-brown liquid produced by submerged fermentation of a genetically-modified strain of food-grade baker's yeast (*Saccharomyces cerevisiae*) in which a synthetic gene for the ISP has been inserted into the yeast's genome. The protein is expressed and secreted into the growth medium where it is separated from the yeast cells by micro-filtration and concentrated by ultra-filtration. As a result, the yeast cells are not transferred into the ISP preparation as such or under an altered form. The ISP preparation consists of native ISP, glycosylated ISP and proteins and peptides from the yeast and sugars as well as acids and salts commonly found in food. The concentrate is stabilised with 10 mM citric acid buffer. Assay: ≥ 5 g/l active ISP pH: 2,5-3,5 Ash: ≤ 2,0 % DNA: Not detectable
Aqueous extract of dried	**Description/Definition:** Dark brown liquid. Aqueous extracts of dried leaves of *Ilex guayusa.* **Composition:**

leaves of *Ilex guayusa*	Protein: < 0,1 g/100 ml Fat: < 0,1 g/100 ml Carbohydrate: 0,2–0,3 g/100 ml Total sugars: < 0,2 g/100 ml Caffeine: 19,8–57,7 mg/100 ml Theobromine: 0,14–2,0 mg/100 ml Chlorogenic acids: 9,9–72,4 mg/100ml
[F25Infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner (Traditional food from a third country)	**Description/Definition:** The traditional food consists of an infusion of leaves from *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner (family: Rubiaceae). The traditional food is prepared by mixing a maximum of 20 g of dried leaves from *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner with 1 L of hot water. Leaves are removed and the infusion is then subjected to pasteurization (at least 71 °C for 15 seconds). **Composition:** Visual: Brown green liquid Odour and taste: Characteristic Chlorogenic acid (5-CQA): < 100 mg/L Caffeine: < 80 mg/L Epigallocatechin gallate (EGCG): < 700 mg/L **Microbiological criteria:** Total plate count: < 500 CFU/g Total yeast and mould count: < 100 CFU/g Total coliforms: < 100 CFU/g *Escherichia coli* : Absence in 1 g *Salmonella* : Absence in 25 g **Heavy metals:** Lead (Pb): < 3,0 mg/L Arsenic (As): < 2,0 mg/L Cadmium (Cd): < 1,0 mg/L CFU: Colony Forming Units**]**
Isomalto-oligosaccharide	**Powder:** Solubility (water) (%): > 99 Glucose (% dry basis): ≤ 5,0 Isomaltose + DP3 to DP9 (% dry basis): ≥ 90 Moisture (%): ≤ 4,0 Sulphated ash(g/100 g): ≤ 0,3 **Heavy metals:** Lead (mg/kg): ≤ 0,5 Arsenic (mg/kg): ≤ 0,5 **Syrup:** Dried solids (g/100 g): > 75 Glucose (% dry basis): ≤ 5,0 Isomaltose + DP3 to DP9 (% dry basis): ≥ 90 pH: 4 - 6 Sulphated ash(g/100 g): ≤ 0,3 **Heavy metals:** Lead (mg/kg): ≤ 0,5 Arsenic (mg/kg): ≤ 0,5
Isomaltulose	**Description/Definition:**

	A reducing disaccharide that consists of one glucose and one fructose moiety linked by an alpha-1,6-glycosidic bond. It is obtained from sucrose by an enzymatic process. The commercial product is the monohydrate. Appearance: Virtually odourless, white or almost white crystals with a sweet tasteChemical name: 6-O-α-D-glucopyranosyl-D-fructofuranose, monohydrate CAS No.: 13718-94-0 Chemical formula: $C_{12}H_{22}O_{11} \cdot H_2O$ Structural formula  Formula weight: 360,3 (monohydrate) **Purity:** Assay: ≥ 98 % on the dry basis Loss on drying: ≤ 6,5 % (60 °C, 5 hours) **Heavy metals:** Lead: ≤ 0,1 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5([1]), 'Instrumental methods' ([1]) Food and Nutrition Paper 5 Rev. 2 — Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA), 1991, 322 pp., English, ISBN 92-5-102991-1.
Lactitol	**Description/Definition:** Crystalline powder or colourless solution manufactured via catalytic hydrogenation of lactose. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst. Chemical name: 4-O-β-D-Galactopyranosyl-D-glucitol Chemical formula: $C_{12}H_{24}O_{11}$ Molecular weight: 344,31 g/mol CAS No: 585-86-4 **Purity:** Solubility (in water): Very soluble in water Specific rotation $[\alpha]_D^{20} = +13^o$ to $+16^o$ Assay: ≥ 95 % d.b (d.b — expressed on the dry weight basis) Water: ≤ 10,5 % Other polyols: ≤ 2,5 % d.b Reducing sugars: ≤ 0,2 % d.b Chlorides: ≤ 100 mg/kg d.b

	Sulphates: ≤ 200 mg/kg d.b Sulphated ash: ≤ 0,1 % d.b Nickel: ≤ 2,0 mg/kg d.b Arsenic: ≤ 3,0 mg/kg d.b Lead: ≤ 1,0 mg/kg d.b
Lacto- *N* -neotetraose (synthetic)	**Definition:** Chemical name: β-D-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)- D-glucopyranose Chemical formula: $C_{26}H_{45}NO_{21}$ CAS No: 13007-32-4 Molecular weight: 707,63 g/mol **Description:** Lacto- *N* -neotetraose is a white to off-white powder. Produced by a chemical synthesis process and is isolated by crystallisation. **Purity:** Assay (water free): ≥ 96 % D-Lactose: ≤ 1,0 % Lacto-N-triose II: ≤ 0,3 % Lacto-N-neotetraose fructose isomer: ≤ 0,6 % pH (20 °C, 5 % solution): 5,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 0,4 % Acetic acid: ≤ 0,3 %Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50 mg/kg singly, ≤ 200 mg/kg in combination Residual proteins: ≤ 0,01 % Palladium: ≤ 0,1 mg/kg Nickel: ≤ 3,0 mg/kg **Microbiological criteria:** Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts: ≤ 10 CFU/g Moulds: ≤ 10 CFU/g Residual endotoxins: ≤ 10 EU/mg
[F68Lacto *N* neotetraose (microbial source)	**Definition:** Chemical name: β-D-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose Chemical formula: $C_{26}H_{45}NO_{21}$ CAS No: 13007-32-4 Molecular weight: 707,63 g/mol **Source:** Genetically modified strain of *Escherichia coli* K-12 **Description:** Lacto- *N* -neotetraose is a white to off-white powder that is produced by a microbiological process. **Purity:** Assay (water free): ≥ 80 % D-Lactose: ≤ 10,0 % Lacto- *N* -triose II: ≤ 3,0 % *para* -Lacto- *N* -neohexaose: ≤ 5,0 % Lacto- *N* -neotetraose fructose isomer: ≤ 1,0 %

	Sum of saccharides (Lacto- *N* -neotetraose, D-Lactose, Lacto- *N* -triose II, *para* -Lacto- *N* -neohexaose, Lacto- *N* -neotetraose fructose isomer): ≥ 92 % pH (20 C, 5 % solution): 4,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 0,4 % Residual solvents (methanol): ≤ 100 mg/kg Residual proteins: ≤ 0,01 % **Microbiological criteria:** Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts: ≤ 10 CFU/g Moulds: ≤ 10 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.**]**
[[F27]Lacto- *N* -tetraose (‘LNT’) **(microbial source)**	**Definition:** Chemical formula: $C_{26}H_{45}O_{21}$ Chemical name: β-D-Galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose Molecular mass: 707,63 Da CAS No 14116-68-8 **Description:** Lacto- *N* -tetraose is a purified, white to off-white amorphous powder that is produced by a microbial process. **Source:** Genetically modified strain of *Escherichia coli* strain K-12 DH1 **Characteristics/Composition:** Appearance: White to off-white powder Sum of lacto- *N* -tetraose, D-Lactose and lacto- *N* -tetraose II (% of dry matter): ≥ 90,0 % (w/w) Lacto- *N* -tetraose (% of dry matter): ≥ 70,0 % (w/w) D-Lactose: ≤ 12,0 % (w/w) Lacto- *N* -tetraose II: ≤ 10,0 % (w/w) *Para* -lacto- *N* -hexaose-2: ≤ 3,5 % (w/w) Lacto- *N* -tetraose fructose isomer: ≤ 1,0 % (w/w) Sum of other carbohydrates: ≤ 5,0 % (w/w) Moisture: ≤ 6,0 % (w/w) Ash, sulfated: ≤ 0,5 % (w/w) pH (20 °C, 5 % solution): 4,0–6,0 Residual protein: ≤ 0,01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1 000 CFU/g *Enterobacteriaceae* : ≤ 10 CFU/g *Salmonella* sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.**]**
[[F28]*Lonicera caerulea* L. berries (haskap)	**Description/Definition:** The traditional food are fresh and frozen berries from *Lonicera caerulea* var. edulis. *Lonicera caerulea* L. is a deciduous shrub belonging to the *Caprifoliaceae* family.

(Traditional food from a third country)	**Typical nutritional components of haskap berries** (given in fresh berries): Carbohydrates: 12,8 % Fibre: 2,1 % Lipids: 0,6 % Proteins: 0,7 % Ash: 0,4 % Water: 85,5 %**]**
Lucerne leaf extract from *Medicago sativa*	**Description/Definition:** The Lucerne (*Medicago sativa* L.) is processed within 2 hours after harvest. It is chopped and crushed. By passing through an oleaginous-type press, the Lucerne provides a fibrous residue and press juice (10 % of dry matter). The dry matter of this juice contains about 35 % of crude protein. The press juice (pH 5,8-6,2) is neutralised. Preheating and vapour injection allows coagulation of proteins associated with carotenoid and chlorophyll pigments. The protein precipitate is separated by centrifugation and thereafter dried. After adding ascorbic acid the Lucerne protein concentrate is granulated and stored in inert gas or in cold storage. **Composition:** Protein: 45-60 % Fat: 9-11 % Free carbohydrates (soluble fibre): 1-2 % Polysaccharides (insoluble fibre): 11-15 % including cellulose: 2-3 % Minerals: 8-13 % Saponins: ≤ 1,4 % Isoflavones: ≤ 350 mg/kg Coumestrol: ≤ 100 mg/kg Phytates: ≤ 200 mg/kg L-canavanine: ≤ 4,5 mg/kg
Lycopene	**Description/Definition:** Synthetic lycopene is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists of ≥ 96 % lycopene and minor quantities of other related carotenoid components. Lycopene is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Antioxidative protection has to be assured. Chemical name: Lycopene CAS No.: 502-65-8 (*all* -trans lycopene) Chemical formula: $C_{40}H_{56}$ Formula weight: 536,85 Da
Lycopene from *Blakeslea trispora*	**Description/Definition:** The purified lycopene from *Blakeslea trispora* consists of ≥ 95 % lycopene and ≤ 5 % other carotenoids. It is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Anti-oxidative protection has to be assured. Chemical name: Lycopene CAS No.: 502-65-8 (all trans lycopene) Chemical formula: $C_{40}H_{56}$ Formula weight: 536,85 Da

Lycopene from tomatoes	**Description/Definition:** The purified lycopene from tomatoes (*Lycopersicon esculantum* L.) consists of ≥ 95 % lycopene and ≤ 5 % other carotenoids. It is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Anti-oxidative protection has to be assured. Chemical name: Lycopene CAS No.: 502-65-8 (all trans lycopene) Chemical formula: $C_{40}H_{56}$ Formula weight: 536,85 Da
Lycopene oleoresin from tomatoes	**Description/Definition:** Lycopene oleoresin from tomatoes is obtained by solvent extraction of ripe tomatoes (*Lycopersicon esculentum Mill.*) with subsequent removal of the solvent. It is a red to dark brown viscous, clear liquid. Total lycopene: 5-15 % Thereof trans-lycopene: 90-95 % Total carotenoids (calculated as lycopene): 6,5-16,5 % Other carotenoids: 1,75 % (Phytoene/phytofluene/β-carotene): (0,5-0,75/0,4-0,65/0,2-0,35 %) Total tocopherols: 1,5-3,0 % Unsaponifiable matter: 13-20 % Total fatty acids: 60-75 % Water (Karl Fischer): ≤ 0,5 %
[F18Hen egg white lysozyme hydrolysate	**Description/Definition** Hen egg white lysozyme hydrolysate is obtained from hen egg white lysozyme by an enzymatic process, using subtilisin from *Bacillus licheniformis* . The product is a white to light yellow powder. **Specification** Protein (TN(*) x 5,30): 80-90 % Tryptophan: 5-7 % Ratio Tryptophan/LNAA(**): 0,18-0.25 Degree of hydrolysis: 19-25 % Moisture: < 5 % Ash: < 10 % Sodium: < 6 % **Heavy metals** Arsenic: < 1 ppm Lead: < 1 ppm Cadmium: < 0,5 ppm Mercury: < 0,1 ppm **Microbiological criteria** Total aerobic count: $< 10^3$ CFU/g Total combined yeasts/moulds count: $< 10^2$ CFU/g Enterobacteria: < 10 CFU/g *Salmonella* spp: Absence in 25 g *Escherichia coli* : Absence in 10 g *Staphylococcus aureus* : Absence in 10 g *Pseudomonas aeruginosa* : Absence in 10 g * TN: total nitrogen

	** LNAA: large neutral amino acids**]**
Magnesium citrate malate	**Description/Definition:** Magnesium citrate malate is a white to yellowish-white, amorphous powder.Chemical formula: $Mg_5(C_6H_5O_7)_2(C_4H_4O_5)_2$ Chemical name: Pentamagnesium di-(2-hydroxybutanedioate)-di-(2-hydroxypropane-1,2,3-tricarboxylate) CAS No.: 1259381-40-2 Molecular weight: 763,99 Daltons (anhydrous) Solubility: Freely soluble in water (about 20 g in 100 ml) Description of the physical state: Amorphous powder Assay magnesium: 12,0-15,0 % Loss on drying (120 °C/4 hours): ≤ 15 % Colour (solid): White to yellowish-white Colour (20 % aqueous solution): Colourless to yellowish Appearance (20 % aqueous solution): Clear solution pH (20 % aqueous solution): Approx. 6,0 **Impurities:** Chloride: ≤ 0,05 % Sulphate: ≤ 0,05 % Arsenic: ≤ 3,0 ppm Lead: ≤ 2,0 ppm Cadmium: ≤ 1 ppm Mercury: ≤ 0,1 ppm
Magnolia Bark Extract	**Description/Definition:** Magnolia bark extract is obtained from the bark of the plant *Magnolia officinalis* L. and produced with supercritical carbon dioxide. The bark is washed and oven dried to reduce moisture content before being crushed and extracted with supercritical carbon dioxide. The extract is dissolved in medical-grade ethanol and re-crystallised to yield magnolia bark extract. Magnolia bark extract is mainly composed of two phenolic compounds, magnolol and honokiol. Appearance: Light brownish powder **Purity:** Magnolol: ≥ 85,2 % Honokiol: ≥ 0,5 % Magnolol & Honokiol: ≥ 94 % Total Eudesmol: ≤ 2 % Moisture: 0,50 % **Heavy metals:** Arsenic (ppm): ≤ 0,5 Lead (ppm): ≤ 0,5 Methyl eugenol (ppm): ≤ 10 Tubocurarine (ppm): ≤ 2,0 Total Alkaloid (ppm): ≤ 100
Maize-germ oil high in unsaponifiable matter	**Description/Definition:** Maize-germ oil high in unsaponifiable matter is produced by vacuum distillation and it is different from refined maize-germ oil in the concentration of the unsaponifiable fraction (1,2 g in refined maize-germ oil and 10 g in ‘maize-germ oil high in unsaponifiable matter’). **Purity:** Unsaponifiable matter: > 9,0 g/100 g

	Tocopherols: ≥ 1,3 g/100 g α-tocopherol (%): 10-25 % β-tocopherol (%): < 3,0 % γ-tocopherol (%): 68-89 % δ-tocopherol (%): < 7,0 % Sterols, triterpenic alcohols, methylsterols: > 6,5 g/100 g Fatty acids in triglycerides: palmitic acid: 10,0-20,0 % stearic acid: < 3,3 % oleic acid: 20,0-42,2 % linoleic acid: 34,0-65,6 % linolenic acid: < 2,0 % Acid value: ≤ 6,0 mg KOH/g Peroxide value (PV): ≤ 10 mEq O_2 /kg **Heavy metals:** Iron (Fe): < 1 500 µg/kg Copper (Cu): < 100 µg/kg **Impurities:** Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 µg/kg Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'maize-germ oil high in unsaponifiable matter'
Methylcellulose	**Description/Definition:** Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups. Chemical name: Methyl ether of cellulose Chemical formula: The polymers contain substituted anhydroglucose units with the following general formula: C6H7O2(OR1)(OR2)(OR3) where R1, R2, R3 each may be one of the following: — H — CH_3 or — CH_2CH_3 Molecular weight: Macromolecules: from about 20 000 (n about 100) up to about 380 000 g/mol (n about 2 000) Assay: Content not less than 25 % and not more than 33 % of methoxyl groups (-OCH_3) and not more than 5 % of hydroxyethoxyl groups (-OCH_2CH_2OH) Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder. Solubility: Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid. **Purity:** Loss on drying: ≤ 10 % (105 °C, 3 hours) Sulphated Ash: ≤ 1,5 % determined at 800 ± 25 °C pH: ≥ 5,0 and ≤ 8,0 (1 % colloidal solution) **Heavy metals:** Arsenic: ≤ 3,0 mg/kg Lead: ≤ 2,0 mg/kg Mercury: ≤ 1,0 mg/kg Cadmium: ≤ 1,0 mg/kg

[F29 1-Methylnicotinamide chloride	**Definition:** Chemical name: 3-carbamoyl-1-methyl-pyridinium chloride Chemical formula: $C_7H_9N_2OCl$ CAS No: 1005-24-9 Molecular weight: 172,61 Da **Description** 1-Methylnicotinamide chloride is white or off-white, crystalline solid produced by a chemical synthesis process. **Characteristics/Composition** Appearance: White – off-white, crystalline solid Purity: ≥ 98,5 % Trigonelline: ≤ 0,05 % Nicotinic Acid: ≤ 0,10 % Nicotinamide: ≤ 0,10 % Largest unknown impurity: ≤ 0,05 % Sum of unknown impurities: ≤ 0,20 % Sum of all impurities: ≤ 0,50 % Solubility: soluble in water and methanol. Practically insoluble in 2-propanol and dichloromethane Moisture: ≤ 0,3 % Loss on drying: ≤ 1,0 % Residue on ignition: ≤ 0,1 % **Residual Solvents and Heavy Metals** Methanol: ≤ 0,3 % Heavy metals: ≤ 0,002 % **Microbiological criteria:** Total aerobic microbial count: ≤ 100 CFU/g Mould/yeast: ≤ 10 CFU/g Enterobacteriaceae: absence in 1 g *Pseudomonas aeruginosa* : absence in 1 g *Staphylococcus aureus* : absent in 1 g CFU: Colony Forming Units**]**
(6S)-5-methyltetrahydrofolic acid, glucosamine salt	**Description/Definition:** Chemical name: N-[4-[[[(6S)-2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl]methyl]amino]benzoyl]-L-glutamic acid, glucosamine salt Chemical formula: $C_{32}H_{51}N_9O_{16}$ Molecular weight: 817,80 g/mol (anhydrous) CAS No.: 1181972-37-1 Appearance: Creamy to light-brown powder **Purity:** Diastereoisomeric purity: At least 99 % of (6S)-5-methyltetrahydrofolic acid Glucosamine assay: 34-46 % in dry basis 5-Methyltetrahydrofolic acid assay: 54-59 % in dry basis Water: ≤ 8,0 % **Heavy metals:** Lead: ≤ 2,0 ppm Cadmium: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm Arsenic: ≤ 2,0 ppm Boron: ≤ 10 ppm **Microbiological criteria:**

	Total aerobic microbial count: ≤ 100 CFU/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli* : Absence in 10g
Monomethylsilanediol (Organic Silicon)	**Description/Definition:** Chemical name: Silanetriol, 1-methyl- Chemical formula: CH_6O_3Si Molecular weight: 94,14 g/mol CAS No: 2445-53-6 **Purity:** Organic Silicon (monomethylsilanetriol) preparation (aqueous solution): Acidity (pH): 6,4-6,8 Silicon: 100-150 mg Si/l **Heavy metals:** Lead: ≤ 1,0 µg/l Mercury: ≤ 1,0 µg/l Cadmium: ≤ 1,0 µg/l Arsenic: ≤ 3,0 µg/l **Solvents:** Methanol: ≤ 5,0 mg/kg (residual presence)
Mycelial extract from Shiitake mushroom (*Lentinula edodes*)	**Description/Definition:** The novel food ingredient is a sterile aqueous extract obtained from the mycelium of *Lentinula edodes* cultivated in a submerged fermentation. It is a light brown, slightly turbid liquid. Lentinan is a β-(1-3) β-(1-6)-D-glucan which has a molecular weight of approximately 5×10^5 Daltons, a degree of branching of 2/5 and a triple helical tertiary structure. **Purity/Composition of the mycelial extract from *Lentinula edodes* :** Moisture: 98 % Dry matter: 2 % Free glucose: < 20 mg/ml Total protein([1]): < 0,1 mg/ml N-containing constituents([2]): < 10 mg/ml Lentinan: 0,8 – 1,2 mg/ml\ ([1]) Bradford method ([2]) Kjeldahl method
[F30Nicotinamide riboside chloride	**Description/Definition:** The novel food is a synthetic form of nicotinamide riboside. The novel food contains ≥ 90 % nicotinamide riboside chloride, predominantly in its β form, the remaining components being residual solvents, reaction by-products and degradation products. Nicotinamide riboside chloride: CAS number: 23111-00-4 EC number: 807-820-5 IUPAC name: 1-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]pyridin-1-ium-3-carboxamide;chloride Chemical formula: $C_{11}H_{15}N_2O_5Cl$ Molecular weight: 290,7 g/mol **Characteristics/Composition:** Colour: White to light brown

	Form: Powder Identification: Conforms by NMR (nuclear magnetic resonance) Nicotinamide riboside chloride: ≥ 90 % Water content: ≤ 2 % **Residual solvents:** Acetone: ≤ 5 000 mg/kg Methanol: ≤ 1 000 mg/kg Acetonitrile: ≤ 50 mg/kg Methyl tert-butyl ether: ≤ 500 mg/kg **Reaction by-products:** Methyl acetate: ≤ 1 000 mg/kg Acetamide: ≤ 27 mg/kg Acetic acid: ≤ 5 000 mg/kg **Heavy metals:** Arsenic: ≤ 1 mg/kg **Microbiological criteria:** Total Plate Count: ≤ 1 000 CFU/g Yeast and Mould: ≤ 100 CFU/g *Escherichia coli* : Absence in 10 g**]**
Noni fruit juice (*Morinda citrifolia*)	**Description/Definition:** Noni fruits (fruits of *Morinda citrifolia* L.) are pressed. The obtained juice is pasteurised. An optional fermentation step before or after the pressing may occur. Rubiadin: ≤ 10 µg/kg Lucidin: ≤ 10 µg/kg
Noni fruit juice powder (*Morinda citrifolia*)	**Description/Definition:** Seeds and skin of the sun-dried fruits of *Morinda citrifolia* are separated. The obtained pulp is filtered to separate juice from the flesh. Desiccation of the produced juice occurs in one or two ways: Either by atomisation using maize maltodextrins, this mixture is obtained by keeping the rates of inflow of the juice and maltodextrins constant Or by zeodratation or drying and then mixing with an excipient, this process allows the juice to be dried initially and then mixed with maltodextrins (same amount as used in atomisation).
Noni fruit puree and concentrate (*Morinda citrifolia*)	**Description/Definition:** The fruits of *Morinda citrifolia* are harvested by hand. Seeds and skin may be separated mechanically from the pureed fruits. After pasteurisation, the puree is packaged in aseptic containers and stored under cold conditions.no_br *Morinda citrifolia* concentrate is prepared from *M. citrifolia* puree by treatment with pectinolytic enzymes (50–60 °C for 1-2 h). Then the puree is heated to inactivate the pectinases and then immediately cooled. The juice is separated in a decanter centrifuge. Afterwards the juice is collected and pasteurised, prior to being concentrated in a vacuum evaporator from a brix of 6 to 8 to a brix of 49 to 51 in the final concentrate. **Composition:** **Puree:** Moisture: 89-93 % Protein: < 0,6 g/100 g Fat: ≤ 0,4 g/100 g Ash: < 1,0 g/100 g

	Total carbohydrates: 5-10 g/100 g Fructose: 0,5-3,82 g/100 g Glucose: 0,5-3,14 g/100 g Dietary fibre: < 0,5-3 g/100 g 5,15-dimethylmorindol (1): ≤ 0,254 µg/ml Lucidin (1): Not detectable Alizarin (1): Not detectable Rubiadin (1): Not detectable **Concentrate:** Moisture: 48-53 % Protein: 3-3,5 g/100 g Fat: < 0,04 g/100 g Ash: 4,5-5,0 g/100 g Total carbohydrates: 37-45 g/100 g Fructose: 9-11 g/100 g Glucose: 9-11 g/100 g Dietary fibre: 1,5-5,0 g/100 g 5,15-dimethylmorindol ([1]): ≤ 0,254 µg/ml ([1]) *By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia puree and concentrate. Limits of detection: 2,5 ng/ml (5,15 dimethylmorindol); 50,0 ng/ml (lucidin); 6,3 ng/ml (alizarin) and 62,5 ng/ml (rubiadin).*
Noni leaves (*Morinda citrifolia*)	**Description/Definition:** After cutting, the leaves of *Morinda citrifolia* are subject to drying and roasting steps. The product has a particle size ranging from broken leaves to coarse powder with fines. It is of greenish brown to brown colour. **Purity/Composition:** Moisture: < 5,2 % Protein: 17- 20 % Carbohydrate: 55-65 % Ash: 10-13 % Fat: 4-9 % Oxalic acid: < 0,14 % Tannic acid: < 2,7 % 5,15-dimethylmorindol: < 47 mg/kg Rubiadin: non detectable, ≤ 10 µg/kg Lucidin: non detectable, ≤ 10 µg/kg
Noni fruit powder (*Morinda citrifolia*)	**Description/Definition:** Noni fruit powder is made from pulped noni (*Morinda citrifolia L.)* fruits by freeze-drying. Fruits are pulped and seeds are removed. After freeze-drying during which water is removed from noni fruits, the remaining noni pulp is milled to a powder and encapsulated. **Purity/Composition** Moisture: 5,3-9 % Protein: 3,8-4,8 g/100 g Fat: 1-2 g/100 g Ash: 4,6-5,7 g/100 g Total carbohydrates: 80-85 g/100 g Fructose: 20,4-22,5 g/100 g Glucose: 22-25 g/100 g

	Dietary fibre: 15,4-24,5 g/100 g 5,15-dimethylmorindol ([1]): ≤ 2,0 μg/ml ([1]) *By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia fruit powder. Limits of detection: 2,5 ng/ml (5,15 dimethylmorindol)*
***Odontella aurita* microalgae**	Silicon: 3,3 % Crystalline silica: max 0,1-0,3 % as impurity
Oil enriched with phytosterols/ phytostanols	**Description/Definition:** Oil enriched with phytosterols/phytostanols is composed of an oil fraction and a phytosterol fraction. **Acylglycerol Distribution:** Free fatty acids (expressed as oleic acid): ≤ 2,0 % Monoacylglycerols (MAG): ≤ 10 % Diacylglycerols (DAG): ≤ 25 % Triacylglycerols (TAG): Making up the balance **Phytosterol fraction:** β-sitosterol: ≤ 80 % β-sitostanol: ≤ 15 % campesterol: ≤ 40 % campestanol: ≤ 5,0 % stigmasterol: ≤ 30 % brassicasterol ≤ 3,0 % other sterols/stanols: ≤ 3,0 % **Others:** Moisture and volatile: ≤ 0,5 % Peroxide value (PV): < 5,0 meq/kg Trans fatty acids: ≤ 1 % Contamination/Purity (GC-FID or equivalent method) of phytosterols/ phytostanols: Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 %.
Oil extracted from squids	Acid value: ≤ 0,5 KOH/g oil Peroxide value (PV): ≤ 5 meq O_2 /kg oil p-Anisidine value: ≤ 20 Cold test at 0 °C: ≤ 3 hours Moisture: ≤ 0,1 % (w/w) Unsaponifiable matter: ≤ 5,0 %Trans fatty acids: ≤ 1,0 % Docosahexaeonic acid: ≥ 20 % Eicosapentaenoic acid: ≥ 10 %
[F7Partially defatted chia seed (*Salvia hispanica*) powders	**Description/Definition:** The novel foods are partially defatted chia seed (*Salvia hispanica*) powders obtained by pressing and grinding of the whole seeds of *Salvia hispanica* L. **Physical–sensorial:** Foreign matter: 0,1 %

	Powder with high protein content	Powder with high fibre content	
Particle size	≤ 130 µm	≤ 400 µm	
Chemical composition:			
	Salvia hispanica powder with high protein content	*Salvia hispanica* powder with high fibre content	
Moisture	≤ 9,0 %	≤ 9,0 %	
Protein	≥ 40,0 %	≥ 24,0 %	
Fat	≤ 17 %	≤ 12 %	
Fibre	≤ 30 %	≥ 50 %	

Microbiological criteria:
Total plate count: ≤ 10 000 CFU/g
Yeasts: ≤ 500 CFU/g
Moulds: ≤ 500 CFU/g
Staphylococcus aureus : ≤ 10 CFU/g
Coliforms: < 100 MPN/g
Enterobacteriaceae: ≤ 100 CFU/g
Bacillus cereus : ≤ 50 CFU/g
Escherichia coli : < 10 MPN/g
Listeria monocytogenes : Absence/g
Salmonella spp.: Absence in 25 g
Contaminants :
Arsenic: ≤ 0,1 ppm
Cadmium: ≤ 0,1 ppm
Lead: ≤ 0,1 ppm
Mercury: ≤ 0,1 ppm
Total aflatoxins: ≤ 4 ppb
Ochratoxin A: ≤ 1 ppb**]**

Pasteurised fruit-based preparations produced using high-pressure treatment	***Parameter***	***Target***	***Comments***
	Fruit storage before high-pressure treatment	Minimum 15 days at – 20 °C	Fruit harvested and stored in conjunction with good/hygienic agricultural and manufacturing practices
	Fruit added	40 % to 60 % of thawed fruit	Fruit homogenised and added to other ingredients
	pH	3,2 to 4,2	
	^{o} Brix	7 to 42	Assured by added sugars
	a_w	< 0,95	Assured by added sugars
	Final storage	60 days maximum at + 5 °C maximum	Equivalent to storage regimen for conventionally processed product

[F31Phenylcapsaicin	**Description/Definition:** Phenylcapsaicin (*N* -[(4-hydroxy-3-methoxyphenyl)methyl]-7-phenylhept-6-ynamide, $C_{21}H_{23}NO_3$, CAS no: 848127-67-3), is synthesized chemically via a two step synthesis process involving in a first step the production of the acetylenic acid intermediate through a reaction of phenyl acetylene with a carboxylic acid derivative, and in a second step a series of reactions of the acetylenic acid intermediate with vanillylamine derivative to produce phenylcapsaicin. **Characteristics/Composition:** Purity (% of dry matter): ≥ 98 % Moisture: ≤ 0,5 % Total synthesis related production by-products: ≤ 1,0 % *N,N* -dimethyl formamide: ≤ 880 mg/kg Dichloromethane: ≤ 600 mg/kg Dimethoxyethane: ≤ 100 mg/kg Ethyl acetate: ≤ 0,5 % Other solvents: ≤ 0,5 % **Heavy metals:** Lead: ≤ 1,0 mg/kg Cadmium: ≤ 1,0 mg/kg Mercury: ≤ 0,1 mg/kg Arsenic: ≤ 1,0 mg/kg **Microbiological criteria:** Total plate count: ≤ 10 CFU/g Coliforms: ≤ 10 CFU/g *Escherichia coli* : Negative/10 g *Salmonella* sp.: Negative/10 g Yeast and mould: ≤ 10 CFU/g CFU: Colony Forming Units**]**
Phosphated maize starch	**Description/Definition:** Phosphated maize starch (phosphated distarch phosphate) is a chemically modified resistant starch derived from high amylose starch by combining chemical treatments to create phosphate cross-links between carbohydrate residues and esterified hydroxyl groups. The novel food ingredient is a white or nearly white powder. CAS No: 11120-02-8 Chemical formula: $(C_6H_{10}O_5)_n$ $[(C_6H_9O_5)_2PO_2H]x$ $[(C_6H_9O_5)PO_3H_2]y$ n = number of glucose units; x, y = degrees of substitution The chemical characteristics of phosphated distarch phosphate: Loss on drying: 10-14 % pH: 4,5-7,5 Dietary fibre: ≥ 70 % Starch: 7-14 % Protein: ≤ 0,8 % Lipids: ≤ 0,8 % Residual bound phosphorus: ≤ 0,4 % (as phosphorus) ‘high amylose maize’ as source
Phosphatidylserine from fish phospholipids	**Description/Definition:**

	The novel food ingredient is yellow to brown powder. Phosphatidylserine is obtained from fish phospholipids by an enzymatic transphosphorylation with the amino acid L-serine. **Specification of the phosphatidylserine product manufactured from fish phospholipids:** Moisture: < 5,0 % Phospholipids: ≥ 75 % Phosphatidylserine: ≥ 35 % Glycerides: < 4,0 % Free L-serine: < 1,0 % Tocopherols: < 0,5 % ([1]) Peroxide value (PV): < 5,0 meq O_2/kg ([1]) Tocopherols may be added as antioxidants according to Commission Regulation (EU) No 1129/2011
Phosphatidylserine from soya phospholipids	**Description/Definition:** The novel food ingredient is off-white to light yellow powder. It is also available in liquid form with a clear brown to orange colour. The liquid form contains medium chain triacylglycerides (MCT) as a carrier. It contains lower levels of Phosphatidylserine due to the fact that it includes significant amounts of oil (MCT). Phosphatidylserine from soya phospholipids is obtained through enzymatic transphosphatidylation of high-phosphatidylcholine soybean lecithin with the amino acid L-serine. Phosphatidylserine consists of a glycerophosphate skeleton conjugated with two fatty acids and L-serine via a phosphodiester linkage. **Characteristics of Phosphatidylserine from soya phospholipids:** **Powder form:** Moisture: < 2,0 % Phospholipids: ≥ 85 % Phosphatidylserine: ≥ 61 % Glycerides: < 2,0 % free L-serine: < 1,0 % Tocopherols: < 0,3 % Phytosterols: < 0,2 % **Liquid form:** Moisture: < 2,0 % Phospholipids: ≥ 25 %Phosphatidylserine: ≥ 20 % Glycerides: not applicable free L-serine: < 1,0 % Tocopherols: < 0,3 % Phytosterols: < 0,2 %
Phospholipid product containing equal amounts of phosphatidylserine and phosphatidic acid	**Description/Definition:** The product is manufactured through enzymatic conversion of soy lecithin. The phospholipid product is a highly concentrated, yellow-brown powder form of phosphatidylserine and phosphatidic acid at an equal level. **Specification of the product:** Moisture: ≤ 2,0 % Total phospholipids: ≥ 70 % Phosphatidylserine: ≥ 20 % Phosphatidic acid: ≥ 20 %

	Glycerides: ≤ 1,0 % Free L-serine: ≤ 1,0 % Tocopherols: ≤ 0,3 % Phytosterols: ≤ 2,0 % Silicon dioxide is used with a maximum content of 1,0 %
Phospholipides from egg yolk	85 % and 100 % pure Phospholipides from egg yolk
Phytoglycogen	**Description:** White to off-white powder which is an odourless, colourless, flavourless polysaccharide derived from non-GM sweet corn using conventional food processing techniques **Definition:** Glucose polymer $(C_6H_{12}O_6)n$ with linear linkages of α(1 – 4) glycosidic bonds branched every 8 to 12 glucose units by α(1 – 6) glycosidic bonds **Specifications:** Carbohydrates: 97 % Sugars: 0,5 % Fibre: 0,8 % Fat: 0,2 % Protein: 0,6 %
Phytosterols/ phytostanols	**Description/Definition:** Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids. **Composition** (with GC-FID or equivalent method): β-sitosterol: < 81 % β-sitostanol: < 35 % campesterol: < 40 % campestanol: < 15 % stigmasterol: < 30 % brassicasterol: < 3,0 % other sterols/stanols: < 3,0 % **Contamination/Purity** (GC-FID or equivalent method): Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.
Plum kernel oil	**Description/Definition:** Plum kernel oil is a vegetable oil obtained by cold pressing of plum (*Prunus domestica*) kernels. **Composition:** Oleic acid (C18:1): 68 % Linoleic acid (C18:2): 23 % γ-Tocopherol:80 % of total tocopherols β-Sitosterol: 80-90 % of total sterols Triolein: 40-55 % of triglycerides Cyanhydric acid: maximum 5 mg/kg oil
Potato proteins (coagulated) and	Dry substance: ≥ 800 mg/g Protein (N * 6,25): ≥ 600 mg/g (dry substance) Ash: ≤ 400 mg/g (dry substance) Glycoalkaloid (total): ≤ 150 mg/kg

hydrolysates thereof	Lysinoalanine (total): ≤ 500 mg/kg Lysinoalanine (free): ≤ 10 mg/kg
Prolyl oligopeptidase (enzyme preparation)	**Specification of the enzyme:** Systematic name: Prolyl oligopeptidase Synonyms: Prolyl endopeptidase, proline-specific endopeptidase, endoprolylpeptidase Molecular weight: 66 kDa Enzyme Commission number: EC 3.4.21.26 CAS number: 72162-84-6 Source: A genetically modified strain of *Aspergillus niger* (GEP-44) **Description:** Prolyl oligopeptidase is available as an enzyme preparation containing approximately 30 % maltodextrin. **Specifications of the enzyme preparation of prolyl oligopeptidase:** Activity: > 580 000 PPI([1])/g (> 34,8 PPU([2])/g) Appearance: Microgranulate Colour: Off-white to orange yellowish. The colour may change from batch to batch Dry Matter: > 94 % Gluten: < 20 ppm **Heavy metals:** Lead: ≤ 1,0 mg/kg Arsenic: ≤ 1,0 mg/kg Cadmium: ≤ 0,5 mg/kg Mercury: ≤ 0,1 mg/kg **Microbiological criteria:** Total aerobic plate count: ≤ 10^3 CFU/g Total yeasts and moulds: ≤ 10^2 CFU/g Sulphite reducing anaerobes: ≤ 30 CFU/g *Enterobacteriaceae* : < 10 CFU/g *Salmonella* : Absence in 25 g *Escherichia coli* : Absence in 25 g *Staphylococcus aureus* : Absence in 10 g *Pseudomonas aeruginosa* : Absence in 10 g *Listeria monocytogenes* : Absence in 25 g Antimicrobial activity: AbsentMycotoxins: Below limits of detection: Aflatoxin B1, B2, G1, G2 (< 0,25 µg/kg), total Aflatoxins (< 2,0 µg/kg), Ochratoxin A (< 0,20 µg/kg), T-2 Toxin (< 5 µg/kg), Zearalenone (< 2,5 µg/kg), Fumonisin B1 and B2 (< 2,5 µg/kg) ([1]) PPI – Protease Picomole International ([2]) PPU – Prolyl Peptidase Units or Proline Protease Units
[F32Protein extract from pig kidneys	**Description/Definition:** The protein extract is obtained from homogenised pig kidneys through a combination of salt precipitation and high speed centrifugation. The obtained precipitate contains essentially proteins with 7 % of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22) and is resuspended in a physiologic buffer system. The obtained pig kidney extract is formulated as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. Basic Product:

	Specification: pig kidney protein excerpt with natural content of Diamine oxidase (DAO): Physical condition: liquid Colour: brownish Appearance: slightly turbid solution pH value: 6,4–6,8 Enzymatic activity: > 2 677 kHDU DAO/ml (DAO REA (DAO Radioextractionassay)) **Microbiological criteria:** *Brachyspira* spp.: negative (Real Time PCR) *Listeria monocytogenes* : negative (Real Time PCR) *Staphylococcus aureus* : < 100 CFU/g Influenza A: negative (Reverse Transcription Real Time PCR) *Escherichia coli* : < 10 CFU/g Total aerobic microbiological count: $< 10^5$ CFU/g Yeasts/moulds count: $< 10^5$ CFU/g *Salmonella* : Absence/10g Bile salt resistant enterobacteriaceae: $< 10^4$ CFU/g **Final product:** Specification pig kidney protein excerpt with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation: Physical condition: solid Colour: yellow grey Appearance: micropellets or tablets Enzymatic activity: 110-220 kHDU DAO/g pellet or g tablet (DAO REA (DAO Radioextractionassay)) Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 68 kHDU DAO/g pellet or g tablet (DAO REA (DAO Radioextractionassay)) Humidity: < 10 % *Staphylococcus aureus* : < 100 CFU/g *Escherichia coli* : < 10 CFU/g Total aerobic microbiological count: $< 10^4$ CFU/g Total combined yeasts/moulds count: $< 10^3$ CFU/g *Salmonella* : Absence/10g Bile salt resistant enterobacteriaceae: $< 10^2$ CFU/g**]**
[F33Pyrroloquinoline quinone disodium salt	**Definition:** Chemical name: disodium 9-carboxy-4,5-dioxo-1 *H* -pyrrolo[5,4-f]quinoline-2,7-dicarboxylate Chemical formula: $C_{14}H_4N_2Na_2O_8$ CAS No: 122628-50-6 Molecular weight: 374,17 Da **Description** Pyrroloquinoline quinone disodium salt is a reddish–brown powder produced by the non-genetically modified bacterium *Hyphomicrobium denitrificans* strain CK-275. **Characteristics/Composition** Appearance: Reddish-brown powder Purity: ≥ 99,0 % (dry weight) UV absorbance (A322/A259): 0,56 ± 0,03 UV absorbance (A233/A259): 0,90 ± 0,09

	Moisture: ≤ 12,0 % **Residual Solvent** Ethanol: ≤ 0,05 % **Heavy metals** Lead: < 3 mg/kg Arsenic: < 2 mg/kg **Microbiological criteria:** Total viable cell count: ≤ 300 CFU/g Mould/yeast: ≤ 12 CFU/g Coliforms: absent in 1 g *Hyphomicrobium denitrificans* : ≤ 25 CFU/g CFU: Colony Forming Units**]**
Rapeseed oil high in unsaponifiable matter	**Description/Definition:** Rapeseed oil high in unsaponifiable matter' is produced by vacuum distillation and it is different from refined rapeseed oil in the concentration of the unsaponifiable fraction (1 g in refined rapeseed oil and 9 g in 'rapeseed oil high in unsaponifiable matter'). There is a minor reduction of triglycerides containing monounsaturated and polyunsaturated fatty acids. **Purity:** Unsaponifiable matter: > 7,0 g/100 g Tocopherols: > 0,8 g/100 g α-tocopherol (%): 30-50 % γ-tocopherol (%): 50-70 % δ-tocopherol (%): < 6,0 % Sterols, triterpenic alcohols, methylsterols: > 5,0 g/100 g **Fatty acids in triglycerides:** palmitic acid: 3-8 % stearic acid: 0,8-2,5 % oleic acid: 50-70 % linoleic acid: 15-28 % linolenic acid: 6-14 % erucic acid: < 2,0 % Acid value: ≤ 6,0 mg KOH/g Peroxide value (PV): ≤ 10 mEq O_2 /kg **Heavy metals:** Iron (Fe): < 1 000 µg/kg Copper (Cu): < 100 µg/kg **Impurities:** Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 µg/kg Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'rapeseed oil high in unsaponifiable matter.
Rapeseed Protein	**Definition:** Rapeseed protein is an aqueous protein-rich extract from rapeseed press cake originating from non-genetically modified *Brassica napus* L. and *Brassica rapa* L. **Description:** White to off-white, spray dried powder Total protein: ≥ 90 % Soluble protein: ≥ 85 % Moisture: ≤ 7,0 %

	Carbohydrates: ≤ 7,0 % Fat: ≤ 2,0 % Ash: ≤ 4,0 % Fibre: ≤ 0,5 % Total glucosinolates: ≤ 1 mmol/kg **Purity:** Total phytate: ≤ 1,5 % Lead: ≤ 0,5 mg/kg **Microbiological criteria:** Yeast and mould count: ≤ 100 CFU/g Aerobic bacteria count: ≤ 10 000 CFU/g Total coliform count: ≤ 10 CFU/g *Escherichia coli:* Absence in 10 g *Salmonella* : Absence in 25 g
[[F34]Refined shrimp peptide concentrate	**Description** Refined shrimp peptide concentrate is a peptide mixture obtained from northern shrimp (*Pandalus borealis*) shells and heads via a series of purification steps following enzymatic proteolysis using a protease from *Bacillus licheniformis* and/or *Bacillus amyloliquefaciens* . **Characteristics/Composition** Total Dry matter (%): ≥ 95,0 % Peptides (w/weight dry matter): ≥ 87,0 % of which peptides with molecular weight < 2 kDa: ≥ 99,9 % Fat (w/w): ≤ 1,0 % Carbohydrates (w/w): ≤ 1,0 % Ash (w/w): ≤ 15,0 % Calcium: ≤ 2,0 % Potassium: ≤ 0,15 % Sodium: ≤ 3,5 % **Heavy Metals** Arsenic (inorganic): ≤ 0,22 mg/kg Arsenic (organic): ≤ 51,0 mg/kg Cadmium: ≤ 0,09 mg/kg Lead: ≤ 0,18 mg/kg Total mercury: ≤ 0,03 mg/kg **Microbiological criteria:** Total viable cell count: ≤ 20 000 CFU/g *Salmonella* : ND/25g *Listeria monocytogenes* : ND/25g *Escherichia coli* : ≤ 20 CFU/g Coagulase positive *Staphylococcus aureus:* ≤ 200 CFU/g *Pseudomonas aeruginosa* : ND/25g Mould/yeast: ≤ 20 CFU/g CFU : Colony Forming Units ND : Not Detectable**]**
Trans-resveratrol	**Description/Definition:** **Synthetic** *Trans* -resveratrol is off-white to beige crystals. Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol Chemical formula: $C_{14}H_{12}O_3$ Molecular weight: 228,25 Da CAS No: 501-36-0

	Purity: *Trans* -resveratrol: ≥ 98 %-99 % Total by-products (related substances): ≤ 0,5 % Any single related substance: ≤ 0,1 % Sulphated ash: ≤ 0,1 % Loss on drying: ≤ 0,5 % **Heavy metals:** Lead: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm Arsenic: ≤ 1,0 ppm **Impurities:** Diisopropylamine: ≤ 50 mg/kg ***Microbial source*** : A genetically modified strain of *Saccharomyces cerevisiae* Appearance: Off-white to slight yellow powder Particle size: 100 % less than 62,23 μm Trans-resveratrol content: Min. 98 % w/w (dry weight basis) Ash: Max. 0,5 % w/w Moisture: Max. 3 % w/w
Rooster comb extract	**Description/Definition:** Rooster comb extract is obtained from *Gallus gallus* by enzymatic hydrolysis of rooster comb and by subsequent filtration, concentration and precipitation steps. The principal constituents of rooster comb extract are the glycosaminoglycans hyaluronic acid, chondroitin sulphate A and dermatan sulphate (chondroitin sulphate B). White or almost white hygroscopic powder. Hyaluronic acid: 60-80 % Chondroitin sulphate A: ≤ 5,0 %Dermatan sulphate (chondroitin sulphate B): ≤ 25 % pH: 5,0-8,5 **Purity:** Chlorides: ≤ 1,0 % Nitrogen: ≤ 8,0 % Loss on drying: (105 °C for 6 hours): ≤ 10 % **Heavy metals:** Mercury: ≤ 0,1 mg/kg Arsenic: ≤ 1,0 mg/kg Cadmium: ≤ 1,0 mg/kg Chromium: ≤ 10 mg/kg Lead: ≤ 0,5 mg/kg **Microbiological criteria:** Total viable aerobic count: ≤ 10^2 CFU/g *Escherichia coli* : Absence in 1 g *Salmonella* : Absence in 1 g *Staphylococcus aureus* : Absence in 1 g *Pseudomonas aeruginosa* : Absence in 1g
Sacha Inchi oil from *Plukenetia volubilis*	**Description/Definition:** Sacha inchi oil is a 100 % cold pressed vegetable oil obtained from the seeds of *Plukenetia volubiis* L. It is a transparent, fluid (liquid) and shiny oil at room temperature. It has a fruity, light, green vegetable taste without undesirable flavours.

	Aspect, limpidity, shine, colour: Fluid at room temperature, clean, shiny yellow gold Odour and taste: Fruity, vegetable without non acceptable taste or odour **Purity:** Water and Volatiles: < 0,2 g/100 g Impurities insoluble in hexane: < 0,05 g/100 g Oleic acidity: < 2,0 g/100 g Peroxide value (PV): < 15 meq O_2 /kg Trans fatty acids: < 1,0 g/100 g Total unsaturated fatty acids: > 90 %Omega 3 alpha linolenic acid (ALA): > 45 % Saturated fatty acids: < 10 % No trans fatty acids (< 0,5 %) No erucic acid (< 0,2 %) More than 50 % of tri-linolenin and di-linolenin-triglycerides Phytosterols composition and level No cholesterol (< 5,0 mg/100 g)
Salatrims	**Description/Definition:** Salatrim is the internationally recognised acronym for (short and long chain acyl triglyceride molecules). Salatrim is prepared by non-enzymatic inter-esterification of triacetin, tripropionin, tributyrin, or their mixtures with hydrogenated canola, soybean, cottonseed, or sunflower oil. Description: Clear, slightly amber liquid to a light coloured waxy solid at room temperature. Free of particulate matter and of foreign or rancid odour. Glycerol ester disribution: Triacylglycerols: > 87 % Diacylglycerols: ≤ 10 % Monoacylglycerols: ≤ 2,0 % Fatty acid composition: MOLE % LCFA (long chain fatty acids): 33-70 % MOLE % SCFA (short chain fatty acids): 30-67 % Saturated long chain fatty acids: < 70 % by weight Trans fatty acids: ≤ 1,0 % Free fatty acids as oleic acid: ≤ 0,5 % Triacylglycerol profile: Triesters (short/long of 0,5 to 2,0): ≥ 90 % Triesters (short/long = 0): ≤ 10 % Unsaponifiable material: ≤ 1,0 % Moisture: ≤ 0,3 % Ash: ≤ 0,1 % Colour: ≤ 3,5 Red (Lovibond) Peroxide value (PV): ≤ 2,0 Meq/Kg
***Schizochytrium sp.* oil rich in DHA and EPA**	Acid value: ≤ 0,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Oxidative stability: All food products containing *Schizochytrium sp.* oil rich in DHA and EPA should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC) Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1 %

	DHA content: ≥ 22,5 % EPA content: ≥ 10 %
[F35*Schizochytrium* sp. (ATCC PTA-9695) oil	The novel food is obtained from the strain ATCC PTA-9695 of the microalgae *Schizochytrium* sp. Peroxide value (PV): ≤ 5,0 meq/kg oil Unsaponifiables: ≤ 3,5 % Trans-fatty acids: ≤ 2,0 % Free fatty acids: ≤ 0,4 % Docosapentaenoic acid (DPA) n-6: ≤ 7,5 % DHA content: ≥ 35 %**]**
[F69*Schizochytrium sp.* strain (FCC-3204) oil	**Description/Definition:** The novel food is an oil produced from the strain FCC-3204 of the microalgae Schizochytrium sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10**]**
***Schizochytrium* sp. oil**	Acid value: ≤ 0,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % DHA content: ≥ 32,0 %
[F70*Schizochytrium* sp. (T18) oil	Acid value: ≤ 0,8 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 3,5 % Trans-fatty acids: ≤ 2,0 % Free fatty acids: ≤ 0,4 % DHA content: ≥ 35 %**]**
[F71*Schizochytrium* sp. (WZU477) oil	**Description/Definition:** The novel food is an oil produced from the strain WZU477 of the microalgae Schizochytrium sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10**]**
[F43 Syrup from *Sorghum bicolor* (L.) Moench.	**Description/Definition** The traditional food is syrup from *Sorghum bicolor* (L.) Moench (genus, *Sorghum* ; family, *Poaceae* (alt. *Gramineae*)).

(Traditional food from a third country)	The syrup is obtained from stalks of *S. bicolor* , after applying production processes such as crushing, extraction, and evaporation including a heat treatment in order to obtain a minimum of 74 °Brix syrup **Compositional data of syrup from *Sorghum bicolor* (L.) Moench** Water: 22,7 g/100 g Ash: 2,4 Sugars, total: > 74,0 g/100 g**]**
Fermented soybean extract	**Description/Definition:** Fermented soybean extract is an odourless milk-white coloured powder. It is comprised of 30 % fermented soybean extract powder and 70 % resistant dextrin (as carrier) from corn-starch, which is added during the processing. Vitamin K_2 is removed during the manufacturing process. Fermented soybean extract contains nattokinase isolated from natto, a foodstuff produced by the fermentation of non-genetically modified soybeans (*Glycine max* (L.)) with a selected strain of *Bacillus subtilis* var. natto. Nattokinase activity: 20 000 -28 000 Fibrin degradation unit/g([1]) Identity: Confirmable Condition: No offensive taste or smell Loss on drying: ≤ 10 % Vitamin K_2 : ≤ 0,1 mg/kg **Heavy metals:** Lead: ≤ 5,0 mg/kg Arsenic: ≤ 3,0 mg/kg **Microbiological criteria:** Total viable aerobic count: ≤ 10^3 CFU([3])/g Yeast and mould: ≤ 10^2 CFU/g Coliforms: ≤ 30 CFU/g Spore-forming bacteria: ≤ 10 CFU/g *Escherichia coli* : Absence/25 g *Salmonella* : Absence/25 g *Listeria* : Absence/25 g ([1]) Assay method as described by Takaoka et al. (2010).
[F72Spermidine-rich wheat germ extract (*Triticum aestivum*)	**Description/Definition:** Spermidine-rich wheat germ extract is obtained from non-fermented, non-sprouting wheat germs (*Triticum aestivum*) by the process of solid-liquid extraction targeting specifically, but not exclusively polyamines. Spermidine:(N-(3-aminopropyl)butane-1,4-diamine):0,8-2,4 mg/g Spermine: 0,4-1,2 mg/g Spermidine trichloride < 0,1 µg/g Putrescine: < 0,3 mg/g Cadaverine: ≤ 16,0 µg/g **Mycotoxins:** Aflatoxins (total): < 0,4 µg/kg **Microbiological criteria:** Total aerobic bacteria: < 10 000 CFU/g Yeast and moulds: < 100 CFU/g *Escherichia coli:* < 10 CFU/g *Salmonella:* Absence/25g *Listeria monocytogenes:* Absence/25g**]**

Sucromalt	**Description/Definition:** Sucromalt is a complex mixture of saccharides which is produced from sucrose and a starch hydrolysate by means of an enzymatic reaction. In this process, glucose units are attached to saccharides from the starch hydrolysate by means of an enzyme produced by the bacterium *Leuconostoc citreum* or by means of a recombinant strain of the production organism *Bacillus licheniformis* . The resulting oligosaccharides are characterised by the presence of α-(1→6) and α-(l→3) glycosidic compounds. The overall product is syrup, in addition to these oligosaccharides, contains mainly fructose but also the disaccharide leucrose and other disaccharides. Total solids: 75-80 % Moisture: 20-25 % Sulphatase: Max 0,05 % pH: 3,5-6,0 Conductivity < 200 (30 %) Nitrogen < 10 ppm Fructose: 35-45 % d.w. Leucrose: 7-15 % d.w. Other disaccharides: Max 3 % Higher saccharides: 40-60 % d.w
Sugar cane fibre	**Description/Definition:** Sugar Cane Fibre is derived from the dry cell wall or fibrous residue remaining after expression or extraction of sugar juice from sugar cane, of the Saccharum genotype. It consists primarily of cellulose and hemicellulose. The production process consists of several steps, including: chipping, alkaline digestion, removal of lignins and other non-cellulosic components, bleaching of purified fibres, acid washing and neutralization.Moisture: ≤ 7,0 % Ash: ≤ 0,3 % Total Dietary Fibre (AOAC) dry basis (all insoluble): ≥ 95 % of which: Hemicellulose (20-25 %) and cellulose (70-75 %) Silica (ppm): ≤ 200 Protein: 0,0 % Fat: Trace pH: 4-7 **Heavy metals:** Mercury (ppm): ≤ 0,1 Lead (ppm): ≤ 1,0 Arsenic (ppm): ≤ 1,0 Cadmium (ppm): ≤ 0,1 **Microbiological criteria:** Yeast and moulds (CFU/g): ≤ 1 000 *Salmonella* : Absence *Listeria monocytogenes* : Absence
[F44Sugars obtained from cocoa (*Theobroma cacao* L.) pulp	**Description/Definition:** Sugars are obtained from the concentrated cocoa pulp (*Theobroma cacao* L.) juice either via a drying process or via a purification process to produce high purity glucose or fructose. **Sugars produced by a drying process**

	Nutritional composition: Total sugars (g/100g): > 80 Moisture (%): < 5 Microbiological criteria: Total Plate Count (aerobic) (cfu/g): $< 10^4$ Moulds and Yeasts (cfu/g): < 50 Enterobacteriaceae (cfu/g): < 10 *Salmonella* spp.: Absence in 25 g *Alicyclobacillus:* Absence in 50 g Thermo-acidophilic bacteria: Absence in 50 g **Sugars produced by a purification process** Nutritional composition of Glucose obtained from cocoa (*Theobroma cacao* L.) pulp: Glucose content (%): > 93 Ash (%): < 0,2 Moisture (%): < 1,0 Nutritional composition of Fructose obtained from cocoa (*Theobroma cacao* L.) pulp: Fructose content (%): > 98 Glucose content (%): < 0,5 % Ash (%): < 0,2 Moisture (%):< 0,5 Microbiological criteria for glucose and fructose obtained from cocoa (*Theobroma cacao* L.) pulp: Total Plate Count (aerobic) (cfu/g): $< 10^4$ *Salmonella* spp.: Absence in 25 g**]**
Sunflower oil extract	**Description/Definition:** The sunflower extract is obtained by a concentration factor of 10 of the unsaponifiable fraction of refined sunflower oil extracted from the seeds of the sunflower, *Helianthus Annuus* L. **Composition:** Oleic acid (C18:1): 20 % Linoleic acid (C18:2): 70 % Unsaponifiable matter: 8,0 % Phytosterols: 5,5 % Tocopherols: 1,1 %
Dried *Tetraselmis chuii* microalgae	**Description/Definition:** The dried product is obtained from the marine microalgae *Tetraselmis chuii* , belonging to the *Chlorodendraceae* family, cultivated in sterile sea water in closed photobioreactors insulated from the outside air. **Purity/Composition:** Identified by means of nuclear marker rDNA 18 S (sequence analysed no less than 1 600 base pairs) in the National Centre for Biotechnology information (NCBI) database: Not less than 99,9 % Humidity: ≤ 7,0 % Proteins: 35-40 % Ashes: 14-16 % Carbohydrates: 30-32 % Fibre: 2-3 % Fat: 5-8 % Saturated fatty acids: 29-31 % of total fatty acids

	Monounsaturated fatty acids: 21-24 % of total fatty acids Polyunsaturated fatty acids: 44-49 % of total fatty acids Iodine: ≤ 15 mg/kg
***Therapon barcoo* / Scortum**	**Description/Definition:** Scortum/ *Therapon barcoo* is a species of fish in the family Terapontidae. It is an endemic fresh water species from Australia. It is now reared in fish farms. Taxonomic Identification: Class: Actinopterygii > order: Perciformes > family: Terapontidae > genus: *Therapon* or *Scortum barcoo* Composition of fish flesh: Protein (%): 18-25 Moisture (%): 65-75 Ash (%): 0,5-2,0 Energy (KJ/Kg): 6000-11500 Carbohydrates (%): 0,0 Fat (%): 5-15 Fatty acids (mg FA/g fillet): Σ PUFA n-3: 1,2-20,0 Σ PUFA n-6: 0,3-2,0 PUFA n-3/n-6: 1,5-15,0 Total omega 3 acids: 1,6-40,0 Total omega 6 acids: 2,6-10,0
D-Tagatose	**Description/Definition:** Tagatose is produced by isomerization of galactose by means of chemical or enzymatic conversion, or by epimerization of fructose by means of enzymatic conversion. These are single-step conversions. Appearance: White or almost white crystals Chemical name: D-tagatose Synonym: D- *lyxo* -Hexulose CAS number: 87-81-0 Chemical formula: $C_6H_{12}O_6$ Formula weight: 180,16 (g/mol) **Purity:** Assay: ≥ 98 % on a dry weight basis Loss on drying: ≤ 0,5 % (102 °C, 2 hours) Specific Rotation: $[\alpha]_D^{20}$: – 4 to – 5,6 ^{o} (1 % aqueous solution)([1]) Melting range: 133– 137 °C **Heavy metals:** Lead: ≤ 1,0 mg/kg(*) (*) Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5. 'Instrumental methods'([1]). ([1]) Food and nutrition paper 5 Rev 2 – Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 307 p.; English – ISBN 92-5-102991-1
[F20Taxifolin-rich extract]	**Description:**

Taxifolin-rich extract from the wood of Dahurian Larch (*Larix gmelinii* (Rupr.) Rupr) is a white to pale-yellow powder that crystallizes from hot aqueous solutions.

[F20Definition:

Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)- dihydroquercetin] and with no more than 2 % of the cis-form**]**

Specifications:

Physical parameter

Moisture: ≤ 10 % *Compound analysis*

Taxifolin (m/m): ≥ 90,0 % of the dry weight

Heavy Metals, Pesticide

Lead: ≤ 0,5 mg/kg

Arsenic: ≤ 0,02 mg/kg

Cadmium: ≤ 0,5 mg/kg

Mercury: ≤ 0,1 mg/kg

Dichlorodiphenyltrichloroethane (DDT): ≤ 0,05 mg/kg

Residual solvents

Ethanol: < 5 000 mg/kg

Microbiological criteria

Total Plate Count (TPC): ≤ 10^4 CFU/g

Enterobacteria: ≤ 100/g

Yeast and Mould: ≤ 100 CFU/g

Escherichia coli : Absence/1 g

Salmonella : Absence/10 g

Staphylococcus aureus : Absence/1 g

Pseudomonas : Absence/1g

Usual range of components of the Taxifolin-rich extract (as per dry substance)

Extract component	*Content, usual observed range (%)*
Taxifolin	90 – 93
Aromadendrin	2,5 – 3,5
Eriodictyol	0,1 – 0,3
Quercetin	0,3 – 0,5
Naringenin	0,2 – 0,3
Kaempferol	0,01 – 0,1
Pinocembrin	0,05 – 0,12
Unidentified flavonoids	1 – 3
Water(*)	1,5

(*) Taxifolin in its hydrated form and during the drying process is a crystal. This results on the inclusion of water of crystallisation in a quantity of 1,5 %.

Trehalose	**Description/Definition:**

A non-reducing disaccharide that consists of two glucose moieties linkes by an α-1,1-glucosidic bond. It is obtained from liquefied starch or from sucrose by a multistep enzymatic process. The commercial product is the dihydrate. Virtually odourless, white or almost white crystals with a sweet taste

Synonyms: α,α-trehalose

Chemical name: α-D-glucopyranosyl-α-D-glucopyranoside, dihydrate

CAS No.: 6138-23-4 (dihydrate)

Chemical formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$ (dihydrate)

Formula weight: 378,33 (dihydrate)

Assay: ≥ 98 % on the dry basis

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5 (1), 'Instrumental methods'

Method of assay:

Principle: trehalose is identified by liquid chromatography and quantified by comparison to a reference standard containing standard trehalose

Preparation of sample solution: weigh accurately about 3 g of dry sample into a 100 ml volumetric flask and add about 80 ml of purified, deionised water. Bring sample to complete dissolution and dilute to mark with purified deionised water. Filter through a 0,45 micron filter

Preparation of standard solution: dissolve accurately weighed quantities of dry standard reference trehalose in water to obtain a solution having known concentration of about 30 mg of trehalose per ml.

Apparatus: liquid chromatography equipped with a refractive index detector and integrating recorder

Conditions:

Column: Shodex Ionpack KS-801 (Showa Denko Co.) or equivalent

— length: 300 mm

— diameter: 10 mm

— temperature: 50 °C

Mobile phase: water

flow rate: 0,4 ml/min

Injection volume: 8 µl

Procedure: inject separately equal volumes of the sample solution and the standard solution into the chromatograph.

Record the chromatograms and measure the size of response of the trehalose peak

Calculate the quantity, in mg, of trehalose in 1 ml of the sample solution by the following formula:% trehalose = $100 \times (R_U/R_S)(W_S/W_U)$

where

R_S = peak area of trehalose in the standard preparation

R_U = peak area of trehalose in the sample preparation

W_S = weight in mg of trehalose in the standard preparation

W_U = weight of dry sample in mg

Characteristics:

Identification:

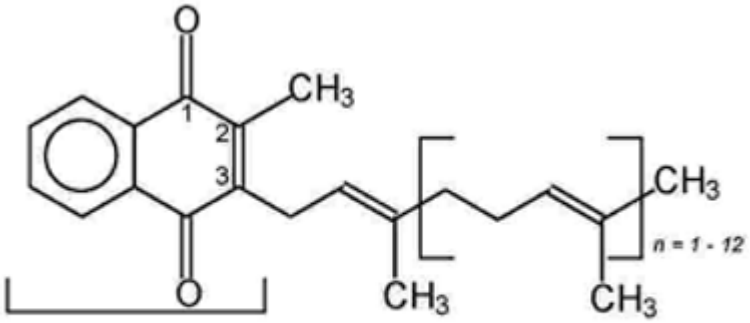
Solubility: Freely soluble in water, very slightly soluble in ethanol

Specific rotation: $[\alpha]_D^{20} = +179^o$ (5 % aqueous solution, dihydrate), $+199^o$ (5 % aqueous solution, anhydrous substance)

	Melting point: 97 °C (dihydrate) **Purity:** Loss on drying: ≤ 1,5 % (60 °C, 5h) Total ash: ≤ 0,05 % **Heavy metals:** Lead: ≤ 1,0 mg/kg
[F20UV-treated mushrooms *(Agaricus bisporus)*	**Description/Definition** Commercially grown *Agaricus bisporus* to which UV light treatment is applied to harvested mushrooms. UV radiation: a process of radiation in ultraviolet light within the wavelength of 200-800 nm. **Vitamin D_2** Chemical name: (3β,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol Synonym: Ergocalciferol CAS No: 50-14-6 Molecular weight: 396,65 g/mol **Contents** Vitamin D_2 in the final product: 5-20 µg/100 g fresh weight at the expiration of shelf life.**]**
[F73UV-treated baker's yeast (*Saccharomyces cerevisiae*)	**Description/Definition** Baker's yeast *(Saccharomyces cerevisiae)* is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D# (ergocalciferol). Vitamin D# content in the yeast concentrate varies between 800,000 - 3,500,000 IU vitamin D/100g (200-875 µg/g). The yeast is inactivated for use in infant formula, follow-on formula, processed cereal-based food, and food for special medical purposes as defined by Regulation (EU) No. 609/2013. The yeast can be active or inactive for use in other foods. The yeast concentrate is blended with regular baker's yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking. Tan-coloured, free-flowing granules. **Vitamin D#** Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol Synonym: Ergocalciferol CAS No.: 50-14-6 Molecular weight: 396.65 g/mol **Microbiological criteria for the yeast concentrate** Coliforms: ≤ 10^3 CFU/g *Escherichia coli*: ≤ 10 CFU/g *Salmonella* spp: Absence in 25 g CFU: Colony Forming Units.**]**
UV-treated bread	**Description/Definition:** UV-treated bread is yeast leavened bread and rolls (without toppings) to which a treatment with ultraviolet radiation is applied after baking in order to convert ergosterol to vitamin D_2 (ergocalciferol). UV radiation: A process of radiation in ultraviolet light within the wavelength of 240-315 nm for maximum of 5 seconds with energy input of 10-50 mJ/cm^2.

	Vitamin D_2 : Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol Synonym: Ergocalciferol CAS No: 50-14-6 Molecular weight: 396,65 g/mol **Contents:** Vitamin D_2 (ergocalciferol) in the final product: 0,75-3 µg/100 g([1]) Yeast in dough: 1-5 g/100 g ([2]) ([1]) EN 12821, 2009, European Standard. ([2]) Recipe calculation.
UV-treated milk	**Description/Definition:** UV-treated milk is cow's milk (whole and semi-skimmed) to which a treatment with ultraviolet (UV) radiation via turbulent flow is applied after pasteurisation. The treatment of the pasteurised milk with UV radiation results in an increase in the vitamin D_3 (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin D_3. UV radiation: A process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1 045 J/l. **Vitamin D_3 :** Chemical name: (1S,3Z)-3-[(2E)-2-[(1R,3aS,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol Synonym: Cholecalciferol CAS No: 67-97-0 Molecular weight: 384,6377 g/mol **Contents:** Vitamin D_3 in the final product: Whole milk([1])0,5-3,2 µg/100 g([2]) Semi-skimmed milk(1): 0,1–1,5 µg/100 g([2]) ([1]) As defined by Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671). ([2]) HPLC
[F9Vitamin D_2 mushroom powder	**Description/Definition** Vitamin D_2 mushroom powder is a granular powder made from homogenised *Agaricus bisporus* mushrooms that have been exposed to UV light. The mushrooms are washed, homogenised and suspended in water to produce a mushroom slurry. The mushroom slurry is passed under a UV lamp. The slurry is then filtered, dried and ground, producing vitamin D_2 mushroom powder.

	UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under the novel food regulation. **Characteristics/Composition** Vitamin D_2 content: 1 000–1 300 µg/g of mushroom powder[I] Moisture: ≤ 10,0 % Ash: ≤ 13,5 % **Heavy Metals** Lead (as Pb): ≤ 0,5 mg/kg Cadmium: ≤ 0,5 mg/kg Mercury: ≤ 0,1 mg/kg Arsenic: ≤ 0,3 mg/kg **Mycotoxins** Aflatoxins (sum of B1+B2+G1+G2): < 4 µg/kg **Microbiological criteria:** Total plate count: ≤ 5 000 CFU[g]/g Yeast and mould: ≤ 100 CFU/g *Salmonella* sp.: Absent in 25 g *Staphylococcus aureus* : ≤ 10 CFU/g *Escherichia coli* : ≤ 10 CFU/g Coliforms: ≤ 10 CFU/g *Enterobacteriaceae* : ≤ 10 CFU/g *Listeria monocytogenes* : Absent in 25 g**]**
[F74Vitamin D# mushroom powder	**Description/Definition** The novel food is mushroom powder produced from dried whole *Agaricus bisporus* mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to ultraviolet light. **Characteristics/Composition** Vitamin D# content: 580-595 µg/g of mushroom powder Ash: ≤ 13.5% Water activity: < 0.5 Moisture content: ≤ 7.5% Carbohydrates: ≤ 35% Total dietary fibre: ≥ 15% Crude protein (N x 6.25): ≥ 22% Fat: ≤ 4.5% **Heavy metals** Lead: ≤ 0.5 mg/kg Cadmium: ≤ 0.5 mg/kg Mercury: ≤ 0.1 mg/kg Arsenic: ≤ 0.3 mg/kg **Mycotoxins** Aflatoxin B1: ≤ 0.1 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria** Total plate count: ≤ 5000 CFU 14 Total yeast and mould count: ≤ 100 CFU/g *Escherichia coli*: < 10 CFU/g *Salmonella* spp.: Absence in 25 g *Staphylococcus aureus*: ≤ 10 CFU/g Coliforms: ≤ 10 CFU/g *Listeria* spp.: Absence in 25 g

	Enterobacteriaceae: < 10 CFU/g CFU: Colony Forming Units.]
Vitamin K 2 (menaquinone)	This novel food is produced by a synthetic or microbiological process. Vitamin K_2 (2-methyl-3-all-trans-polyprenyl-1,4-naphthoquinones), or the menaquinone series, is a group of prenylated naphthoquinone derivatives. The number of isoprene residues, where 1 isoprene unit consists of 5 carbons comprising the side chain, is used to characterise the menaquinone homologues containing primarily MK-7 and to a smaller extent MK-6. Vitamin K_2 (menaquinones) series with menaquinone-7 (MK-7)(n = 6) being $C_{46}H_{64}O_2$, menaquinone-6 (MK-6)(n = 5) being $C_{41}H_{56}O_2$ and menaquinone-4 (MK-4)(n = 3) being $C_{31}H_{40}O_2$. Chemical Name: (all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaheptaenyl)-3-methyl-1,4-naphtalenedione CAS Number: 2124-57-4 Molecular formula: $C_{46}H_{64}O_2$ Molecular weight: 649 g/mol  *2-methyl-1,4-naphthoquinone (menadione moiety)* ***Specification of synthetic Vitamin K 2 (menaquinone-7)*** Appearance: Yellow powder Purity: Max 6,0 % cis-isomer, max 2,0 % other impurities Content: 97-102 % Menaquinone-7 (including at least 92 % all-trans Menaquinone-7) ***Specifications of microbiologically produced Vitamin K 2 (menaquinone-7)*** Source: *Bacillus subtilis* spp. natto and *Bacillus licheniformis* Appearance: Yellow powder or oil suspension
Wheat bran extract	**Description/Definition:** White crystalline powder obtained by enzymatic extraction from *Triticum aestivum* L. bran, rich in arabinoxylan oligosaccharides Dry matter: Min. 94 % Arabinoxylan oligosaccharides: Min 70 % of dry matter Average degree of polymerisation of arabinoxylan oligosaccharides: 3-8 Ferulic acid (bound to arabinoxylan oligosaccharides): 1-3 % of dry matter Total poly/oligosaccharides: Min 90 % Protein: Max 2 % of dry matter

	Ash: Max 2 % of dry matter **Microbiological parameters:** Mesophilic bacteria – total count: Max 10 000/g Yeasts: Max 100/g Fungi: Max 100/g *Salmonella* : Absence in 25g *Bacillus cereus* : Max 1000/g *Clostridium perfringens* : Max 1000/g
[F75Xylo-oligosaccharides	**Description:** The novel food is a mixture of xylo-oligosaccharides (XOS) which are obtained from corncobs (*Zea mays* subsp. *mays*) via hydrolysis by a xylanase from *Trichoderma reesei* followed by a purification process. **Characteristics/Composition**

Parameter	**Powder form 1**	**Powder form 2**	**Syrup form**
Moisture (%)	≤ 5,0	≤ 5,0	70-75
Protein (g/100 g)	< 0,2		
Ash (%)	≤ 0,3		
pH	3,5-5,0		
Total carbohydrate content (g/100 g)	≥ 97	≥ 95	≥ 70
XOS content (dry basis) (g/100 g)	≥ 95	≥ 70	≥ 70
Other carbohydrates (g/100 g) ([a])	2,5-7,5	2-16	1,5-31,5
Monosaccharides total (g/100 g)	0-4,5	0-13	0-29
Glucose (g/100 g)	0-2	0-5	0-4
Arabinose (g/100 g)	0-1,5	0-3	0-10
Xylose (g/100 g)	0-1,0	0-5	0-15
Disaccharides total (g/100 g)	27,5-48	25-43	26,5-42,5
Xylobiose (XOS DP2) (g/100 g)	25-45	23-40	25-40
Cellobiose (g/100 g)	2,5-3	2-3	1,5-2,5

Oligosaccharides total (g/100 g)	41-77	36-72	32-71
xylotriose (XOS DP3) (g/100 g)	27-35	18-30	18-30
xylotetraose (XOS DP4) (g/100 g)	10-20	10-20	8-20
xylopentaose (XOS DP5) (g/100 g)	3-10	5-10	3-10
xylohexaose (XOS DP6) (g/100 g)	1-5	1-5	1-5
Xyloheptaose (XOS DP7) (g/100 g)	0-7	2-7	2-6
Maltodextrin (g/100 g) ([b])	0	20-25	0
Copper (mg/kg)	< 5,0		
Lead (mg/kg)	< 0,5		
Arsenic (mg/kg)	< 0,3		
Salmonella (CFU ([c])/25 g)	Negative		
E, coli (MPN ([d])/100 g)	Negative		
Yeast (CFU/g)	< 10		
Mould (CFU/g)	< 10		

DP : Degree of polymerization

([a]) Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose.

([b]) Maltodextrin content is calculated according to the amount added in the process.

([c]) CFU: Colony Forming Units.

([d]) MPN: Most Probable Number.]

[F52*Yarrowia lipolytica* yeast biomass	**Description/Definition:** The novel food is the dried and heat-killed biomass of the yeast *Yarrowia lipolytica* . **Characteristics/Composition:** Protein: 45-55 g/100 g Dietary fibre: 24-30 g/100 g Sugars: < 1,0 g/100 g

	Fat: 7-10 g/100 g Total ash: ≤ 12 % Water content: ≤ 5 % Dry matter content: ≥ 95 % **Microbiological criteria:** Total Aerobic Microbial Count: ≤ 5×10^3 CFU/g Total Yeast and Mould Count: ≤ 10^2 CFU/g Viable *Yarrowia lipolytica* cells[j]: < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g**]**
[[F76]3'-Sialyllactose (3'-SL) sodium salt **(microbial source)**	**Description:** 3'-Sialyllactose (3'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid **Source:** Genetically modified strain of Escherichia coli K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655.53 Da CAS No 128596-80-5 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90.0 % (w/w) 3'-Sialyllactose sodium salt (% of dry matter): ≥ 88.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 1.5 % (w/w) 3'-Sialyl-lactulose: ≤ 5.0 % (w/w) Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 8.0 % (w/w) Sodium: 2.5 – 4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5 -6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g Salmonella sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units**]**
[[F77]6'-Sialyllactose (6'-SL) sodium salt **(microbial source)**	**Description:** 6'-Sialyllactose (6'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6'-sialyl-lactulose, and sialic acid **Source:** Genetically modified strain of Escherichia coli K-12 DH1 **Definition:**

	Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655.53 Da CAS No 157574-76-0 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94.0 % (w/w) 6'-Sialyllactose sodium salt (% of dry matter): ≥ 90.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 2.0 % (w/w) 6'-Sialyl-lactulose: ≤ 3.0 % (w/w) Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 6.0 % (w/w) Sodium: 2.5-4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5-6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g Salmonella sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units**]**
Yeast beta-glucans	**Description/Definition:** Beta-glucans are complex, high molecular mass (100–200 kDa) polysaccharides, found in the cell wall of many yeasts and cereals. The chemical name for 'yeast beta-glucans' is (1-3),(1-6)-ß-D-glucans. Beta-glucans consist of a backbone of ß-1-3-linked glucose residues that are branched by ß-1-6-linkages, to which chitin and mannoproteins are linked by ß-1-4-bonds. Beta-glucans are isolated from yeast *Saccharomyces cerevisiae* . The tertiary structure of the glucan cell wall of *Saccharomyces cerevisiae* consists of chains of ß-1,3-linked glucose residues, branched by ß-1,6-linkages, forming a backbone to which are linked chitin via ß-1,4- bonds, ß-1,6-glucans and some mannoproteins. This novel food is available in three different forms: soluble, insoluble and insoluble in water, but dispersible in many liquid matrices. **Chemical characteristics yeast (*Saccharomyces cerevisiae*) beta-glucans:** **Soluble form:** Total carbohydrates: > 75 % Beta-glucans (1,3/1,6): > 75 % Ash: < 4,0 % Moisture: < 8,0 % Protein: < 3,5 % Fat: < 10 % **Insoluble form:** Total carbohydrates: > 70 %

	Beta-glucans (1,3/1,6): > 70 % Ash: ≤ 12 % Moisture: < 8,0 % Protein: < 10 % Fat: < 20 % **Insoluble in water, but dispersible in many liquid matrices:** (1,3)-(1,6)-ß-D-Glucans: > 80 % Ash: < 2,0 % Moisture: < 6,0 % Protein: < 4,0 % Total fat: < 3,0 % *Microbiological data for insoluble in water, but dispersible in many liquid matrices:* Total plate count: < 1 000 CFU/g Enterobacteriaceae: < 100 CFU/g Total coliforms: < 10 CFU/g Yeast: < 25 CFU/g Mould: < 25 CFU/g *Salmonella* : Absence in 25 g *Escherichia coli* : Absence in 1 g *Bacillus cereus* : < 100 CFU/g *Staphylococcus aureus* : Absence in 1 g *Heavy metals for insoluble in water, but dispersible in many liquid matrices:* **[**[F17]Lead: < 0,2 mg/kg Arsenic: < 0,2 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 0,1 mg/kg**]**
Zeaxanthin	**Description/Definition:** Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid. The synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base (‘beadlets’) with added α-tocopherol and ascorbyl palmitate or as a corn oil suspension with added α-tocopherol. Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules. Orange-red crystalline powder with little or no odour. Chemical formula: $C_{40}H_{56}O_2$ CAS No: 144-68-3 Molecular weight: 568,9 daltons **Physical-chemical properties:** Loss on drying: < 0,2 % *All* -trans zeaxanthin: > 96 % Cis-zeaxanthin: < 2,0 % Other carotenoids: < 1,5 % Triphenylphosphine oxid (CAS No 791-28-6): < 50 mg/kg
Zinc L-pidolate	**Description/Definition:** Zinc L-pidolate is a white to off-white powder, with characteristic odour. International non-proprietary name (INN): L-pyroglutamic acid, Zinc salt Synonyms: Zinc 5-oxoproline, Zinc pyroglutamate, Zinc pyrrolidone carboxylate, Zinc PCA, L-Zinc pidolate CAS No.: 15454-75-8

	Molecular formula: $(C_5 H_6 NO_3)_2 Zn$ Relative anhydrous molecular mass: 321,4 Appearance: White to slightly white powder **Purity:** Zinc L-pidolate (purity): ≥ 98 % pH (10 % aqueous sol.): 5,0-6,0 Specific rotation: 19,6 ^{o} - 22,8 ^{o} Water: ≤ 10,0 % Glutamic acid: < 2,0 % **Heavy metals:** Lead: ≤ 3,0 ppm Arsenic: ≤ 2,0 ppm Cadmium: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm **Microbiological criteria:** Total viable mesophilic count: ≤ 1 000 CFU/g Yeasts and moulds: ≤ 100 CFU/g Pathogen: Absence

a	Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).
b	Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).
c	**[**F14OSC-DMAC (4-dimethylaminocinnamaldehyde) method (Ocean Spray Cranberries, Inc) Martin MA, Ramos S, Mateos R, Marais JPJ, Bravo-Clemente, L, Khoo C and Goya L. Food Res Intl 2015 71: 68-82. Modified from Cunningham DG, Vannozzi S, O'Shea E, Turk R (2002) In: Ho C-T, Zheng QY (eds) Quality Management of Nutraceuticals ACS Symposium series 803, Washington DC. *Quantitation of PACs by DMAC Color Reaction pp* 151-166.
d	BL-DMAC 4-dimethylaminocinnamaldehyde) method (Brunswick Lab) Multi-laboratory validation of a standard method for quantifying proanthocyanidins in cranberry powders. Prior RL, Fan E, Ji H, Howell A, Nio C, Payne MJ, Reed J. *J Sci Food Agric.* 2010 Jul;90(9):1473-8.
e	The different values for these three parameters are due to the different methods used.
f	GAE: Gallic Acid Equivalents.
g	**[**F59CFU: Colony Forming Units.**]]**
h	**[**F10HPLC/RI: High-performance liquid chromatography coupled with refractive index detection.
i	CFU: Colony-forming unit.**]**
j	**[**F52To be tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable *Yarrowia lipolytica* cells during packaging and/or storage of the NF.**]**
k	**[**F223'-Fucosyllactose, 2'-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates.**]**
l	**[**F9Converted from International Units (IU) using the conversion factor of 0,025 µg = 1 IU.**]]**

Textual Amendments

F59 Substituted by Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020 authorising the placing on the market of vitamin D2 mushroom powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F60 Substituted by Commission Implementing Regulation (EU) 2019/108 of 24 January 2019 authorising the change of specifications of the novel food ingredient lipid extract from Antarctic Krill (Euphausia superba) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F61 Substituted by Commission Implementing Regulation (EU) 2019/2165 of 17 December 2019 authorising the change of the specifications of the novel food coriander seed oil from Coriandrum sativum under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F62 Substituted by Commission Implementing Regulation (EU) 2019/388 of 11 March 2019 authorising the change of the specifications of the novel food 2′-fucosyllactose produced with Escherichia coli K-12 under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F63 Inserted by Commission implementing Regulation (EU) 2019/1979 of 26 November 2019 authorising the placing on the market of 2'-Fucosyllactose/Difucosyllactose mixture as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F64 Words in Annex Table 2 substituted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 1 para. 2(a)**

F65 Words in Annex Table 2 substituted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 1 para. 2(b)**

F66 Words in Annex Table 2 substituted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **Sch. 4**

F67 Words in Annex Table 2 substituted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 1 para. 2**

F68 Substituted by Commission Implementing Regulation (EU) 2019/1314 of 2 August 2019 authorising the change of the specifications of the novel food Lacto-N-neotetraose produced with Escherichia coli K-12 under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F69 Words in Annex Table 2 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **Sch. 5**; inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 2 para. 2**; and inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 2 para. 2**

F70 Substituted by Commission Implementing Regulation (EU) 2020/478 of 1 April 2020 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance).

F71 Words in Annex Table 2 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **Sch. 6**; inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 3 para. 2**; and inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 3 para. 2**

F72 Substituted by Commission Implementing Regulation (EU) 2020/443 of 25 March 2020 authorising the change of the specifications of the novel food spermidine-rich wheat germ extract (Triticum aestivum) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F73 Words in Annex Table 2 substituted (E.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (England) Regulations 2023 (S.I. 2023/334), reg. 1(1), **Sch. 6** (with reg. 4);

substituted (S.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023 (S.S.I. 2023/78), reg. 1(1), **sch. 4 para. 2** (with reg. 5); and substituted (W.) (15.5.2023) by The Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023 (S.I. 2023/343), reg. 1(4), **Sch. 4 para. 3** (with reg. 4)

F74 Words in Annex Table 2 inserted (E.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (England) Regulations 2023 (S.I. 2023/334), reg. 1(1), **Sch. 7** (with reg. 4); inserted (S.) (15.5.2023) by The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023 (S.S.I. 2023/78), reg. 1(1), **sch. 5 para. 2** (with reg. 5); and inserted (W.) (15.5.2023) by The Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023 (S.I. 2023/343), reg. 1(4), **Sch. 5 para. 3** (with reg. 4

F75 Inserted by Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018 authorising the placing on the market of xylo-oligosaccharides as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).

F76 Words in Annex Table 2 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **Sch. 7**; inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 4 para. 2**; and inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 4 para. 2**

F77 Words in Annex Table 2 inserted (E.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560), regs. 1(3), **Sch. 7** (as amended by S.I. 2022/619, regs. 1(1), **2(3)**); inserted (S.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 (S.S.I. 2022/168), reg. 1(3), **sch. 5 para. 2**; and inserted (W.) (30.6.2022) by The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022 (S.I. 2022/575), reg. 1(4), **Sch. 5 para. 2**

(**1**) OJ L 327, 11.12.2015, p. 1.

(**2**) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

Changes to legislation:
Commission Implementing Regulation (EU) 2017/2470 is up to date with all changes known to be in force on or before 08 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Annex Table 1 words inserted by S.I. 2024/685 Sch. 3
- Annex Table 1 words inserted by S.I. 2024/685 Sch. 5
- Annex Table 1 words inserted by S.I. 2024/685 Sch. 6
- Annex Table 1 words inserted by S.I. 2024/685 Sch. 7
- Annex Table 2 words inserted by S.I. 2024/685 Sch. 8
- Annex Table 2 words inserted by S.I. 2024/685 Sch. 9
- Annex Table 2 words inserted by S.I. 2024/685 Sch. 10
- Annex Table 2 words inserted by S.I. 2024/685 Sch. 11
- Annex Table 2 words inserted by S.I. 2024/685 reg. 6(3)(e)
- Annex Table 1 words substituted by S.I. 2024/685 Sch. 4