►**B**

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)

(OJ L 351, 30.12.2017, p. 72)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2018/460 of 20 March 2018	L 78	2	21.3.2018
►**M2**	Commission Implementing Regulation (EU) 2018/461 of 20 March 2018	L 78	7	21.3.2018
►**M3**	Commission Implementing Regulation (EU) 2018/462 of 20 March 2018	L 78	11	21.3.2018
►**M4**	Commission Implementing Regulation (EU) 2018/469 of 21 March 2018	L 79	11	22.3.2018
►**M5**	Commission Implementing Regulation (EU) 2018/991 of 12 July 2018	L 177	9	13.7.2018
►**M6**	Commission Implementing Regulation (EU) 2018/1011 of 17 July 2018	L 181	4	18.7.2018
►**M7**	Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018	L 183	9	19.7.2018
►**M8**	Commission Implementing Regulation (EU) 2018/1032 of 20 July 2018	L 185	9	23.7.2018
►**M9**	Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018	L 187	1	24.7.2018
►**M10**	Commission Implementing Regulation (EU) 2018/1122 of 10 August 2018	L 204	36	13.8.2018
►**M11**	Commission Implementing Regulation (EU) 2018/1123 of 10 August 2018	L 204	41	13.8.2018
►**M12**	Commission Implementing Regulation (EU) 2018/1132 of 13 August 2018	L 205	15	14.8.2018
►**M13**	Commission Implementing Regulation (EU) 2018/1133 of 13 August 2018	L 205	18	14.8.2018
►**M14**	Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018	L 243	2	27.9.2018
►**M15**	Commission Implementing Regulation (EU) 2018/1631 of 30 October 2018	L 272	17	31.10.2018
►**M16**	Commission Implementing Regulation (EU) 2018/1632 of 30 October 2018	L 272	23	31.10.2018

►**M17**	Commission Implementing Regulation (EU) 2018/1633 of 30 October 2018	L 272	29	31.10.2018
►**M18**	Commission Implementing Regulation (EU) 2018/1647 of 31 October 2018	L 274	51	5.11.2018
►**M19**	Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018	L 275	1	6.11.2018
►**M20**	amended by Commission Implementing Regulation (EU) 2023/65 of 6 January 2023	L 6	1	9.1.2023
►**M21**	Commission Implementing Regulation (EU) 2018/1991 of 13 December 2018	L 320	22	17.12.2018
►**M22**	Commission Implementing Regulation (EU) 2018/2016 of 18 December 2018	L 323	1	19.12.2018
►**M23**	Commission Implementing Regulation (EU) 2018/2017 of 18 December 2018	L 323	4	19.12.2018
►**M24**	Commission Implementing Regulation (EU) 2019/108 of 24 January 2019	L 23	4	25.1.2019
►**M25**	Commission Implementing Regulation (EU) 2019/109 of 24 January 2019	L 23	7	25.1.2019
►**M26**	Commission Implementing Regulation (EU) 2019/110 of 24 January 2019	L 23	11	25.1.2019
►**M27**	Commission Implementing Regulation (EU) 2019/387 of 11 March 2019	L 70	17	12.3.2019
►**M28**	Commission Implementing Regulation (EU) 2019/388 of 11 March 2019	L 70	21	12.3.2019
►**M29**	Commission Implementing Regulation (EU) 2019/456 of 20 March 2019	L 79	13	21.3.2019
►**M30**	Commission Implementing Regulation (EU) 2019/506 of 26 March 2019	L 85	11	27.3.2019
►**M31**	Commission Implementing Regulation (EU) 2019/760 of 13 May 2019	L 125	13	14.5.2019
►**M32**	Commission Implementing Regulation (EU) 2019/1272 of 29 July 2019	L 201	3	30.7.2019
►**M33**	Commission Implementing Regulation (EU) 2019/1294 of 1 August 2019	L 204	16	2.8.2019
►**M34**	Commission Implementing Regulation (EU) 2019/1314 of 2 August 2019	L 205	4	5.8.2019
►**M35**	Commission Implementing Regulation (EU) 2019/1686 of 8 October 2019	L 258	13	9.10.2019
►**M36**	amended by Commission Implementing Regulation (EU) 2023/65 of 6 January 2023	L 6	1	9.1.2023
►**M37**	Commission Implementing Regulation (EU) 2019/1976 of 25 November 2019	L 308	40	29.11.2019
►**M38**	Commission Implementing Regulation (EU) 2019/1979 of 26 November 2019	L 308	62	29.11.2019
►**M39**	Commission Implementing Regulation (EU) 2019/2165 of 17 December 2019	L 328	81	18.12.2019
►**M40**	Commission Implementing Regulation (EU) 2020/16 of 10 January 2020	L 7	6	13.1.2020
►**M41**	Commission Implementing Regulation (EU) 2020/24 of 13 January 2020	L 8	12	14.1.2020
►**M42**	Commission Implementing Regulation (EU) 2020/206 of 14 February 2020	L 43	66	17.2.2020
►**M43**	Commission Implementing Regulation (EU) 2020/443 of 25 March 2020	L 92	7	26.3.2020

►**M44**	Commission Implementing Regulation (EU) 2020/478 of 1 April 2020	L 102	1	2.4.2020
►**M45**	Commission Implementing Regulation (EU) 2020/484 of 2 April 2020	L 103	3	3.4.2020
►**M46**	amended by Commission Implementing Regulation (EU) 2021/1318 of 9 August 2021	L 286	5	10.8.2021
►**M47**	Commission Implementing Regulation (EU) 2020/500 of 6 April 2020	L 109	2	7.4.2020
►**M48**	Commission Implementing Regulation (EU) 2020/916 of 1 July 2020	L 209	6	2.7.2020
►**M49**	Commission Implementing Regulation (EU) 2020/917 of 1 July 2020	L 209	10	2.7.2020
►**M50**	Commission Implementing Regulation (EU) 2020/973 of 6 July 2020	L 215	7	7.7.2020
►**M51**	Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020	L 258	1	7.8.2020
►**M52**	Commission Implementing Regulation (EU) 2020/1559 of 26 October 2020	L 357	7	27.10.2020
►**M53**	Commission Implementing Regulation (EU) 2020/1634 of 4 November 2020	L 367	39	5.11.2020
►**M54**	Commission Implementing Regulation (EU) 2020/1820 of 2 December 2020	L 406	29	3.12.2020
►**M55**	Commission Implementing Regulation (EU) 2020/1821 of 2 December 2020	L 406	34	3.12.2020
►**M56**	Commission Implementing Regulation (EU) 2020/1822 of 2 December 2020	L 406	39	3.12.2020
►**M57**	Commission Implementing Regulation (EU) 2020/1993 of 4 December 2020	L 410	62	7.12.2020
►**M58**	Commission Implementing Regulation (EU) 2021/50 of 22 January 2021	L 23	7	25.1.2021
►**M59**	Commission Implementing Regulation (EU) 2021/51 of 22 January 2021	L 23	10	25.1.2021
►**M60**	Commission Implementing Regulation (EU) 2021/82 of 27 January 2021	L 29	16	28.1.2021
►**M61**	Commission Implementing Regulation (EU) 2021/96 of 28 January 2021	L 31	201	29.1.2021
►**M62**	amended by Commission Implementing Regulation (EU) 2023/65 of 6 January 2023	L 6	1	9.1.2023
►**M63**	Commission Implementing Regulation (EU) 2021/120 of 2 February 2021	L 37	1	3.2.2021
►**M64**	Commission Implementing Regulation (EU) 2021/668 of 23 April 2021	L 141	3	26.4.2021
►**M65**	Commission Implementing Regulation (EU) 2021/670 of 23 April 2021	L 141	14	26.4.2021
►**M66**	Commission Implementing Regulation (EU) 2021/882 of 1 June 2021	L 194	16	2.6.2021
►**M67**	Commission Implementing Regulation (EU) 2021/900 of 3 June 2021	L 197	71	4.6.2021
►**M68**	Commission Implementing Regulation (EU) 2021/912 of 4 June 2021	L 199	10	7.6.2021
►**M69**	Commission Implementing Regulation (EU) 2021/1318 of 9 August 2021	L 286	5	10.8.2021
►**M70**	Commission Implementing Regulation (EU) 2021/1319 of 9 August 2021	L 286	12	10.8.2021
►**M71**	Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021	L 288	24	11.8.2021
►**M72**	Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021	L 297	20	20.8.2021
►**M73**	Commission Implementing Regulation (EU) 2021/1974 of 12 November 2021	L 402	5	15.11.2021
►**M74**	Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021	L 402	10	15.11.2021
►**M75**	Commission Implementing Regulation (EU) 2021/2029 of 19 November 2021	L 415	9	22.11.2021
►**M76**	Commission Implementing Regulation (EU) 2021/2079 of 26 November 2021	L 426	16	29.11.2021

►**M77**	Commission Implementing Regulation (EU) 2021/2129 of 2 December 2021	L 432	13	3.12.2021
►**M78**	Commission Implementing Regulation (EU) 2021/2191 of 10 December 2021	L 445	1	13.12.2021
►**M79**	Commission Implementing Regulation (EU) 2022/47 of 13 January 2022	L 9	29	14.1.2022
►**M80**	Commission Implementing Regulation (EU) 2022/168 of 8 February 2022	L 28	5	9.2.2022
►**M81**	Commission Implementing Regulation (EU) 2022/169 of 8 February 2022	L 28	10	9.2.2022
►**M82**	Commission Implementing Regulation (EU) 2022/187 of 10 February 2022	L 30	102	11.2.2022
►**M83**	Commission Implementing Regulation (EU) 2022/188 of 10 February 2022	L 30	108	11.2.2022
►**M84**	Commission Implementing Regulation (EU) 2022/196 of 11 February 2022	L 31	46	14.2.2022
►**M85**	Commission Implementing Regulation (EU) 2022/202 of 14 February 2022	L 33	41	15.2.2022
►**M86**	Commission Implementing Regulation (EU) 2022/672 of 22 April 2022	L 122	24	25.4.2022
►**M87**	Commission Implementing Regulation (EU) 2022/673 of 22 April 2022	L 122	27	25.4.2022
►**M88**	Commission Implementing Regulation (EU) 2022/684 of 28 April 2022	L 126	10	29.4.2022
►**M89**	Commission Implementing Regulation (EU) 2022/961 of 20 June 2022	L 165	41	21.6.2022
►**M90**	Commission Implementing Regulation (EU) 2022/965 of 21 June 2022	L 166	118	22.6.2022
►**M91**	Commission Implementing Regulation (EU) 2022/966 of 21 June 2022	L 166	125	22.6.2022
►**M92**	Commission Implementing Regulation (EU) 2022/1160 of 5 July 2022	L 179	25	6.7.2022
►**M93**	Commission Implementing Regulation (EU) 2022/1365 of 4 August 2022	L 205	230	5.8.2022
►**M94**	Commission Implementing Regulation (EU) 2022/1373 of 5 August 2022	L 206	28	8.8.2022
►**M95**	Commission Implementing Regulation (EU) 2022/1381 of 8 August 2022	L 207	12	9.8.2022
►**M96**	Commission Implementing Regulation (EU) 2022/2534 of 21 December 2022	L 328	85	22.12.2022
►**M97**	Commission Implementing Regulation (EU) 2022/2535 of 21 December 2022	L 328	91	22.12.2022
►**M98**	Commission Implementing Regulation (EU) 2023/4 of 3 January 2023	L 2	3	4.1.2023
►**M99**	Commission Implementing Regulation (EU) 2023/5 of 3 January 2023	L 2	9	4.1.2023
►**M100**	Commission Implementing Regulation (EU) 2023/6 of 3 January 2023	L 2	16	4.1.2023
►**M101**	Commission Implementing Regulation (EU) 2023/7 of 3 January 2023	L 2	21	4.1.2023
►**M102**	Commission Implementing Regulation (EU) 2023/52 of 4 January 2023	L 3	1	5.1.2023
►**M103**	Commission Implementing Regulation (EU) 2023/58 of 5 January 2023	L 5	10	6.1.2023
►**M104**	Commission Implementing Regulation (EU) 2023/65 of 6 January 2023	L 6	1	9.1.2023
►**M105**	Commission Implementing Regulation (EU) 2023/113 of 16 January 2023	L 15	1	17.1.2023

►**M106**	Commission Implementing Regulation (EU) 2023/267 of 8 February 2023	L 39	1	9.2.2023
►**M107**	Commission Implementing Regulation (EU) 2023/463 of 3 March 2023	L 68	32	6.3.2023
►**M108**	Commission Implementing Regulation (EU) 2023/652 of 20 March 2023	L 81	23	21.3.2023
►**M109**	Commission Implementing Regulation (EU) 2023/667 of 22 March 2023	L 84	3	23.3.2023
►**M110**	Commission Implementing Regulation (EU) 2023/859 of 25 April 2023	L 111	17	26.4.2023
►**M111**	Commission Implementing Regulation (EU) 2023/931 of 8 May 2023	L 124	1	10.5.2023
►**M112**	Commission Implementing Regulation (EU) 2023/937 of 10 May 2023	L 125	12	11.5.2023
►**M113**	Commission Implementing Regulation (EU) 2023/938 of 10 May 2023	L 125	16	11.5.2023
►**M114**	Commission Implementing Regulation (EU) 2023/943 of 11 May 2023	L 126	41	12.5.2023
►**M115**	Commission Implementing Regulation (EU) 2023/948 of 12 May 2023	L 128	52	15.5.2023
►**M116**	Commission Implementing Regulation (EU) 2023/949 of 12 May 2023	L 128	60	15.5.2023
►**M117**	Commission Implementing Regulation (EU) 2023/950 of 12 May 2023	L 128	68	15.5.2023
►**M118**	Commission Implementing Regulation (EU) 2023/951 of 12 May 2023	L 128	73	15.5.2023
►**M119**	Commission Implementing Regulation (EU) 2023/961 of 12 May 2023	L 129	3	16.5.2023
►**M120**	Commission Implementing Regulation (EU) 2023/972 of 10 May 2023	L 132	46	17.5.2023
►**M121**	Commission Implementing Regulation (EU) 2023/1581 of 1 August 2023	L 194	4	2.8.2023
►**M122**	Commission Implementing Regulation (EU) 2023/1582 of 1 August 2023	L 194	8	2.8.2023
►**M123**	Commission Implementing Regulation (EU) 2023/1583 of 1 August 2023	L 194	13	2.8.2023
►**M124**	Commission Implementing Regulation (EU) 2023/2145 of 16 October 2023	L 2145	1	17.10.2023
►**M125**	Commission Implementing Regulation (EU) 2023/2210 of 20 October 2023	L 2210	1	23.10.2023
►**M126**	Commission Implementing Regulation (EU) 2023/2214 of 23 October 2023	L 2214	1	24.10.2023
►**M127**	Commission Implementing Regulation (EU) 2023/2215 of 23 October 2023	L 2215	1	24.10.2023
►**M128**	Commission Implementing Regulation (EU) 2023/2847 of 20 December 2023	L 2847	1	21.12.2023
►**M129**	Commission Implementing Regulation (EU) 2023/2851 of 20 December 2023	L 2851	1	21.12.2023
►**M130**	Commission Implementing Regulation (EU) 2024/1023 of 8 April 2024	L 1023	1	9.4.2024
►**M131**	Commission Implementing Regulation (EU) 2024/1026 of 8 April 2024	L 1026	1	9.4.2024
►**M132**	Commission Implementing Regulation (EU) 2024/1027 of 8 April 2024	L 1027	1	9.4.2024
►**M133**	Commission Implementing Regulation (EU) 2024/1037 of 9 April 2024	L 1037	1	10.4.2024
►**M134**	Commission Implementing Regulation (EU) 2024/1046 of 9 April 2024	L 1046	1	10.4.2024

►**M135**	Commission Implementing Regulation (EU) 2024/1047 of 9 April 2024	L 1047	1	10.4.2024
►**M136**	Commission Implementing Regulation (EU) 2024/1048 of 9 April 2024	L 1048	1	10.4.2024
►**M137**	Commission Implementing Regulation (EU) 2024/1052 of 10 April 2024	L 1052	1	11.4.2024
►**M138**	Commission Implementing Regulation (EU) 2024/1611 of 6 June 2024	L 1611	1	7.6.2024
►**M139**	Commission Implementing Regulation (EU) 2024/2036 of 29 July 2024	L 2036	1	30.7.2024
►**M140**	Commission Implementing Regulation (EU) 2024/2044 of 29 July 2024	L 2044	1	30.7.2024
►**M141**	Commission Implementing Regulation (EU) 2024/2046 of 29 July 2024	L 2046	1	30.7.2024
►**M142**	Commission Implementing Regulation (EU) 2024/2047 of 29 July 2024	L 2047	1	30.7.2024
►**M143**	Commission Implementing Regulation (EU) 2024/2048 of 29 July 2024	L 2048	1	30.7.2024
►**M144**	Commission Implementing Regulation (EU) 2024/2090 of 29 July 2024	L 2090	1	30.7.2024
►**M145**	Commission Implementing Regulation (EU) 2024/2049 of 30 July 2024	L 2049	1	31.7.2024
►**M146**	Commission Implementing Regulation (EU) 2024/2061 of 30 July 2024	L 2061	1	31.7.2024
►**M147**	Commission Implementing Regulation (EU) 2024/2062 of 30 July 2024	L 2062	1	31.7.2024
►**M148**	Commission Implementing Regulation (EU) 2024/2101 of 30 July 2024	L 2101	1	31.7.2024
►**M149**	Commission Implementing Regulation (EU) 2024/2102 of 30 July 2024	L 2102	1	31.7.2024

▼B

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)

Article 1

Union list of authorised novel foods

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

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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼**M9**

ANNEX

UNION LIST OF NOVEL FOODS

Content of the list

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

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

▼M9

Table 1: Authorised novel foods

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data 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' 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.		
	Infant and follow-on formulae as defined by Regulation (EU) No 609/2013 ([1])	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			
	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 requirements of Commission Implementing Regulation (EU) No 828/2014 ([2])	1,25 g/kg			
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,05 g/L			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 extracts; tea, plant, fruit and cereal preparations for infusions	0,2 g/kg			
	Food Supplements as defined in Directive 2002/46/EC ([3])	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M99					
***Acheta domesticus* (house cricket) partially defatted powder**	*Specified food category*	*Maximum levels (g/100 g) (marketed as such or reconstituted according to the instructions)*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Acheta domesticus* (house cricket) partially defatted powder'. 2. The labelling of the foodstuffs containing *Acheta domesticus* (house cricket) partially defatted powder shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, molluscs, and products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 24.1.2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Cricket One Co. Ltd', 383/3/51 Quang Trung street, Ward 10, Go Vap district, Ho Chi Minh City, Vietnam. During the period of data protection, the novel food *Acheta domesticus* (house cricket) partially defatted powder is authorised for placing on the market within the Union only by 'Cricket One Co. Ltd', unless a subsequent applicant obtains authorisation for that 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 'Cricket One Co. Ltd'. End date of the data protection: 24.1.2028.
	Multigrain bread and rolls; crackers and breadsticks	2			
	Cereal bars	3			
	Pre-mixes for baked products (dry)	3			
	Biscuits	1,5			
	Pasta-based products (dry)	0,25			
	Stuffed pasta-based products (dry)	3			
	Sauces	1			
	Processed potato products, legume- and vegetable-based dishes, pizza, pasta-based dishes	1			
	Whey powder	3			
	Meat analogues	5			
	Soups and soup concentrates or powders	1			
	Maize flour based snacks	4			
	Beer-like beverages	0,1			
	Chocolate confectionary	2			
	Nuts and oilseeds	2			
	Snacks other than chips	5			
	Meat preparations	2			
▼M9					
***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'		

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M103					
Frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm)	*Specified food category*	*Maximum levels (g/100g)*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Frozen/ paste *Alphitobius diaperinus* larvae (lesser mealworm)' or 'Dried/powder *Alphitobius diaperinus* larvae (lesser mealworm)' depending on the form used. 2. The labelling of food supplements containing the novel food shall bear a statement that those food supplements should not be consumed by persons under 18 years of age. 3. The labelling of the foodstuffs containing frozen, paste, dried or powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, and products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 26.1.2023. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Ynsect NL B.V, Harderwijkerweg 141B, 3852 AB Ermelo, the Netherlands. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Ynsect NL B.V., unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283, or with the agreement of Ynsect NL B.V. End date of the data protection: 26.1.2028.
	Cereal bars	25 (Dried form) 25 (Powder form)			
	Bread and rolls	20 (Powder form)			
	Processed and breakfast cereals	10 (Dried form) 10 (Powder form)			
	Porridge	15 (Powder form)			
	Pre-mixes (dry) for baked products	10 (Powder form)			
	Dried pasta-based products	10 (Powder form)			
	Stuffed pasta-based products	28 (Frozen or paste form) 10 (Powder form)			
	Whey powder	35 (Powder form)			
	Soups	15 (Powder form)			
	Cereal-, pasta-based dishes	5 (Powder form)			
	Pizza-based dishes	5 (Dried form) 5 (Powder form)			
	Noodles	10 (Powder form)			
	Snacks other than chips	10 (Dried form) 10 (Powder form)			
	Chips/crisps	10 (Powder form)			
	Crackers and bread sticks	10 (Powder form)			
	Peanut butter	15 (Powder form)			
	Ready-to-eat savoury based sandwich	20 (Powder form)			
	Meat preparations	14 (Frozen or paste form) 5 (Powder form)			
	Meat analogues	40 (Frozen or paste form) 15 (Powder form)			
	Milk and dairy analogues	10 (Powder form)			
	Chocolate confectionary	5 (Powder form)			
	Food supplements as defined in Directive 2002/46/EC for the adult population	4 g/day (Powder form)			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Specified food category	*Maximum levels*			
***Ajuga reptans* extract from cell cultures**	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*			
▼M80					
***Akkermansia muciniphila* (pasteurised)**	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	$3,4 \times 10^{10}$ cells/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'pasteurised *Akkermansia muciniphila*'. The labelling of food supplements containing pasteurised *Akkermansia muciniphila* shall bear a statement that they should be consumed by adults only, excluding pregnant and lactating women.		Authorised on 1 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: A-Mansia Biotech S.A., rue Granbonpré, 11, Bâtiment H, 1435 Mont-Saint-Guibert. Belgium. During the period of data protection, the novel food pasteurised *Akkermansia muciniphila* is authorised for placing on the market within the Union only by A-Mansia Biotech 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 Mansia Biotech S.A.. End date of the data protection: 1 March 2027.
	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	$3,4 \times 10^{10}$ cells/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M26					
***Allanblackia* 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 the food category: Dairy analogues, including beverage whiteners)	30 g/100 g			
	(*) Except olive oils and olive pomace oils as defined in Part VIII of Annex VII of Regulation (EU) No 1308/2013.				
▼M9					
***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.			
▼M146					
Juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice')	*Specified food category*	*Maximum levels (expressed on the juice)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ashitaba (*Angelica keiskei*) stem juice'. The labelling of food supplements containing the juice of the stems of the *Angelica keiskei* plant (Ashitaba stem juice) shall bear a statement that they should be consumed by adults only, excluding pregnant and lactating women.		Authorised on 20 August 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Japan Bio Science Laboratory (JBSL)-USA, Inc.', 1547 Palos Verdes Mall No 131, Walnut Creek, California 94597, United States of America.
	Food Supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	137 mg/day			

▼M146

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					During the period of data protection, the novel food juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice') is authorised for placing on the market within the Union only by 'Japan Bio Science Laboratory (JBSL)-USA, 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 'Japan Bio Science Laboratory (JBSL)-USA, Inc.'. End date of the data protection: 20 August 2029

▼M9

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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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				
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 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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 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				
▼M97 ***Antrodia camphorata* mycelia powder**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of food supplements containing it shall be '*Antrodia camphorata* mycelia powder'. 2. The labelling of the food supplements containing *Antrodia camphorata* mycelia powder shall bear a statement that this food supplement should not be consumed by infants, children, and adolescents younger than 14 years of age.		
	Food supplements as defined in Directive 2002/46/EC, excluding infants, children, and adolescents younger than 14 years of age	990 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M120					
Aqueous ethanolic extract of *Labisia pumila*	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'aqueous ethanolic extract of *Labisia pumila*'. 2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by persons above 18 years of age excluding pregnant and lactating women.		Authorised on 6 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Medika Natura Sdn. Bhd., No. 44B Jalan Bola Tampar 13/14 Section 13, 40100 Shah Alam Selangor, Malaysia. During the period of data protection, the novel food aqueous ethanolic extract of *Labisia pumila* is authorised for placing on the market within the Union only by Medika Natura Sdn. Bhd., 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 Medika Natura Sdn. Bhd. End date of the date protection: 6 June 2028.
	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	350 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M128 **Apple fruit cell culture biomass**	*Specified food category*	*Maximum levels*			
	Food supplements as defined in Directive 2002/46/EC for the adult population	0,15 mg/day	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'apple fruit cell culture biomass'. 2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by persons above 18 years of age.		
▼M69 **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 infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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			

▼M121

Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	*Specified food category*	*Maximum levels of astaxanthin*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Astaxanthin rich oleoresin from *Haematococcus pluvialis* algae' The labelling of food supplements containing Astaxanthin rich oleoresin from *Haematococcus pluvialis* algae shall bear a statement that they should not be consumed: (a) if other food supplements containing astaxanthin esters are consumed on the same day (b) by infants and young children under 3 years of age (c) by infants and children under 10 years of age ([12]) (d) by infants, children and adolescents under 14 years of age ([12]).		
	Food supplements as defined in Directive 2002/46/EC excluding infants and young children	2,3 mg astaxanthin per day for children 3 to less than 10 years of age			
		5,7 mg astaxanthin per day for adolescents 10 to less than 14 years of age			
		8 mg astaxanthin per day for general population older than 14 years of age			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M141					
Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Partially hydrolysed protein from barley and rice'. In accordance with Article 21 of Regulation (EU) No 1169/2011.		Authorised on 10 January 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Evergrain LLC, 3205 S. 9th St, St. Louis, Missouri, 63118 USA. During the period of data protection, the novel food partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) is authorised for placing on the market within the Union only by Evergrain 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 Evergrain LLC. End date of the date protection: 10 January 2029.
	Fried or extruded cereal, seed or root-based products	5 g/100 g			
	Confectionery including chocolate	5 g/100 g			
	Breakfast cereals	5 g/100 g			
	Pastas and rice (or other cereal)-based dishes	8 g/100 g			
	Soups (dry mixture)	50 g/100 g			
	Soups (ready-to-eat)	5 g/100 g			
	Sauces	10 g/100 g			
	Dried sauce preparation	50 g/100 g			
	Meat analogues	15 g/100 g			
	Cereal bars	30 g/100 g			
	Butter and margarine/oil blends	10 g/100 g			
	Milk analogues based ice creams	10 g/100 g			
	Milk analogues	5 g/100 ml			
	Nut/seeds paste/emulsion	15 g/100 g			
	Energy drinks	8 g/100 ml			
	Soft drinks marketed in relation to physical exercise	5 g/100 ml			
	Cola type drinks	5 g/100 g			
	Powdered drink bases	90 g/100 g			
	Beverages based on fruit and/or vegetable juices	5 g/100 ml			
	Cream, cheese and yoghurt (non-soy) analogues	10 g/100 g			
	Hummus	10 g/100 g			
	Alcohol-free beer	5 g/100 ml			
	Meal replacement for weight control	30 g/100 g			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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*)			

▼M134

Beta-glucan from *Euglena gracilis* microalgae	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'beta-glucan from *Euglena gracilis* microalgae'.		Authorised on 30 April 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Kemin Foods L.C., 1900 Scott Avenue Des Moines, IA 50317, United States. During the period of data protection, the novel food beta-glucan from *Euglena gracilis* microalgae is authorised for placing on the market within the Union only by Kemin Foods L.C., 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 Kemin Foods L.C. End date of the date protection 30 April 2029.
	Cereal bars	670 mg/100 g			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	600 mg/day			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	100 mg/day for children from 3 to 9 years of age 150 mg/day for children from 10 to 17 years of age 200 mg/day for adults	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'beta-glucan from *Euglena gracilis* microalgae'. 2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by persons above 3 years of age/above 9 years of age/adults, depending on the age group the product is intended for		

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M33					
Betaine	*Specified food category*	*Maximum levels* (7)	The designation of the novel food on the labelling of 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.		Authorised on 22 August 2019. This inclusion is based on 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 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 DuPont Nutrition Biosciences ApS, End date of the data protection: 22 August 2024.
	Drink powders, isotonic and energy drinks intended for sportsmen	60 mg/100 g			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Processed cereal food (solid)	670 mg/100 g			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	Depending on the needs of 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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M35 ▼M36 **Bovine 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 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.		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: 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 of Armor Protéines S.A.S. End date of the data protection: 20 November 2023.
	Infant formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder)			
		3,9 mg/100 mL (reconstituted)			
	Follow-on formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder)			
		4,2 mg/100 mL (reconstituted)			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	300 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	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			
		610 mg/day for adults			
	Food supplements as defined in Directive 2002/46/EC	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M96					
Bovine milk beta-lactoglobulin (*β*-lactoglobulin)	*Specified food category*	*Maximum levels (g NF/100 ml)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'bovine milk beta-lactoglobulin' or 'bovine milk *β*-lactoglobulin'.		Authorised on 11 January 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Arla Foods Ingredients Group P/S, Sønderhøj 10-12, 8260 Viby J, Denmark. During the period of data protection, the novel food beta-lactoglobulin (*β*-lactoglobulin) is authorised for placing on the market within the Union only by Arla Foods Ingredients Group P/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 Arla Foods Ingredients Group P/S. End date of the data protection: 11 January 2028.
	Soft drinks marketed in relation to physical exercise	25			
	Whey powder (reconstituted)	8			
	Milk based drinks and similar products	12			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013 intended for the general population older than 3 years of age, excluding pregnant and lactating women	In accordance with the particular nutritional requirements of the persons for whom the products are intended			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M107					
Bovine milk osteopontin	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Bovine milk Osteopontin'.		Authorised on 26 March 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Arla Foods Ingredients Group P/S., Sønderhøj 10-12 8260 Viby J Denmark. During the period of data protection, the novel food Bovine milk osteopontin is authorised for placing on the market within the Union only by Arla Foods Ingredients Group P/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 Arla Foods Ingredients Group P/S. End date of the data protection: 26 March 2028.
	Infant formula as defined in Regulation (EU) No 609/2013 ([13])	151 mg/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 ([13])	151 mg/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk-based drinks intended for young children	151 mg/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
***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 purposes as defined in Regulation (EU) No 609/2013, excluding foods for special medical purposes intended for infants and young children	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			

▼M91

***Calanus finmarchicus* oil**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from *Calanus finmarchicus* (crustacean)'. 2. The labelling of food supplements containing *Calanus finmarchicus oil* shall bear a statement that those food supplements should not be consumed:		
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1,0 g/day (< 0,1 % astaxanthin esters, resulting in < 1,0 mg astaxanthin per day) for the general population, excluding infants and young children 2,3 g/day (from 0,1 % to ≤ 0,25 % astaxanthin esters, resulting in ≤ 5,75 mg astaxanthin per day) for the general population older than 14 years of age			

▼M91

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
			a) if other food supplements containing astaxanthin esters are consumed on the same day. b) by infants and children younger than 3 years. c) by children younger than 14 years, if the ingredient contains ≥ 0,1 % astaxanthin.		
▼M77 Calcium fructoborate	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'calcium fructoborate'. 2. The labelling of food supplements containing calcium fructoborate shall bear a statement that those food supplements should not be consumed by population under 18 years of age and by pregnant and lactating women.		Authorised on 23 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: VDF Future-Ceuticals, Inc., 300 West 6th Street Momence, Illinois 60954, the United States. During the period of data protection, the novel food calcium fructoborate is authorised for placing on the market within the Union only by VDF Future-Ceuticals, 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 VDF Future-Ceuticals, Inc. End date of the date protection: 23 December 2026
	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding food supplements for pregnant and lactating women	220 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M85					
Calcium L-Methyl-folate	*Specified food category*	*Maximum levels (expressed as folic acid)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Calcium L-Methylfolate'.		
	Foods for special medical purposes and total diet replacement for weight control as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Infant formulae and follow-on formula as defined by 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 by Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Food supplements as defined in Directive 2002/46/EC	In accordance with Directive 2002/46/EC			
	Food fortified in accordance with Regulation (EC) No 1925/2006	In accordance with Regulation (EC) No 1925/2006			
▼M137					
Calcidiol monohydrate	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'calcidiol (calcifediol) monohydrate (vitamin D)'.		Authorised on 1 May 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	10 µg/day for children from 11 years of age and adults 5 µg/day for children from 3 to 10 years of age			

▼M137

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
			2. The labelling of food supplements containing the novel food shall bear a statement that they should not be consumed by infants and children under 3 years of age/ children under 11 years of age, depending on the age group the product is intended for.		Applicant: DSM Nutritional Products Ltd., Wurmisweg 576, 4303 Kaiseraugst, Switzerland. During the period of data protection, the novel food calcidiol monohydrate is authorised for placing on the market within the Union only by DSM Nutritional Products 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 DSM Nutritional Products Ltd. End date of the date protection: 1 May 2029.
▼M106 **Dried nuts of *Canarium ovatum* Engl.**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'nuts of *Canarium ovatum*' and/or 'pilinuts' and/or 'pili (*Canarium ovatum*) nuts'.		
	Not specified				

▼M106

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
			2. The labelling of the foodstuffs containing dried nuts of *Canarium ovatum* Engl. shall bear a statement that the dried nuts of *Canarium ovatum* Engl. may cause allergic reactions to consumers with known allergies to cashew and walnut. This statement shall appear in close proximity to the list of ingredients or, in the absence of a list of ingredients, in close proximity to the name of the food.		
▼M109 **_Canarium indicum_ L. dried nuts (Kenari) (Traditional food from a third country)**	*Specified food category*	*Maximum levels (g/100 g)*	1. The designation of the traditional food on the labelling of the foodstuffs containing it shall be 'dried kenari *(Canarium indicum)* nuts'. 2. The labelling of the foodstuffs containing dried nuts of *Canarium indicum* L. shall bear a statement that the nuts may cause allergic reactions to consumers with known allergies to hazel, cashew and pistachio. This statement shall appear in close proximity to the list of ingredients or, in the absence of a list of ingredient, in close proximity to the name of the food.		
	Not specified				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M114					
Cellobiose	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘cellobiose’. 2. The labelling of food supplements containing cellobiose shall bear a statement that those food supplements should not be consumed by infants and young children.		Authorised on 1 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: SAVANNA Ingredients GmbH, Dürener Straße 67, 50189 Elsdorf, Germany. During the period of data protection, the novel food cellobiose is authorised for placing on the market within the Union only by SAVANNA Ingredients GmbH, 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 SAVANNA Ingredients GmbH. End date of the data protection: 1 June 2028.
	Food supplements as defined in Directive 2002/46/EC for the general population, excluding infants and young children	3 g/day			
	Dried, canned-tinned, raw cured (or seasoned), cooked cured (or seasoned) meat	2 g/100 g			
	Fresh raw, preserved or partly preserved sausages	2 g/100 g			
	Meat based spreadable-textured specialties	2 g/100 g			
	Liver based spreadable-textured specialties	2 g/100 g			
	Savoury sauce dry preparation	40 g/100 g			
	Table-top sweeteners in powder form	60 g/100 g			
	Table-top sweeteners in tablets	60 g/100 g			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M82					
Cetylated fatty acids	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the food supplements containing it shall be 'cetylated fatty acids preparation'. 2. The labelling of food supplements containing the novel food shall bear a statement that those food supplements should not be consumed by persons under 18 years of age.		Authorised on 3 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Pharmanutra S.p.A., Via Delle Lenze 216/b, 56122 Pisa, Italy. During the period of data protection, the novel food cetylated fatty acids is authorised for placing on the market within the Union only by Pharmanutra S.p.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 Pharmanutra S.p.A. End date of the date protection: 3 March 2027
	Food supplements as defined in Directive 2002/46/EC for the adult population	1,6 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Chewing gum base (monomethoxypoly-ethylene 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-homopolymer, maleated, esters with polyethylene glycol mono-Me ether)' or 'Gum base (including CAS No: 1246080-53-4)'		
	Chewing gum	8 %			
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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M64					
Chia 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, pseudocereal grains and/or pulses	5 % whole chia seeds			
	Fruit, nut and seed mixes				
	Chia seeds 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				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 extract from *Aspergillus niger*'		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of chitosan from crustaceans			
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 ([4])				

▼M56

Chromium-containing yeast (*Yarrowia lipolytica*) biomass	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'chromium-containing yeast (*Yarrowia lipolytica*) biomass' The labelling of food supplements containing chromium-containing yeast (*Yarrowia lipolytica*) biomass shall bear a statement that the food supplements should not be consumed by infants and young children (children under 3 years of age)/ children from 3 to 9 years of age ([12]).		
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	2 g/day for children from 3 to 9 years of age, resulting in 46 µg of chromium per day 4 g/day for children from 10 years of age, adolescents and adults, resulting in 92 µg of chromium per day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
***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 novel food on the labelling of the foodstuffs containing it shall be 'Citicoline' 2. The labelling of foods containing citicoline shall bear a statement that the product is not intended to be consumed by children		
	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	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M79					
Coffea arabica L. and/or *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion (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 ‘coffee cherry pulp’ and/or ‘cascara (coffee cherry pulp)’, and/or ‘coffee cherry pulp infusion’ and/or ‘coffee cherry pulp dried infusion’. If the product containing the novel food contains more than 150 mg/l of caffeine (as such or after reconstitution), it shall be labelled with the following indication: ‘High caffeine content. Not recommended for children or pregnant or breast-feeding women’ in the same field of vision as the name of the food, followed by the caffeine content expressed in mg per 100 ml. Typical infusion preparations are prepared with up to 6 g of coffee cherry pulp per 100 ml of hot water (> 75 °C). For the coffee cherry pulp placed on the market as such for the preparation of infusions, instructions shall be given to the consumer on the preparation.		
	Coffee cherry pulp from *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner for the preparation of infusions				
	Coffee, coffee and chicory extracts, instant coffee, tea, herbal- and fruit-infusions, coffee substitutes, coffee mixes and instant mixes for hot beverages (and their flavoured counterparts).				
	Flavoured and unflavoured non-alcoholic ready-to-drink beverages				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M30					
D-ribose	*Specified food category*	*Maximum levels*	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.		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 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).
	Cereal bars	0,20 g/100 g			
	Fine bakery wares	0,31 g/100 g			
	Chocolate confectionery (excluding chocolate bars)	0,17 g/100 g			
	Milk-based drinks (excluding malts and shakes)	0,08 g/100 g			
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen, isotonic and energy drinks	0,80 g/100 g			
	Bars intended to meet the expenditure of intense muscular effort especially for sportsmen	3,3 g/100 g			
	Meal replacement for weight control (as drinks)'	0,13 g/100 g			
	Meal replacement for weight control (as bars)	3,30 g/100 g			
	Confectionery	0,20 g/100 g			
	Tea and infusions (in powder form to be reconstituted)	0,23 g/100 g			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 flavanols per day		
	Foods including food supplements as defined in Directive 2002/46/EC	730 mg per serving and around 1,2 g/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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M15					
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 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.
	Food Supplements as defined in Directive 2002/46/EC for the adult population	350 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
***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 ([5])				
	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'		
▼M22 **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'		
▼M9 **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 %			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 least 80 % diacylglycerols)'		
	Cooking oils				
	Fat spreads				
	Salad dressings				
	Mayonnaise				
	Meal replacement for weight control (as drinks)				
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			
▼M54 **Dried *Euglena gracilis***	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried biomass of *Euglena gracilis* algae'. The labelling of food supplements containing dried *Euglena gracilis* shall bear a statement that those food supplements should not be consumed by infants/children under 3 years of age/children under 10 years of age/children and adolescents under 18 years of age ([12]).		Authorised on 23 December 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Kemin Foods L.C., 2100 Maury Street Des Moines, IA 50317, USA.
	Breakfast cereal bars, granola bars and protein bars	630 mg/100 g			
	Yoghurt	150 mg/100 g			
	Yoghurt Beverages	95 mg/100 g			
	Fruit and vegetable juices, nectars, fruit/vegetable blend beverages	120 mg/100 g			
	Fruit-Flavoured Drinks	40 mg/100 g			
	Meal replacement beverages	75 mg/100 g			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	100 mg/day for young children 150 mg/day for children from 3 to 9 years of age 225 mg/day for children from 10 years of age and adolescents (to 17 years of age) 375 mg/day for adults			

▼M54

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Total diet replacement for weight control as defined by Regulation (EU) No 609/2013	190 mg/meal			During the period of data protection, the novel food is authorised for placing on the market within the Union only by Kemin Foods L.C. unless a subsequent applicant obtains authorisation for that 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 Kemin Foods L.C. End date of the data protection: 23 December 2025.
▼M13 **Dried 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 26 of Regulation (EU) 2015/2283. Applicant: Desert Labs, Ltd Kibbutz Yotvata, 88820 Israel.
	Food Supplements as defined in Directive 2002/46/EC for adult population	9,4 mg/day			

▼M13

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					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.
▼M9 **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*			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M32 ***Echinacea 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*			
▼M9 ***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 delivered in a single dose	250 mg/100 g; 75 mg/100 g for drinks			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M52					
***Ecklonia 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 as defined in Directive 2002/46/EC intended for the general population, excluding children under the age of 12 years	163 mg/day for adolescents from 12 to 14 years of age 230 mg/day for adolescents above 14 years of age 263 mg/day for adults	Food supplements containing *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.		

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M18					
Egg membrane hydrolysate	*Specified food category*	*Maximum levels*	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
	Food Supplements as defined in Directive 2002/46/EC intended for the general adult population	450 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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			

▼M52

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
L-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				

▼M108

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) (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 'roasted seeds of *Euryale ferox*' or 'makhana (*Euryale ferox*) roasted seeds'		
	Processed nuts				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M52 **Extract 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)'. 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.		
	Food supplements as defined in Directive 2002/46/EC for adult population	175 mg/day			
▼M9 **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 it shall be 'Ferrous ammonium phosphate'		
	Food supplements as defined in Directive 2002/46/EC	To be used in compliance with Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006			
	Foods covered by Regulation (EU) No 609/2013				
	Foods fortified in accordance with Regulation (EC) No 1925/2006				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 it shall be 'Flavonoids from *Glycyrrhiza glabra L.*' 2. 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 product under medical supervision; (c) 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.	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				
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M42 **Fruit 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.			
▼M9 **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			
▼M149 **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'. 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.		
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l			
	Unflavoured fermented milk-based products	1,2 g/l for beverages			
		19,2 g/kg for products other than beverages			
	Flavoured fermented milk-based products including heat-treated products	1,2 g/l for beverages			
		19,2 g/kg for products other than beverages			

▼M149

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Dairy analogues, including beverage whiteners	1,2 g/l for beverages	3. The labelling of food supplements containing 2′-Fucosyllactose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added 2′-fucosyllactose are consumed the same day.		
		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	3,0 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	3,64 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods and baby foods 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 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

▼M149

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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	4,8 g/l for drinks			
		40 g/kg for bars			
	Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of 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, for the general population, excluding infants	3,0 g/day for general population			
		1,2 g/day for young children			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M38					
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 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.
	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			

▼M38

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			
▼M58	Milk-based drinks and similar products intended for young children	1,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
▼M75					
3-Fucosyllactose (3-FL) **(microbial source)**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '3-Fucosyllactose'. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that they should not be consumed: a) if foods containing added 3-Fucosyllactose are consumed on the same day; b) by infants and children under 3 years of age.		Authorised on 12 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,85 g/L			
	Unflavoured and flavoured fermented milk-based products including heat-treated products	0,5 g/L (beverages)			
		5,0 g/kg (products other than beverages)			
	Dairy analogues	0,85 g/L (beverages)			
		8,5 g/kg (products other than beverages)			

▼M75

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Flavoured drinks, energy and sports drinks	1,0 g/L			Applicant: DuPont Nutrition & Biosciences ApS Langebrogade 1, 1001 Copenhagen K, Denmark. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the Union only by DuPont Nutrition & Biosciences ApS, 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 DuPont Nutrition & Biosciences ApS. End date of the data protection: 12 December 2026.
	Cereal bars	30,0 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,85 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	0,85 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	0,85 g/L (beverages) 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	0,3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		3,0 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)			
		30,0 g/kg (products other than beverages)			
	Foods 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, excluding food supplements for infants and young children	5,0 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M102					
3-Fucosyllactose ('3-FL') (produced by a derivative strain of *E. coli* BL21(DE3))	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '3-fucosyllactose'. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.		Authorised on 25.1.2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Chr. Hansen A/S', Bøge Allé 10-12, 2970 Hørsholm, Denmark. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the Union only by Chr. Hansen 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 'Chr. Hansen A/S'. End date of the data protection: 25.1.2028.
	Infant formula as defined under Regulation (EU) No 609/2013	0,90 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	1,20 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	1,20 g/l or 1,20 g/kg 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	1,20 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Foods for special medical purposes for infants and young children as defined under 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 0,9 g/l or 0,9 g/kg (if it is intended for infants from 0 until 6 months) and 1,2 g/l or 1,2 g/kg (if it is intended for infants of 6-12 months and/or for young children) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	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, for the general population, excluding infants and young children	3 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M125					
3-Fucosyllactose ('3-FL') (produced by derivative strain of *E. coli* K-12 DH1)	*Specified food category*	*Maximum levels (expressed as 3-Fucosyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '3-Fucosyllactose'. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.		Authorised on 12 November 2023. 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, 2970 Hørsholm, Denmark. During the period of data protection, the novel food 3-Fucosyllactose produced by derivative strain of *E. coli* K-12 DH1 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 with Article 26 of Regulation (EU) 2015/2283 or with the agreement of 'Glycom A/S'. End date of the data protection: 12 November 2028.
	Infant formula as defined under Regulation (EU) No 609/2013	1,75 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	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2,0 g/L			
	Unflavoured fermented milk-based products	2,0 g/L (beverages)			
		4,0 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	2,0 g/L (beverages)			
		12,0 g/kg (products other than beverages)			
	Cereal bars	25,0 g/kg			

▼M125

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Milk based drinks and similar products	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		12,0 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	1,25 g/L			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages)			
		25,0 g/kg (products other than beverages)			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher 4,0 g/L or 4,0 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,0 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M95					
Galacto-oligos-accharide	*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			
	Food supplements as defined in Directive 2002/46/EC, excluding infants and young children	0,450 (corresponding to 5,4 g galacto-oligosaccharide/serving; maximum 3 servings/day up to a maximum of 16,2 g/day)			
	Foods for special medical purposes as defined by Regulation (EU) No 609/2013, excluding infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended but not more than 0,128 (corresponding to a maximum of 8,25 g galacto-oligosaccharide/day)			
	Milk	0,020			
	Milk drinks	0,030			
	Meal replacement for weight control (as drinks)	0,020			
	Dairy analogue drinks	0,020			
	Yoghurt	0,033			
	Dairy based desserts	0,043			
	Frozen dairy desserts	0,043			
	Fruit drinks and energy drinks	0,021			
	Infant meal replacement drinks	0,012			
	Baby juice	0,025			
	Baby yogurt drink	0,024			

▼M95

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Baby dessert	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 filling	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			
	Dairy confectionery	0,05			
	Cheese and processed cheese	0,1			
	Butter and spreadable fats	0,1			

▼M9

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				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 containing it shall be 'Guar Gum'. 2. 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 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 product		
	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			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
			before consumption, in order to take into account the potential risk of gastro-intestinal obstruction.		
Heat-treated milk products fermented with *Bacteroides xylanisolvens*	*Specified food category*	*Maximum levels*			
	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 for cooking, baking or frying'		
	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 ([6])), 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			
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				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M111					
Infusion 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' or 'Dried infusion from coffee leaves', depending on the form to be marketed.		
	Infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner placed on the market as such				
	Flavoured and unflavoured non-alcoholic ready-to-drink beverages ([14])				
	Coffee, coffee and chicory extracts, instant coffee, tea, herbal- and fruit-infusions, coffee substitutes, coffee mixes and instant mixes for beverages (and their flavoured counterparts) ([14])				
▼M94					
Iron hydroxide adipate tartrate	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'iron hydroxide adipate tartrate (nano)'. The labelling of food supplements containing iron hydroxide adipate tartrate shall bear a statement that they should not be consumed by children and adolescents under the age of 18/children under 4 years of age (*) (*) Depending on the age group the food supplement is intended for.		Authorised on 28.8.2022. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Nemysis Limited, Suite 4.01 Ormond Building 31-36 Ormond Quay Upper Arran Quay Dublin 7, D07 F6DC, Dublin, Ireland. During the period of data protection, the novel food iron hydroxide adipate tartrate is authorised for placing on the market within the Union only by Nemysis Limited, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Nemysis Limited. End date of the data protection: 28.8.2027.
	Food supplements as defined in Directive 2002/46/EC for the adult population	≤ 100 mg/day (≤ 30 mg Fe/day)			
	Food supplements as defined in Directive 2002/46/EC for children and adolescents under 18 years of age, excluding children under 4 years of age	≤ 50 mg/day (≤ 14 mg Fe/day)			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M116					
Iron milk caseinate	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'iron milk caseinate'. The labelling of food supplements containing iron milk caseinate shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be consumed if other foods containing iron milk caseinate and/or if other foods with added iron are consumed the same day.		Authorised on 4 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Société des Produits Nestlé S.A.', Avenue Nestlé 55, 1800 Vevey, Switzerland. During the period of data protection, the iron milk caseinate is authorised for placing on the market within the Union only by 'Société des Produits Nestlé 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 'Société des Produits Nestlé S.A.'. End date of the data protection: 4 June 2028.
	Milk and dairy powder products	500 mg/100 g (≤ 10 mg Fe/100 g)			
	Soft-drinks marketed in relation to physical exercise	85 mg/100 g (≤ 1,7 mg Fe/100 g)			
	Powder cocoa beverage preparations	400 mg/100 g (≤ 8 mg Fe/100 g)			
	Powder or liquid malt-based coffee substitutes	1 050 mg/100 g (≤ 21 mg Fe/100 g)			
	Cereal bars	350 mg/100 g (≤ 7 mg Fe/100 g)			
	Noodles other than glass noodles	75 mg/100 g (≤ 1,5 mg Fe/100 g)			
	Stock cubes or granulates (bouillon base)	4 750 mg/100 g (≤ 95 mg Fe/100 g)			
	Single meal replacements for weight control	120 mg/100 g (≤ 2,4 mg Fe/100 g)			
	Total diet replacement for weight control as defined under Regulation (EU) No 609/2013	235 mg/meal (≤ 4,7 mg Fe/meal) or 700 mg/day (≤ 14,0 mg/Fe/day)			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	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, for the adult population	700 mg/day (≤ 14 mg Fe/day)			
	Food supplements as defined in Directive 2002/46/EC, for children and adolescents under 18 years of age, excluding infants and young children	350 mg/day (≤ 7 mg Fe/day)			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Isomalto-oligos-accharide	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Isom-altooligosaccharide'. 2. Foods containing the novel ingredient must be labelled as 'a source of glucose'.		
	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 %			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Isomaltulose	Not specified		1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Isomaltulose'. 2. The designation of the novel food on the labelling shall be accompanied by indication that the 'Isomaltulose is a source of glucose and fructose'.		

▼M138

Isomaltulose powder	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'isomaltulose powder'. 2. The designation of the novel food on the labelling shall be accompanied by indication that the 'Isomaltulose is a source of glucose and fructose'.		
	All foods, excluding foods and drinks intended specifically for infants and young children				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M90					
***Jatropha curcas* L. (edible variety) kernels**	*Specified food category*	*Maximum levels (g/100g)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'kernels from edible *Jatropha curcas* L.'		Authorised on 12 July 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'JatroSolutions GmbH', Echterdinger Strasse 30, 70599 Stuttgart, Germany. During the period of data protection, the novel food kernels from the edible variety of *Jatropha curcas* L. is authorised for placing on the market within the Union only by 'JatroSolutions GmbH', 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 'JatroSolutions GmbH'. End date of the data protection: 12 July 2027.
	Kernels as such, candied or sugar preserved and as processed nuts				
	Cereal bars	5			
	Breakfast cereals	5			
	Dried fruits	5			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M130					
Lactitol	*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 intended for the adult population	20 g/day			
▼M144					
Lacto-*N*-fucopentaose I and 2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture (produced using a derivative strain of *E. coli* K-12 DH1)	Specified food category	Maximum levels (expressed as Lacto-N-fucopentaose I and 2'-Fucosyllactose mixture)	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture'. The labelling of food supplements containing Lacto-*N*-fucopentaose I and 2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture produced by a derivative strain of *E. coli* K-12 DH1 shall bear a statement that: (a) they should not be consumed by children under 3 years of age; (b) they should not be used, if other foods containing added Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture and/or foods containing added 2'-Fucosyllactose are consumed on the same day.		Authorised on 19.8.2024. 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, 2970 Hørsholm, Denmark. During the period of data protection, the novel food Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture produced using a derivative strain of *E. coli* K-12 DH1 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 with Article 26 of Regulation (EU) 2015/2283 or with the agreement of 'Glycom A/S'. End date of the data protection: 19.8.2029.
	Infant formula as defined under Regulation (EU) No 609/2013	2,0 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	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1,5 g/L			
	Unflavoured fermented milk-based products	1,5 g/L (beverages)			
		3,0 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	1,5 g/L (beverages)			
		15,0 g/kg (products other than beverages)			
	Milk based drinks and similar products	1,5 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

▼M144

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Food for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher than the maximum levels specified for the proposed food categories or higher than 2,0 g/L or 2,0 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Food for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher than the maximum levels specified for the proposed food categories or higher than 4,5 g/day 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 under Regulation (EU) No 609/2013	3,0 g/L (beverages)			
		4,5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	1,5 g/kg			
	Cereal bars	15,0 g/kg			
	Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	1,5 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		9,1 g/kg for products other than beverages			

▼M144

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,5 g/day			

▼M119

Lacto-*N*-neotetraose	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'lacto-*N*-neotetraose'. 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. 3. The labelling of food 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.		
	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			
	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 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			

▼M119

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			
	Processed cereal-based foods and baby foods for infants and young children as defined under 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 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Foods 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			
	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			

▼M119

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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	4,8 g/l – the maximum level refers to the products ready to use			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants	1,5 g/day for general population 0,6 g/day for young children			
▼M45 **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 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	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			

▼M45

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			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 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, excluding infants	2,0 g/day for young children, children, adolescents, and adults			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M101					
Lacto-*N*-tetraose ('LNT') (produced by derivative strains of *E. coli* BL21(DE3))	*Specified food category*	*Maximum levels (expressed as lacto-N-tetraose)*	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 (LNT) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added lacto-*N*-tetraose are consumed the same day.		Authorised on 24.1.2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Chr. Hansen A/S', Boege Allé 10-12, 2970 Hoersholm, 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 'Chr. Hansen 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 'Chr. Hansen A/S'. End date of the data protection: 24.1.2028.
	Infant formula as defined under Regulation (EU) No 609/2013	1,82 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	1,82 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	1,82 g/L or 1,82 g/kg 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	1,82 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Foods for special medical purposes for infants and young children as defined under 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 1,82 g/L or 1,82 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	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, for the general population, excluding infants and young children	4,6 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M21					
***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'		
▼M9					
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 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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			
▼M52 **Hen 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			
▼M9 **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 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.			
	Chewing gum				
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 %			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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				

▼M11

1-Methylnicotinamide chloride	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs 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		Authorised on 2 September 2018. This inclusion is based on proprietary 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 the
	Food Supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	58 mg/day			

▼M11

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					novel 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
▼M9 **(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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M133					
Monosodium salt of L-5-methyltetrahydrofolic acid	*Specified food category*	*Maximum levels (expressed as folic acid)*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Monosodium salt of L-5-methyltetrahydrofolic acid (folic acid)'. 2. The labelling of food supplements containing monosodium salt of L-5-methyltetrahydrofolic acid shall bear a statement that the food supplements should not be consumed by infants and young children (children under 3 years of age)		Authorised on 30 April 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Merck & Cie KmG, Im Laternenacker 5, 8200 Schaffhausen, Switzerland. During the period of data protection, the novel food monosodium salt of L-5-methyltetrahydrofolic acid is authorised for placing on the market within the Union only by Merck & Cie KmG, 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 Merck & Cie KmG. End date of the date protection: 30 April 2029.
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	In accordance with Directive 2002/46/EC			
	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	In accordance with Regulation (EU) No 609/2013			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Food fortified in accordance with Regulation (EC) No 1925/2006	In accordance with Regulation (EC) No 1925/2006			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M87 **Mung bean (*Vigna radiata)* protein**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'mung bean protein from *Vigna radiata*'.		Authorised on 15 May 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Eat Just, Inc., 2000 Folsom Street San Francisco, CA 94110 USA. During the period of data protection, the novel mung bean protein is authorised for placing on the market within the Union only by Eat Just, 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 Eat Just, Inc. End date of the date protection: 15 May 2027.
	Protein products	20 g/100 g			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 *Lentinula edodes*' or 'extract from Shiitake 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			
	Food supplements as defined in Directive 2002/46/EC	2,5 ml per day dose			

▼M92

Nicotinamide 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 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.
	Food supplements as defined in Directive 2002/46/EC	300 mg/day for the adult population, excluding pregnant and lactating women 230 mg/day for pregnant and lactating women			

▼M92

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Foods for special medical purposes as defined by Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	In accordance with the particular nutritional requirements of the persons for whom the products are intended	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'nicotinamide riboside chloride' 2. The labelling of foodstuffs containing the novel food shall bear a statement that those foods should only be consumed by persons above 18 years of age excluding pregnant and lactating women.		
	Total diet replacement for weight control as defined by Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	500 mg/day			
	Meal replacements for the adult population, excluding pregnant and lactating women	150 mg/meal (maximum 2 meals/day up to a maximum of 300 mg/day)			
▼M9 **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*'		

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Noni fruit puree and concentrate (*Morinda citrifolia*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of 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'		
		Fruit puree			
	Candy/confectionery	45 g/100 g			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 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.		
	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*			
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 'Noni fruit powder'		
	Food Supplements as defined in Directive 2002/46/EC	2,4 g per/day			
***Odontella aurita* microalgae**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Odontella aurita* microalgae'		
	Flavoured pasta	1,5 %			
	Fish soups	1 %			
	Marine terrines	0,5 %			
	Broth preparations	1 %			
	Crackers	1,5 %			
	Frozen breaded fish	1,5 %			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Oil enriched with phytosterols/ phytostanols	*Specified food category*	*Maximum levels of phytosterols/ phytostanols*	In accordance with Annex III.5 to Regulation (EU) No 1169/2011		
	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	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 of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/ phytostanols. 2. The amount of phytosterols/ phytostanols added to a container of beverages shall not exceed 3 g. 3. Salad dressings, mayonnaise and spicy sauces shall be packed as single portions.			
	Milk based products, such as products based on semi-skimmed and skimmed milk products, 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				
	Soya drinks				
	Salad dressings, mayonnaise and spicy sauces				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 it shall be 'Squid oil'.		
	Dairy products except milk-based beverages	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			
	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 609/2013 and meal replacements for weight control	200 mg/meal			

▼M55

Extract from *Panax notoginseng* and *Astragalus membranaceus*	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Extract from *Panax notoginseng* and *Astragalus membranaceus*' The labelling of food supplements containing extract from *Panax notoginseng* and *Astragalus membranaceus* shall bear a statement that those food supplements should not be consumed by the population under 18 years of age and by pregnant women.		Authorised on 23 December 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Food supplements as defined in Directive 2002/46/EC for the general adult population, excluding food supplements for pregnant women	35 mg/day			

▼M55

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					Applicant: NuLiv Science, 1050 W. Central Ave., Building C, Brea, CA 92821, USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by NuLiv Science, unless a subsequent applicant obtains authorisation for that 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 NuLiv Science. End date of the data protection: 23 December 2025.
▼M126 **Partially defatted chia seed (*Salvia hispanica* L.) 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 %			

▼M126

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Fruit juices as defined by Council Directive 2001/112/EC ([8]) and vegetable juices	2,5 %			
	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	2,5 %			
	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				Authorised for use in cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products on 13 November 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Functional Products Trading Arica S.A./ BENEXIA, Luis Pasteur 5850, Oficina 403, Quinto Piso. Vitacura, Santiago – Chile. During the period of data protection, partially defatted chia seed (*Salvia hispanica* L.) powder with a high fibre content for use in cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products is authorised for placing on the
	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			
	Cakes and pastries	5 g/100 g			
	Processed fruit and vegetables (including vegetable-based dishes)	10 g/100 g			
	Bread and rolls	10 g/100 g			
	Pasta based products	8 g/100 g			
	Protein products	10 g/100 g			

▼M126

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					market within the Union only by Functional Products Trading Arica S.A./ BENEXIA, unless a subsequent applicant obtains authorisation for the same 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 Functional Products Trading Arica S.A./BENEXIA. End date of the data protection: 13 November 2028.

▼M63

Partially defatted rapeseed powder from *Brassica rapa* L. and ***Brassica napus* L.**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Partially defatted Rapeseed powder'. Any foodstuff containing 'Partially defatted Rapeseed powder' from *Brassica rapa* L. and *Brassica napus* L.' shall bear a statement that this ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof. That statement shall appear in close proximity to the list of ingredients.		
	Cereal bars mixed	20 g/100 g			
	Muesli and similar breakfast cereals	20 g/100 g			
	Extruded breakfast cereal products	20 g/100 g			
	Snacks (excluding potato crisps)	15 g/100 g			
	Breads and rolls with added special ingredients (such as seeds, raisins, herbs)	7 g/100 g			
	Brown breads bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	7 g/100 g			

▼M63

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Multigrain bread and rolls	7 g/100 g			
	Meat substitutes	10 g/100 g			
	Meat balls	10 g/100 g			

▼M9

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				

▼M100

Pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Pea and rice protein fermented by Shiitake mushroom mycelia'.		Authorised on 24.1.2023. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MycoTechnology, Inc., 18250 E. 40th Avenue, Suite 50, Aurora, 80011 Colorado, United States. During the period of data protection, the novel food pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia is authorised for placing on the market within the Union only by MycoTechnology, Inc. unless a subsequent applicant obtains authorisation for the novel food
	Bakery wares, breads, rolls, croutons, pizza	5 g/100 g			
	Breakfast cereals and cereal bars	33 g/100 g			
	Fruit- and vegetable-based drinks	20 g/100 ml			
	Ready-to-mix beverage powders	93 g/100 g			
	Cocoa and chocolate confectionary	7 g/100 g			
	Dairy analogues and non-dairy meal replacements for weight control	11 g/100 g			
	Fermented milk-based products	5 g/100 g			
	Pasta-based products	15 g/100 g			
	Meat preparations and meat products	14 g/100 g			
	Soups (ready-to-eat) and soup concentrates or powders	3 g/100 g			
	Salads	26 g/100 g			
	Meat analogues	40 g/100 g			
	Milk-based drinks	1 g/100 g			
	Single meal replacements for weight control	1 g/100 g			

▼M100

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of MycoTechnology, Inc. End date of the data protection: 24.1.2028.
▼M37 **Phenylcapsaicin**	*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 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.
	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 under the age of 11 years	2,5 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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				

▼M112

Phosphated wheat starch	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated wheat starch'.		
	Baked bakery products	15 %			
	Pasta				
	Breakfast cereals				
	Cereal bars				

▼M9

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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 phosphatidylserine and phosphatidic acid	*Specified food category*	*Maximum levels of phosphatidylserine*	The designation of the novel food on the labelling of the foodstuffs containing shall be 'Soy phosphatidylserine and phosphatidic acid'	The product is not intended to be marketed to pregnant or breast-feeding women	
	Breakfast cereals	80 mg/100 g			
	Cereal bars	350 mg/100 g			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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 (EU) No 1169/2011		
	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. Salad dressings, mayonnaise and spicy sauces shall be packed as single portions			
	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				
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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) and hydrolysates thereof	Not specified		The designation of the novel 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			

▼M136

Protein concentrate from *Lemna gibba* and *Lemna minor*	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'protein concentrate from the *Lemna gibba* and *Lemna minor* plants' or 'protein concentrate from the *Lemna gibba* plant' depending on the presence of *Lemna minor*. 2. Where foods containing the novel food include an amount of vitamin K that is considered significant in accordance with point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011, the nutrition declaration shall indicate the amount of vitamin K.		Authorised on 30 April 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Cereal bars	10 g/100 g			
	Prepacked bread and rolls	1,7 g/100 g			
	Powdered drink mixes	20 g/100 g			
	Noodles	6 g/100 g			

▼M136

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Food supplements as defined in Directive 2002/46/EC for the adult population	1 g/day	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'protein concentrate from the *Lemna gibba* and *Lemna minor* plants' or 'protein concentrate from *Lemna gibba* plant' depending on the presence of *Lemna minor*. 2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by adults. 3. Where food supplements containing the novel food include an amount of vitamin K that is considered significant in accordance with point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 and Article 8 of Directive 2002/46/EC, the labelling of food supplements containing novel food shall indicate the amount of vitamin K.		Applicant: ABC Kroos BV, Drosteweg 8, 8101 NB Raalte, NETHERLANDS. During the period of data protection, the novel food protein concentrate from *Lemna gibba* and *Lemna minor* is authorised for placing on the market within the Union only by ABC Kroos 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 ABC Kroos BV. End date of the date protection: 30 April 2029.
▼M143 **Protein extract from pig kidneys**	*Specified food category*	*Maximum levels*			
	Food supplements as defined in Directive 2002/46/EC	12,6 mg protein extract from pig kidney/day containing 0,9 mg/day diamine oxidase (DAO) taken in 3 doses per day, each dose containing a maximum of 0,3 mg DAO			
	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, but not higher than 12,6 mg protein extract from pig kidney/day containing 0,9 mg/day DAO			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M10					
Pyrroloquinoline quinone disodium salt	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of 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		Authorised on 2 September 2018. This inclusion is based on proprietary 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
	Food Supplements as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women	20 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
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.		
▼M17 **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 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 peptide
	Food Supplements as defined in Directive 2002/46/EC for the adult population	1 200 mg/day			

▼M17

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
					concentrate 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.
▼M59 ***Trans*-resveratrol**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the food supplements containing it shall be '*Trans*-resveratrol'. 2. The labelling of food supplements containing *trans*-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.		
	Food supplements as defined in Directive 2002/46/EC for the adult population	150 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Trans-resveratrol (microbial source)	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the food supplements containing it shall be '*Trans*-resveratrol'. 2. The labelling of food supplements containing trans-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.		
	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*)			
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 the foodstuffs containing it shall be 'Sacha inchi oil (Plukenetia volubilis)'		
	As for linseed oil	In line with normal food use of linseed oil			
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 by children.		
	Bakery products and confectionary				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M93					
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 the 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 products intended for young children	200 mg/100 g			
	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)				
	Breakfast cereals	500 mg/100 g			
	Cooking fats	360 mg/100 g			

▼M93

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			
	Fish analogues	300 mg/100 g			
	Meat analogues	300 mg/100 g			

▼M27

***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			

▼M27

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g			
	Fruit/vegetable puree	100 mg/100 g			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M148					
***Schizochytrium* sp. (CABIO-A-2) 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.'.		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
▼M71					
Schizochytrium 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 shall be 'Oil from the microalgae *Schizochytrium* sp.'. The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil shall bear a statement that they should not be consumed by infants and children under 3 years of age.		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Food supplements as defined in Directive 2002/46/EC for the general population above 3 years of age	1 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M25					
***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 for young children	200 mg/100 g			
	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				

▼M25

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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, 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			
	Fruit/vegetable puree	100 mg/100 g			
▼M52					
***Schizochytrium* 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			

▼M52

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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/100g			

▼M52

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M65					
***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 shall be 'Oil from the microalgae *Schizochytrium* sp.'		Authorised on 16 May 2021. 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. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Progress Biotech bv unless a subsequent applicant obtains authorisation for that 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. End date of the data protection: 16 May 2026 (5 years).
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M145					
***Schizochytrium limacinum* (TKD-1) 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 limacinum*'.		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
▼M142					
Seeds and seed flour of *Vigna subterranea* (L.) Verdc. (traditional food from a third country)	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Bambara (*Vigna subterranea)* seeds/nut/bean/groundnut' or 'Bambara (*Vigna subterranean)* seed/nut/bean/groundnut flour' depending on the form used. 2. The labelling of the foodstuffs containing the traditional food shall bear a statement that the seeds and the seed flour of *Vigna subterranea* may cause allergic reactions to consumers with known allergies to peanuts and soybeans. This statement shall appear in close proximity to the list of ingredients or, in the absence of a list of ingredients, in close proximity to the name of the food. 3. When the seeds are sold uncooked, the labelling shall bear a statement that they should be soaked and boiled before consumption.		
	Not specified				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M57 **Selenium-containing yeast (*Yarrowia lipolytica*) biomass**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'selenium-containing yeast (*Yarrowia lipolytica*) biomass'. The labelling of food supplements containing selenium-containing yeast (*Yarrowia lipolytica*) biomass shall bear a statement that the food supplements should not be consumed by infants and children under 4 years of age/children under 7 years of age/children under 11 years of age/children and adolescents under 18 years of age ([12]).		
	Food supplements as defined in Directive 2002/46/EC ([3]), excluding food supplements for infants and children under 4 years of age	50 mg/day for children from 4 to 6 years of age, resulting in 10 µg of selenium per day 100 mg/day for children from 7 to 10 years of age, resulting in 20 µg of selenium per day 500 mg/day for adolescents from 11 to 17 years of age, resulting in 100 µg of selenium per day 800 mg/day for adults, resulting in 160 µg of selenium per day			
▼M61 ▼M62 **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 shall be '3'-Sialyllactose sodium salt'. The labelling of food supplements containing 3'-Sialyllactose sodium salt shall 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		Authorised on 18 February 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L			
	Unflavoured fermented milk-based products	0,25 g/L (beverages)			
		0,5 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	0,25 g/L (beverages)			
		2,5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0,25 g/L			
	Cereal bars	2,5 g/kg			

▼M62

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			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 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 with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. End date of the data protection: 18 February 2026.
	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 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 foods for weight control as defined in Regulation (EU) No 609/2013	0,5 g/L (beverages)			
		5 g/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 Directive 2002/46/EC, excluding food supplements for infants and young children	0,5 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M122					
3′-Sialyllactose (‘3′-SL’) sodium salt (produced by derivative strains of *E. coli* BL21(DE3))	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘3′-Sialyllactose sodium salt’. The labelling of food supplements containing 3′-Sialyllactose (3′-SL) sodium salt shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3′-sialyllactose sodium salt are consumed the same day.		Authorised on 6 February 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: ‘Chr. Hansen A/S’, Boege Allé 10-12, 2970 Hoersholm, Denmark. During the period of data protection, the novel food 3′-Sialyllactose sodium salt is authorised for placing on the market within the Union only by Chr. Hansen 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 ‘Chr. Hansen A/S’. End date of the data protection: 6 February 2028.
	Infant formula as defined under Regulation (EU) No 609/2013	0,28 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	0,28 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	0,28 g/L or 0,28 g/kg 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	0,28 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

▼M122

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Foods for special medical purposes for infants and young children as defined under 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 0,28 g/L or 0,28 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	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, for the general population, excluding infants and young children	0,7 g/day			
▼M135					
3′-Sialyllactose (3′-SL) sodium salt	*Specified food category*	*Maximum levels (expressed as 3′-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '3′-Sialyllactose sodium salt'. The labelling of food supplements containing 3′-Sialyllactose (3′-SL) sodium salt shall bear a statement that they should not be consumed: (a) if foods containing added 3′-Sialyllactose sodium salt are consumed on the same day; (b) by children under 3 years of age.		Authorised on 30 April 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Kyowa Hakko Bio Co., Ltd, Nakano Central Park South, Nakano 4-10-2, Nakano-ku Tokyo, 164-0001 Japan. During the period of data protection, the novel food 3′-sialyllactose sodium salt
(produced using a derivative strain of *E. coli* W (ATCC 9637))	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L			
	Unflavoured fermented milk-based products	0,25 g/L (beverages)			
		0,5 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	0,25 g/L (beverages)			
		2,5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0,25 g/L			

▼M135

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Cereal bars	2,5 g/kg			produced using a derivative strain of E. coli W (ATCC 9637) is authorised for placing on the market within the Union only by Kyowa Hakko Bio Co., 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 Kyowa Hakko Bio Co., Ltd. End date of the data protection: 30 April 2029.
	Infant formula as defined under 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 under 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 under 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 for products other than beverages			
	Milk based drinks and similar products	0,15 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 under Regulation (EU) No 609/2013	0,5 g/L (beverages)			
		5,0 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 Directive 2002/46/EC, excluding food supplements for infants and young children	1,0 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M60					
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 shall be '6'-Sialyllactose sodium salt'. The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt shall 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		Authorised on 17 February 2021. 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 6'-sialyllactose sodium salt 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 with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. End date of the data protection: 17 February 2026.
	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 under 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 under 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 under 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 for products other than beverages			

▼M60

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 under 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 Directive 2002/46/EC, excluding food supplements for infants and young children	1,0 g/day			
▼M115					
6'-Sialyllactose ('6′-SL') sodium salt **(produced by derivative strains of *E. coli* BL21(DE3))**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '6′-Sialyllactose sodium salt'. The labelling of food supplements containing 6′-Sialyllactose (6′-SL) sodium salt shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be consumed if other foods containing added 6′-sialyllactose sodium salt are consumed the same day.		Authorised on 4 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Chr. Hansen A/S', Bøge Allé 10-12, 2970 Hoersholm, Denmark. During the period of data protection, the novel food 6′-Sialyllactose sodium salt is authorised for placing on the market within the Union only by Chr. Hansen A/S unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data
	Infant formula as defined under Regulation (EU) No 609/2013	0,70 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	0,70 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	0,70 g/L or 0,70 g/kg 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	0,70 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

▼M115

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Foods for special medical purposes for infants and young children as defined under 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 0,70 g/L or 0,70 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of 'Chr. Hansen A/S'. End date of the data protection: 4 June 2028.
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	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, for the general population, excluding infants and young children	1,8 g/day			

▼M127

6′-Sialyllactose (6′-SL) sodium salt **(produced by derivative strain of *E. coli* W (ATCC 9637))**	*Specified food category*	*Maximum levels (expressed as 6′-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '6′-Sialyllactose sodium salt'. The labelling of food supplements containing 6′-Sialyllactose (6′-SL) sodium salt shall 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 children under 3 years of age.		Authorised on 13.11.2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Kyowa Hakko Bio Co., Ltd, 1-9-2, Otemachi, Choyoda-ku Tokyo, 100-0004, Japan. During the period of data protection, the novel food 6′-sialyllactose sodium salt produced by derivative strain of *E. coli* W (ATCC 9637) is authorised for placing on the market within
	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			

▼M127

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Infant formula as defined under 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			the Union only by Kyowa Hakko Bio Co., 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 Kyowa Hakko Bio Co., Ltd. End date of the data protection: 13.11.2028.
	Follow-on formula as defined under 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 under 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 for products other than beverages			
	Milk based drinks and similar products	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 under Regulation (EU) No 609/2013	1,0 g/L (beverages)			
		10,0 g/kg (products other than beverages)			

▼M127

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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, excluding food supplements for infants and young children	1,0 g/day			
▼M23 **Syrup from *Sorghum bicolor* (L.) Moench** **(Traditional food from a third country)**	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Sorghum (*Sorghum bicolor*) syrup'		
▼M9 **Fermented soybean extract**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fermented soybean extract'. 2. The labelling of food supplements containing fermented soybean extract shall bear a statement that persons taking medication should only consume the product under medical supervision.		
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Spermidine-rich wheat germ extract (*Triticum aestivum*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the food supplements containing it shall be 'spermidine-rich wheat germ extract'		
	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 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.		
	Not specified				
Sugar cane fibre	*Specified food category*	*Maximum levels*			
	Bread	8 %			
	Bakery goods	5 %			
	Meat and muscle products	3 %			
	Seasonings and spices	3 %			
	Grated cheeses	2 %			
	Special diet foods	5 %			
	Sauces	2 %			
	Beverages	5 %			
▼M53 **Sugars obtained from cocoa (*Theobroma cacao* L.) pulp**	Not specified		The designation of the novel food on the labelling of the foodstuffs 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.		

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Sunflower oil extract	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Sunflower oil extract'		
	Food Supplements as defined in Directive 2002/46/EC	1,1 g/day			

▼M73

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Synsepalum dulcificum dried fruits	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of food supplements containing it shall be 'dried *Synsepalum dulcificum* fruits' 2. The labelling of food supplements containing *Synsepalum dulcificum* dried fruits shall bear a statement that this food supplement should be consumed by adults only excluding pregnant and lactating women.		Authorised on 5 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Medicinal Gardens S.L. Marqués de Urquijo 47, 1° D, Office 1, Madrid, 28008, Spain. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Medicinal Gardens S.L. unless a subsequent applicant obtains authorisation for that 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 Medicinal Gardens S.L. End date of the data protection: 5 December 2026.
	Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	0,7 g/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M89					
Tetrahydrocur-cuminoids	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'tetrahydrocur-cuminoids'. The labelling of food supplements containing tetrahydrocurcuminoids shall bear a statement that a) they should be consumed by adults only, excluding pregnant and lactating women; b) they should not be consumed if other food supplements containing curcumin and/or curcuminoids are consumed on the same day.		Authorised on 11 July 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: 'Sabinsa Europe GmbH', Monzastrasse 4, 63225 Langen, Germany. During the period of data protection, the novel food tetrahydrocurcuminoids is authorised for placing on the market within the Union only by 'Sabinsa Europe GmbH' 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 'Sabinsa Europe GmbH'. End date of the data protection: 11 July 2027.
	Food Supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	140 mg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M66					
Dried *Tenebrio molitor* larva (yellow mealworm)	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Dried *Tenebrio molitor* larva (yellow mealworm)'. 2. The labelling of the foodstuffs containing dried *Tenebrio molitor* larva (yellow mealworm) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans and products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 22 June 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: SAS EAP Group, 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France. During the period of data protection, the novel food is authorised for placing on the market within the Union only by SAS EAP Group, unless a subsequent applicant obtains authorisation for that 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 SAS EAP Group. End date of the data protection: 22 June 2026.
	Dried *Tenebrio molitor* larva, whole or in powder				
	Protein products	10 g/100 g			
	Biscuits	10 g/100 g			
	Legumes-based dishes	10 g/100 g			
	Pasta-based products	10 g/100 g			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Dried *Tetraselmis chuii* microalgae	*Specified food category*	*Maximum levels*	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 microalgae *Tetraselmis chuii* shall bear the following statement: 'Contains negligible amounts of iodine'		
	Sauces	20 % or 250mg/day			
	Special salts	1 %			
	Condiment	250 mg/day			
	Food Supplements as defined in Directive 2002/46/EC	250 mg/day			
***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 beverages containing greater than 1 % D-Tagatose (as consumed) shall bear a statement 'excessive consumption may produce laxative effects'.		
	Not specified				

▼M52

Taxifolin-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			

▼M52

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 the general population, excluding infants, young children, children and adolescents younger than 14 years	100 mg/day			
	(*) When used in milk products Taxifolin-rich extract may not replace in whole or in part, any milk constituent				
▼M9 **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 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’.		
	Not specified				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M52 **UV-treated mushrooms (*Agaricus bisporus*)**	*Specified food category*	*Maximum levels of vitamin D_2*	1. The designation on the label of the novel food as such or of the foodstuffs containing it shall be 'UV-treated mushrooms (*Agaricus bisporus*)'. 2. The designation on the label of the novel food as such or of the foodstuffs containing it shall be accompanied by indication that a 'controlled light treatment was used to increase vitamin D levels' or 'UV treatment was used to increase vitamin D_2 levels'.		
	Mushrooms (*Agaricus bisporus*)	20 µg of vitamin D_2/100 g fresh weight			
▼M84 **UV-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 the foodstuffs containing it shall be 'vitamin D yeast' or 'vitamin D_2 yeast'		
	Yeast-leavened breads and rolls	5 µg/100 g			
	Yeast-leavened fine bakery wares	5 µg/100 g			
	Food supplements as defined in Directive 2002/46/EC	In accordance with Directive 2002/46/EC			
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dried yeast	1. The designation of the novel food on the labelling of the foodstuffs shall be 'vitamin D yeast' or 'vitamin D_2 yeast'.		

▼M84

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
			2. The labelling of the novel food shall bear a statement that the foodstuff is only intended for baking and that it should not be eaten raw. 3. The labelling of the novel food shall bear instructions for use for the final consumers so that a maximum concentration of 5 µg/100 g of vitamin D_2 in final home-baked products is not exceeded.		
	Dishes, incl. ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of the foodstuffs containing it shall be '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 by Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Processed cereal-based food as defined by 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			

▼M84

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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 dessert 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 replacements for weight control	5 µg/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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
UV-treated bread	*Specified food category*	*Maximum levels of vitamin D_2*	The designation on the label of the novel food shall be accompanied by 'contains vitamin D produced by UV-treatment'		
	Yeast leavened bread and rolls (without toppings)	3 µg vitamin D_2/100 g			
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'. 2. Where UV-treated milk contains an amount of vitamin D that is considered significant in 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'.		
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M51					
Vitamin D_2 mushroom powder	*Specified food category*	*Maximum levels of vitamin D_2* [11]	The designation of the novel food on the labelling of the foodstuffs 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		Authorised on 27 August 2020. This inclusion is based on proprietary 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 Regulation (EU) 2015/2283 or with the agreement of Oakshire Naturals, LP. End date of the data protection: 27 August 2025.
	Breakfast cereals	2,25 µg of vitamin D_2/100 g			
	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			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M76					
Vitamin D_2 mushroom powder	*Specified food category*	*Maximum levels of vitamin D_2*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'UV-treated mushroom powder containing vitamin D_2' 2. The labelling of food supplements containing vitamin D_2 mushroom powder shall bear a statement that they should not be consumed by infants and children under 3 years of age.		Authorised on 19 December 2021. 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. 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 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. End date of the date protection: 19 December 2026.
	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)			
	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			
	Foods for Special Medical Purposes as defined under 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 Directive 2002/46/EC excluding food supplements intended for infants and young children	15 µg of vitamin D_2/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M98					
Vitamin D_2 mushroom powder	*Specified food category*	*Maximum levels of vitamin D_2 (µg/100 g or 100 ml)*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'UV-treated mushroom powder containing vitamin D_2' 2. The labelling of food supplements containing vitamin D_2 mushroom powder shall bear a statement that they should not be consumed by infants and children under 3 years of age.		Authorised on 24 January 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Monterey Mushrooms Inc, 260 Westgate Drive Watsonville, CA 95076, the 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 Monterey Mushrooms 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 Monterey Mushrooms Inc. End date of the date protection: 24 January 2028.
	Milk analogues	1,1			
	Dairy analogues other than milks	2,2			
	Breakfast cereals and cereal bars	2,2			
	Soups	2,2			
	Dried soups	22,5			
	Whey powder	14,1			
	Fruit/vegetable juices and nectars	1,1			
	Fruit/vegetable juice powder	12,4			
	Fruit/vegetable juice concentrate (liquid)	3,4			
	Soft drinks marketed in relation to physical exercise and fermented non-alcoholic drinks (with exclusion of dairy fermented drinks)	1,1			
	Foods for Special Medical Purposes as defined under 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 but not higher than 15 µg/day			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	15 µg/day			
	Meal replacements for weight control	5 µg/meal			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	15 µg/day			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
Vitamin K_2 (menaquinone)	To be used in compliance with Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006		The designation of the novel food on the 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			
▼M78					
Wolffia arrhiza and/or *Wolffia globosa* fresh plants (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 '*Wolffia arrhiza* and *Wolffia globosa*' or '*Wolffia arrhiza*' or '*Wolffia globosa*' depending on the plant used.		
	Wolffia arrhiza and/or *Wolffia globosa* fresh plants as such				
▼M48					
Xylo-oligosaccharides	*Specified food category*	*Maximum levels* ([10])	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 ([9])	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
▼M140					
***Yarrowia lipolytica* yeast biomass**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Yarrowia lipolytica* yeast biomass'. 2. Food supplements containing the novel food should bear a statement that they should not be consumed if other foods with added *Yarrowia lipolytica* yeast biomass are consumed on the same day.		
	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			
	Meal replacements for weight control for the adult population	3 g/meal (maximum 2 meals/day up to a maximum of 6 g/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 but not in any case higher than 6 g/day			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	6 g/day			
	Unflavoured milk products	5 g/kg			
	Flavoured fermented milk products	10 g/kg			
	Cheese and cheese products; (excluding desserts)	10 g/kg			
	Nut spreads	30 g/kg			
	Processed potato products	10 g/kg			
	Cocoa and chocolate confectionary	10 g/kg			
	Grains and breakfast cereals	20 g/kg			
	Pasta based products and noodles	10 g/kg			

▼M140

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Pre-cooked or processed cereals	10 g/kg			
	Bread and rolls	6 g/kg			
	Fine bakery wares	15 g/kg			
	Heat-treated meat products	15 g/kg			
	Herbs and spices; seasonings and condiments	50 g/kg			
	Soups and broths	5 g/kg			
	Sauces	10 g/kg			
	Salads and savoury based sandwich spreads	30 g/kg			
	Yeast and yeast products	30 g/kg			
	Protein products, excluding dairy analogues and beverage whiteners	30 g/kg			
	Flavoured drinks	10 g/l			
	Coffee, coffee extracts	20 g/kg			
	Other non-alcoholic beverages	10 g/l			
	Potato-, cereal-, flour- or starch-based snacks	300 g/kg			
	Processed nuts	20 g/kg			
▼M9 **Yeast beta-glucans**	*Specified food category*	*Maximum levels of pure beta-glucans from yeast (Saccharomyces cervisiae)*	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	1,275 g/day for children older than 12 years and general adult population 0,675 g/day for children younger than 12 years			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	1,275 g/day			
	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	1,275 g/day			
	Beverages based on fruit and/or vegetable juices including concentrate and dehydrated juices	1,3 g/kg			
	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			

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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			
▼M12 **Zeaxanthin**	*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			
▼M9 **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				

▼M9

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	►M30 Data Protection ◄
	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				

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

([6]) 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).

►M33 ([7]) Maximum use levels in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer. ◄

►M47 ([8]) Council 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). ◄

►M48 ([9]) When used in milk products xylo-oligosaccharides shall not replace, in whole or in part, any milk constituent.

([10]) Maximum levels calculated on the basis of the specifications of Powder form 1. ◄

►M51 ([11]) The 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. ◄

([12]) Depending on the age group the food supplement is intended for.

([13]) Without prejudice to the requirements of Regulation (EU) No 609/2013 and Regulation (EU) 2016/127.

([14]) Not a traditional food use.

▼M74

Authorised novel food	Conditions under which the novel food may be used			Additional specific labelling requirements	Other requirements	Data protection
▼M83 **Frozen, dried and powder forms of *Acheta domesticus* (house cricket)**	*Specified food category*	*Maximum levels* (g/100g) (marketed as such or reconstituted according to the instructions)		1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Frozen *Acheta domesticus* (house cricket)', 'Dried/powdered *Acheta domesticus* (house cricket)'depending on the form used. 2. The labelling of the foodstuffs containing frozen, dried or powder forms of *Acheta domesticus* (house cricket) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, molluscs and products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 3 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Fair Insects BV, Industriestraat 3, 5107 NC Dongen, the Netherlands. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Fair Insects BV, unless a subsequent applicant obtains authorisation for that 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 Fair Insects BV. End date of the data protection: 3 March 2027.
		Frozen	Dried or powder			
	Frozen, dried, and powder forms of *Acheta domesticus*					
	Protein products other than meat analogues	40	20			
	Bread and rolls	30	10			
	Bakery wares, cereal bars, and stuffed pasta products	30	15			
	Biscuits	30	8			
	Pasta-based products (dry)	3	1			
	Soups and soup concentrates or powders	20	5			
	Processed potato products, legumes- and vegetable- based dishes, and pasta- or pizza-based products	15	5			
	Corn flour based snacks	40	20			
	Beer-like beverages, alcoholic drink mixes	1	1			
	Nuts, oilseeds and chickpeas	40	25			
	Sauces	30	10			
	Meat preparations	40	16			
	Meat analogues	80	50			
	Chocolate confectionary	30	10			
	Frozen fermented milk based products	15	5			

▼M74

Authorised novel food	Conditions under which the novel food may be used			Additional specific labelling requirements	Other requirements	Data protection
Frozen, dried and powder forms of *Locusta migratoria* (migratory locust)	**Specified food category**	**Maximum levels (g/100 g) (marketed as such or reconstituted according to the instructions)**		1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'frozen *Locusta migratoria* (migratory locust)', 'dried/ powder *Locusta migratoria* (migratory locust)', 'Whole *Locusta migratoria* (migratory locust) powder' depending on the form used. 2. The labelling of the foodstuffs containing frozen dried or powder forms of *Locusta migratoria* (migratory locust) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, molluscs and products thereof, and to mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 5.12.2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Fair Insects BV, Industriestraat 3, 5107 NC Dongen, the Netherlands. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Fair Insects BV, unless a subsequent applicant obtains authorisation for that 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 Fair Insects BV. End date of the data protection: 5.12.2026.
		Frozen	**Dried or Powder**			
	Frozen, dried and powder forms of *Locusta migratoria*					
	Processed potato products; legumes-based dishes and pasta-based products	15	5			
	Meat analogues	80	50			
	Soups and concentrated soups	15	5			
	Canned/jarred legumes and vegetables	20	15			
	Salads	15	5			
	Beer-like beverages, Alcoholic drink mixes	2	2			
	Chocolate confectionery	30	10			
	Nuts, oilseeds and chickpeas		20			
	Frozen fermented milk-based products	15	5			
	Sausages	30	10			

▼M74

Authorised novel food	Conditions under which the novel food may be used			Additional specific labelling requirements	Other requirements	Data protection
▼M78 **Frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva)**	Specified food category	Maximum levels (g/100g) (marketed as such or reconstituted according to the instructions)		1. Depending on the form used, the designation of the novel food on the labelling of the foodstuffs containing it shall be 'frozen yellow mealworm (*Tenebrio molitor* larva)', 'dried yellow mealworm (*Tenebrio molitor* larva)', or 'yellow mealworm (*Tenebrio molitor* larva) powder'. 2. The labelling of the foodstuffs containing frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans and products thereof and to dust mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 1 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Fair Insects BV, Industriestraat 3, 5107 NC Dongen, the Netherlands. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Fair Insects BV, unless a subsequent applicant obtains authorisation for that 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 Fair Insects BV. End date of the date protection: 1 March 2027.
		Frozen	Dried or powder			
	Frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva)					
	Multigrain bread and rolls; crackers and breadsticks	30	10			
	Cereal bars	30	15			
	Dried pasta based products; pasta based dishes (excluding dried puffed pasta); pizza and pizza-like dishes	15	10			
	Dried stuffed pasta based products	30	15			
	Pre-mixes (dry) for baked products	30	15			
	Sauces	30	10			
	Potato, legumes based dishes	15	10			
	Whey powder	40	20			
	Meat analogues	80	50			
	Soups and salads	20	5			
	Chips/crisps	40	20			
	Beer-like beverages; mixed alcoholic drinks; alcoholic drink mixes	1	1			
	Chocolate confectionary	30	10			
	Nuts, oilseeds and chickpeas	40	30			
	Frozen fermented milk-based products	15	5			
	Meat preparations	40	16			

▼M9

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)

▼M9

Authorised Novel Food	Specifications
	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.
▼M83 **Frozen, dried and powder forms of *Acheta domesticus* (house cricket)**	**Description/Definition:** The novel food consists of the whole, frozen, dried and powder forms of the house cricket. The term 'house cricket' refers to the adult *Acheta domesticus*, an insect species that belongs to the Gryllidae family. The novel food is intended to be marketed in three different forms, namely: (i) thermally processed and frozen whole *A. domesticus* (AD frozen); (ii) thermally processed and freeze-dried whole *A. domesticus* (AD dried), and (iii) thermally processed freeze-dried and ground whole *A. domesticus* (whole AD powder). A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the adults to discard their bowel content.
	Characteristics/Composition (AD frozen): Ash (% w/w): 0,6–1,2 Moisture (% w/w): 76–82 Crude protein (N x 6,25) (% w/w): 12–21 Digestible Carbohydrates (% w/w): 0,1–2 Fat (% w/w): 3–12 of which saturated (% w/w): 36–45
	Characteristics/Composition (AD dried or powder): Ash (% w/w): 2,9–5,1 Moisture (% w/w): ≤ 5 Crude protein (N x 6,25) (% w/w): 55–65 Digestible Carbohydrates (% w/w): 1–4 Fat (% w/w): 29–35 of which saturated (% w/w): 36–45

▼M83

Authorised Novel Food	Specifications	
	Peroxide value (Meq O_2/kg fat): ≤ 5 Dietary fibre (% w/w): 0,8–3 ([18])Chitin (% w/w): 0,7–3,0 **Heavy metals:** Lead: ≤ 0,05 mg/kg Cadmium: ≤ 0,06 mg/kg **Mycotoxins:** Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1 (µg/kg): ≤ 2 Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg **Dioxins and dioxin like PCBs** Sum of dioxins and dioxin-like PCBs UB, ([19])WHO_{2005} PCDD/F-PCB-TEQ): ≤ 1,25 pg/g fat **Microbiological criteria:** Total aerobic colony count: ≤ 10^5 ([7])CFU/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: ≤ 50 CFU/g *Salmonella* spp.: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g Sulfite-reducing Anaerobes: ≤ 30 CFU/g *Bacillus cereus* (presumptive): ≤ 100 CFU/g Enterobacteriaceae (presumptive): < 100 CFU/g Coagulase-positive *staphylococci*: ≤ 100 CFU/g	Peroxide value (Meq O_2/kg fat): ≤ 5 Dietary fibre (% w/w): 3–6 ([18])Chitin (% w/w): 5,3-10,0 **Heavy metals:** Lead: ≤ 0,05 mg/kg Cadmium: ≤ 0,06 mg/kg **Mycotoxins:** Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1 (µg/kg): ≤ 2 Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg **Dioxins and dioxin like PCBs** Sum of dioxins and dioxin-like PCBs UB, ([19])WHO_{2005} PCDD/F-PCB-TEQ): ≤ 1,25 pg/g fat **Microbiological criteria:** Total aerobic colony count: ≤ 10^5 CFU/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: ≤ 50 CFU/g *Salmonella* spp.: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g Sulfite-reducing Anaerobes: ≤ 30 CFU/g *Bacillus cereus* (presumptive): ≤ 100 CFU/g Enterobacteriaceae (presumptive): < 100 CFU/g Coagulase-positive *staphylococci*: ≤ 100 CFU/g

▼M9

Authorised Novel Food	Specifications
▼M99	
***Acheta domesticus* (house cricket) partially defatted powder**	**Description/Definition**: The novel food is partially defatted powder obtained from whole *Acheta domesticus* (house cricket) following a series of steps involving a 24 hours fasting period of the insects to allow them to discard their bowel content, the sacrifice of the insects by freezing, washing, thermal processing, drying, oil extraction (mechanical extrusion), and grinding.
	Characteristics/Composition: Crude protein (N x 6,25) (% w/w): 74,0 - 78,0 Fat (% w/w): 9,0 – 12,0 Moisture (% w/w): 3,0 – 6,0 Crude fibre (% w/w): 8,0 – 10,0 Chitin ([22]) (% w/w): 4,0-8,5 Ash (% w/w): ≤ 5,6 Peroxide value (Meq O_2/kg fat): ≤ 5,0 Manganese: ≤ 100,0 mg/kg Cyanide: ≤ 5,0 mg/kg **Heavy metals**: Lead: ≤ 0,1 mg/kg Cadmium: ≤ 0,025 mg/kg **Mycotoxins**: Aflatoxins (Sum of B1, B2, G1, G2): ≤ 0,4 µg/kg Deoxynivalenol: ≤ 200,0 µg/kg Ochratoxin A: ≤ 1,0 µg/kg **Dioxins and dioxin like PCBs:** Sum of dioxins and dioxin-like PCBs UB, (([23])WHO_{2005} PCDD/F-PCB-TEF): ≤ 1,25 pg/g fat **Microbiological criteria:** Total aerobic microbial count: ≤ 10^5 CFU/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: ≤ 50 CFU/g *Salmonella* spp.: Not detected in 25 g *Listeria monocytogenes*: Not detected in 25 g *Bacillus cereus* (presumptive): ≤ 100 CFU/g Enterobacteriaceae (presumptive): < 100 CFU/g Coagulase-positive *staphylococci*: ≤ 100 CFU/g

▼M9

Authorised Novel Food	Specifications
***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.

▼M80

***Akkermansia muciniphila* (pasteurised)**	**Description:** Pasteurised *Akkermansia muciniphila* (strain ATCC BAA-835, CIP 107961) is produced by anaerobic growth of the bacteria followed by pasteurisation, concentration of the cells, cryopreservation, and freeze drying. **Characteristics/Composition:** Total *A. muciniphila* cell count (cells/g): $2,5 \times 10^{10}$ to $2,5 \times 10^{12}$ Viable *A. muciniphila* cell count (CFU/g): < 10 (LoD)(*) Water activity: ≤ 0,43 Moisture (%): ≤ 12,0 Protein (%): ≤ 35,0 Fat (%): ≤ 4,0 Crude ash (%): ≤ 21,0 Carbohydrates (%): 36,0 – 86,0 **Microbiological criteria:**Aerobic mesophilic total count: ≤ 500 CFU(**)/g Sulphite reducing anaerobes: ≤ 50 CFU/g $Coagulase^{+}$ Staphylococci: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g

▼M80

Authorised Novel Food	Specifications
	Yeast: ≤ 10 CFU/g Mould: ≤ 10 CFU/g *Bacillus cereus*: ≤ 100 CFU/g *Listeria* spp.: Absence in 25 g *Salmonella* spp.: Absence in 25 g *Escherichia coli*: Absence in 1 g (*) LoD: Limit of Detection; (**) Colony Forming Units.
▼M9 **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 %

▼M9

Authorised Novel Food	Specifications
▼M26	
***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
▼M9	
***Aloe macroclada* Baker leaf extract**	**Description/Definition:** 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 %
▼M103	
Frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm)	**Description/Definition:** The novel food consists of the frozen, paste, dried, and powder forms of the whole lesser mealworm. The term ‘lesser mealworm’ refers to the larval form of *Alphitobius diaperinus*, an insect species that belongs to the family of *Tenebrionidae* (darkling beetles). The entire lesser mealworms are meant for human consumption, no parts are removed. The novel food is intended to be marketed in 4 different forms, namely: (i) whole blanched and frozen *A. diaperinus* larvae (ADL frozen), (ii) paste from whole blanched, ground, and frozen *A. diaperinus* larvae (ADL paste), (iii) whole blanched, and freeze-dried *A. diaperinus* larvae (ADL dried), and (iv) powder from whole blanched, freeze-dried and ground *A. diaperinus* larvae (ADL powder). A minimum 24 hours fasting period is required to allow the larvae to discard their bowel content before killing the insects by a thermal treatment.

▼M103

Authorised Novel Food	Specifications	
	Characteristics/Composition (ADL frozen or paste): Ash (% w/w): ≤ 1,5 Moisture (% w/w): 65-80 Crude protein (N × 6,25) (% w/w): 12-25 Digestible Carbohydrates (% w/w): 0,4-2 Fat (% w/w): 5-12 Peroxide value (Meq O_2/kg fat): ≤ 0,2 Dietary fibre (% w/w): 1-4 ([27]) Chitin (% w/w): 1,0-2,6 **Heavy metals:** Lead: ≤ 0,1 mg/kg Cadmium: ≤ 0,05 mg/kg **Mycotoxins:** Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1 (µg/kg): ≤ 2 Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg **Microbiological criteria:** Total aerobic colony count: ≤ 10^5 ([25]) CFU/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: ≤ 50 CFU/g *Salmonella* spp.: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g Sulphite-reducing Anaerobes: ≤ 30 CFU/g *Bacillus cereus*: ≤ 100 CFU/g Enterobacteriaceae: ≤ 100 CFU/g Coagulase-positive *staphylococci*: ≤ 100 CFU/g	**Characteristics/Composition (ADL dried or powder):** Ash (% w/w): ≤ 5 Moisture (% w/w): 1-5 Crude protein (N × 6,25) (% w/w): 50-70 Digestible Carbohydrates (% w/w): 1,5-3,5 Fat (% w/w): 20-35 Peroxide value (Meq O_2/kg fat): ≤ 5 Dietary fibre (% w/w): 3-6 ([27]) Chitin (% w/w): 3,0-9,1 **Heavy metals:** Lead: ≤ 0,1 mg/kg Cadmium: ≤ 0,05 mg/kg **Mycotoxins:** Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1 (µg/kg): ≤ 2 Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg **Microbiological criteria:** Total aerobic colony count: ≤ 10^5 CFU/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: ≤ 50 CFU/g *Salmonella* spp.: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g Sulfite-reducing Anaerobes: ≤ 30 CFU/g *Bacillus cereus*: ≤ 100 CFU/g Enterobacteriaceae: ≤ 100 CFU/g Coagulase-positive *staphylococci*: ≤ 100 CFU/g

▼M9

Authorised Novel Food	Specifications
▼M146	
Juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice')	**Description:** The novel food is a viscous yellow liquid obtained via physical means of the stems of mature *Angelica keiskei* ('Ashitaba') plants. *Angelica keiskei* is native to Japan and is called Ashitaba in Japanese, hence the reference to Ashitaba stem juice. The juice is then pasteurised, mixed with cyclodextrins at an approximate ratio of 30 % of Ashitaba stem juice to 70 % cyclodextrins, and the mixture is then sterilised, freeze-dried, and sieved. **Source:** *Angelica keiskei (*family *Apiaceae)* **Characteristics/Composition of the juice:** Chalcones (xanthoangelol +4-hydroxyderricin) (% w/v): 1,0–2,25 Carbohydrates (%): 5,0–7,5 Water (%): 90,0–95,0 Fat (% w/v): 0,1–0,3 Protein (% w/v): 0,15-0,45 Sum of angular-type dihydropyranocoumarins: ≤ 10 mg/kg Sum of furanocoumarins: ≤ 100 mg/kg **Heavy metals:** Lead: ≤ 0,1 mg/kg Arsenic: ≤ 0,3 mg/kg Mercury: ≤ 0,1 mg/kg Cadmium: ≤ 1,0 mg/kg **Microbiological criteria:** Total viable aerobic count: ≤ 1 000 CFU/g Total yeast/moulds count: ≤ 100 CFU/g *Escherichia coli*: Absence in 10 g Coliforms: ≤ 30 CFU/g *Salmonella* spp.: Absence in 25 g CFU: Colony Forming Units

▼M9

Authorised Novel Food	Specifications
▼M24 **Antarctic 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 %
▼M9 **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 %

▼M9

Authorised Novel Food	Specifications
▼M97	
***Antrodia camphorata* mycelia powder**	**Description/Definition:** The novel food is the freeze-dried mycelia of the fungus *Antrodia camphorata* (strain BCRC 39106), which has been grown by solid-state cultivation. The freeze-dried mycelia are then milled into a powder. *Antrodia camphorata* is a synonym of *Taiwanofungus camphoratus* (family: Fomitopsidaceae). **Characteristics/Composition:** Loss on drying (Moisture): < 10 % Carbohydrates: ≤ 80 g/100 g Protein: ≤ 20 g/100 g Ash: ≤ 6 g/100g Fat: ≤ 6 g/100 g Total triterpenoids: 1,0 – 10,0 g/100 g Antroquinonol: 1,0 – 20,0 mg/g **Heavy metals:** Arsenic: < 0,5 mg/kg **Microbiological criteria:** Total aerobic microbial count: ≤ 10^3 *CFU/g Total yeast and mould count: ≤ 100 CFU/g *Escherichia coli*: Not detected in 10 g *Salmonella* spp.: Not detected in 25 g *Staphylococcus aureus*: Not detected in 10 g *CFU: Colony Forming Units
▼M120	
Aqueous ethanolic extract of *Labisia pumila*	**Description/Definition:** The novel food is a hydroalcoholic extract obtained from a dried whole plant of *Labisia pumila* (Blume) Fern.-Vill. The production process of the novel food starts with washing, drying and grinding of the plant *Labisia pumila*. The ground plant material is then extracted twice with a mixture of water and ethanol (50/50 v/v). The liquid extract is then concentrated, mixed with maltodextrin (which is used as a drying aid) in a ratio of 2:1 and spray-dried.

▼M120

Authorised Novel Food	Specifications
	Characteristics/composition (including maltodextrin): Particle size: > 90 % through 120 mesh (125 μm) Ash: < 10 % Acid-insoluble ash: < 1 % Moisture: < 8 % Ethanol: < 1 % (w/w) Gallic acid: 2-10 % (w/w) Carbohydrate: 70-90 g/100 g Protein: < 9 % (w/w) Total fat: < 3 % (w/w) Saponin (as ardisiacripsin A): < 1,5 % (w/w) **Microbiological criteria:** Aerobic plate count: $< 1\times10^4$ CFU/g Yeast and mould: $< 5\times10^2$ CFU/g *E. coli*: not detected in 10 g *S.aureus*: not detected in 10 g Salmonella: not detected in 25 g *P. aeruginosa*: not detected in 10 g cfu: colony forming units w/w: weight per weight

▼M128

Apple fruit cell culture biomass	**Description/Definition:** The novel food is a biomass of cultivated and homogenised cells of the Swiss apple variety Uttwiler Spätlauber (Malus domestica Borkh.). The production process consists of collecting under sterile conditions specific sections of the apple, which are then placed on solid medium with the aim to induce the formation of a primary callus tissue comprised of dedifferentiated cells under sterile conditions. The callus cells are then cultivated in liquid medium and subsequently homogenised, heat treated and dried.

▼M128

Authorised Novel Food	Specifications
	Characteristics/composition: Moisture: 10,9–15,5 g/100 g Ash: 11,8–20,8 g/100 g Proteins: 14,3–20,0 g/100 g Fats: 0,6–2,5 g/100 g Non-digestible carbohydrates: 17,1–25,2 g/100 g Other carbohydrates (calculated ([29])): 21,9–38,9 g/100 g Total sugars: 17,1–32,6 g/100g Fructose: 10,8–20,2 g/100 g Glucose: 3,8–7,0 g/100 g Total phenols: 0,15–0,29 g/100 g Malic acid: 0,41–1,19 g/100 g Succinic acid: 0,14–0,26 g/100 g
▼M9 **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 %

▼M9

Authorised Novel Food	Specifications
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

▼M131

Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	**Description:** Astaxanthin is a carotenoid produced by *Haematococcus pluvialis* algae. Production methods for the growth of the algae are variable; using '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). **Characteristics/Composition:** Fat: 42,2-99 % Protein: ≤ 4,4 % Carbohydrate: ≤ 52,8 % Fibre: < 1,0 % Ash: ≤ 4,2 % Specification of Carotenoids % w/w Total Astaxanthins: 2,9-11,1 % 9-cis-astaxanthin: 0,3-30,0 %

▼M131

Authorised Novel Food	Specifications
	13-cis-astaxanthin: 0,2-7,0 % Astaxanthin monoesters: 66,7-91,5 % Astaxanthin diesters: 0,16-32,5 % Beta-Carotene: 0,01-0,3 % Lutein: ≤ 1,8 % Canthaxanthin: ≤ 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
▼M129 **Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)**	**Description/Definition:** The novel food is partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*), residues obtained from the solid by-product of beer production that contains 45-70 % spent barley and 30-55 % spent rice. The novel food is produced by enzymatically treating the pasteurised spent barley and rice residues of the mash step of beer production. Several mechanical treatment steps of the partial hydrolysate are employed to obtain the final product. **Characteristics/composition:** Appearance: powder Degree of hydrolysis: 1-7 % Proteins (N x 6,25): 78-90 % Moisture: 2-8 % Carbohydrates: 2-10 %

▼M129

Authorised Novel Food	Specifications
	Fat: 0-2 % Ash: 1-8 % **Heavy metals:** Arsenic (mg/kg): ≤ 0,2 Cadmium (mg/kg): ≤ 0,1 Lead (mg/kg): ≤ 0,2 Mercury (mg/kg): ≤ 0,01 **Mycotoxins:** Aflatoxin B1: ≤ 2 µg/kg Sum of aflatoxins (B1, B2, G1, G2): ≤ 4 µg/kg Deoxynivalenol: < 200 µg/kg Fumonisins (sum of B1, B2): ≤ 200 µg/kg Ochratoxin A: ≤ 3 µg/kg Zearalenone: ≤ 20 µg/kg Patulin: ≤ 50 µg/kg **Antinutritional factors:** Phytic acid: < 0,25 % **Microbiological criteria:** Total aerobic microbial count (CFU/g): < 10^4 Coliforms (CFU/g): < 100 Total yeast and mould count (CFU/g): < 100 *Salmonella* spp.: Not detected in 25 g Escherichia coli (CFU/g): < 10 Staphylococcus *aureus* (CFU/g): < 10 *Listeria monocytogenes*: Not detected in 25 g *Bacillus cereus* (CFU/g): < 100 CFU: colony forming units

▼M9

Authorised Novel Food	Specifications
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 %
▼M134 **Beta-glucan from *Euglena gracilis* microalgae**	**Description/Definition:** The novel food, beta-glucan from *Euglena gracilis* microalgae (paramylon), is a linear, unbranched beta-1,3-D-glucan polymer derived from the non-GM microalga *Euglena gracilis*. The novel food is produced by fermentation, followed by pH adjustment and homogenization to release the beta-glucan granules. The granules are isolated by decanting and washing, and subsequently, acidified and filtered. After drying, the product is milled. The process includes conditions such as an alkaline pH and heat-killing step of the microalga to ensure the absence of viable *Euglena gracilis* cells in the novel food. **Characteristics/composition:** Appearance: cream white powder Beta-glucan (^{30}): (%) ≥ 95 Moisture (%): ≤ 6 Ash (%): ≤ 1 **Heavy metals:** Lead (mg/kg): ≤ 0,5 Cadmium (mg/kg): ≤ 0,5 Mercury (mg/kg): ≤ 0,05 Arsenic (mg/kg): ≤ 0,02

▼M134

Authorised Novel Food	Specifications
	Microbiological criteria: Total aerobic microbial count (CFU/g): ≤ 3 000 Total yeast and mould count (CFU/g): ≤ 100 Coliforms (MPN/g): ≤ 30 *Escherichia coli*: Not detected in 10 g *Staphylococcus aureus*: Not detected in 10 g *Salmonella* spp.: Not detected in 25 g *Listeria monocytogenes*: Not detected in 25 g CFU: colony forming units, MPN: most probable number.
▼M33 **Betaine**	**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

▼M33

Authorised Novel Food	Specifications
	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.
▼M9 **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

▼M9

Authorised Novel Food	Specifications
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

▼M35

Bovine 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

▼M35

Authorised Novel Food	Specifications
	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

▼M96

Bovine milk beta-lactoglobulin (*β*-lactoglobulin)	**Description:** Beta-lactoglobulin (*β*-lactoglobulin) protein is a white to cream powder produced from bovine whey by a series of steps involving filtration, concentration, crystallisation, re-dissolution (in water), pH adjustment to acidic or neutral pH, re-concentration and drying. CAS number: 9045-23-2 Molecular weight: 36,7 kDa (dimer); 18,3 kDa (monomer)

▼M96

Authorised Novel Food	Specifications
	Characteristics/Composition: pH (10 % solution): 3,5-8,0 Protein (N x 6,38) (%): ≥ 86,0 Beta-lactoglobulin (% of protein): ≥ 90,0 Lactose (%): ≤ 1,0 Fat (%): ≤ 1,0 Ash (%): ≤ 5,0 Moisture (%): ≤ 5,5 **Heavy Metals**: Cadmium (mg/kg): < 0,2 Lead (mg/kg): < 0,1 Mercury (mg/kg): < 0,01 **Contaminants:** Aflatoxin M1 (µg/kg): < 0,01 **Microbiological criteria:** Total plate count: ≤ 5 000 CFU/g Total yeast/moulds count: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absent in 25 g *Bacillus cereus*: < 100 CFU/g *Listeria monocytogenes*: Absent in 25 g *Staphylococcus aureus*: < 10 CFU/g Sulfite-reducing clostridia: < 10 CFU/g CFU: Colony Forming Units; kDa: kiloDaltons
▼M107 **Bovine milk osteopontin**	**Description** Bovine milk osteopontin is isolated from pasteurised or microfiltered bovine whey or milk by ion exchange chromatography, ultrafiltration to remove low molecular weight components and spray drying. During this filtration steps lactose and whey proteins predominantly alpha-lactalbumin and beta lactoglobulin are removed. **Characteristics/Composition** Protein % as is (N × 6,38): 76,5–80,5 Bovine milk osteopontin (bmOPN) (% of protein): ≥ 84,5

▼M107

Authorised Novel Food	Specifications
	Full-length bmOPN (MW 33,9 kDa) (% of bmOPN): ≥ 15 N-terminal fragment bmOPN (MW 19,8 kDa) (% of bmOPN): ≥ 70 Other milk protein (% of protein): ≤ 14,5 Moisture: < 9,5 % Lactose: ≤ 1,0 % Fat: ≤ 1,0 % Ash: ≤ 11 % Insolubility index (mL) ≤ 1,0 **Heavy metals** Lead: < 0,05 mg/kg Cadmium: < 0,05 mg/kg Mercury: < 0,05 mg/kg Arsenic: < 0,5 mg/kg Aflatoxin M1 < 0,1 µg/kg **Microbiological criteria** Total plate count (30 °C) (CFU/g): ≤ 5 000 Mould/yeast (CFU/g): ≤ 100 *Bacillus cereus* (CFU/g): < 50 Sulfur-reducing Clostridia (CFU/g): < 10 *Staphylococcus aureus*: Not detected in 1 g Enterobacteriaceae (CFU/g): < 10 *Salmonella* spp.: Not detected in 25 g CFU: Colony Forming Units

▼M9

***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

▼M9

Authorised Novel Food	Specifications
	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
▼M91	
***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 % Astaxanthin esters: ≤ 0,25 % Peroxide value (PV): < 3,0 meq. O_2/kg
▼M77	
Calcium fructoborate	*Description/Definition* The novel food is calcium fructoborate, a calcium salt tetrahydrate of a bis(fructose) ester of boric acid in the form of a powder, represented by Ca[(C6H10O6)2B]2•4H2O, with a molecular mass of 846 Da.

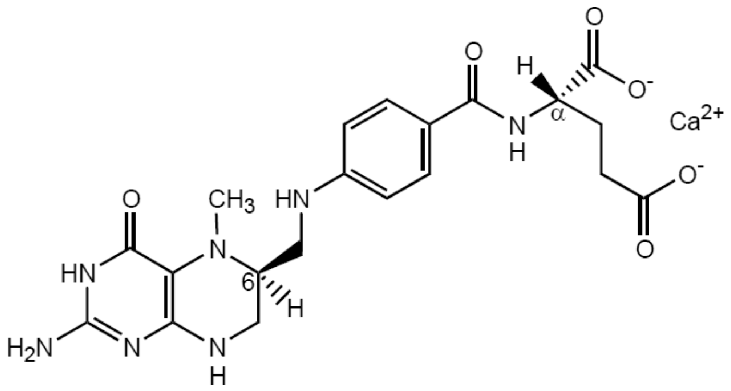
▼M77

Authorised Novel Food	Specifications
	The novel food is produced by chemical synthesis whereby fructose is combined with boric acid in water to produce a bis(fructose) ester of boric acid through various heating and mixing processes. Calcium carbonate is then added to produce a solution containing the calcium salt of fructoborate (tetrahydrate). The solution is freeze-dried, ground to produce the final powdered product, and then packaged and stored under representative storage conditions (22 ± 1°C RH 55-60 %). *Characteristics/composition* Free moisture: < 5,0 % Calcium: 4,5-5 % Boron: 2,5-2,9 % Fructose: 80-85 % Ash: 15-16 % *Heavy metals* Arsenic: ≤ 1 mg/kg *Microbiological criteria* Total plate count: ≤ 1 000 CFU/g [(a)] Yeast and mould: < 100 CFU/g Coliforms: ≤ 10 CFU/g *Escherichia coli*: < 10 CFU/g *Salmonella* spp.: Absence in 25 g Coagulase-positive staphylococci: Absence in 1 g (a) CFU: colony forming units

▼M85

Calcium L-Methylfolate	**Description:** The novel food is produced by chemical synthesis starting from folic acid. It is a white to light yellowish, almost odourless, crystalline powder, sparingly soluble in water and very slightly soluble or insoluble in most organic solvents. **Definition:** Chemical formula: $C_{20}H_{23}CaN_7O_6$

▼M85

Authorised Novel Food	Specifications
	Systematic 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, calcium salt. CAS Numbers: 129025-21-4 (Calcium salt with an unspecified ratio of L-5-MTHF/Ca^{2+}) and 151533-22-1 (Calcium salt with specified 1:1 ratio of L-5-MTHF/Ca^{2+}). Molecular weight: 497,5 Daltons Synonyms: L-methylfolate, calcium; L-5-methyltetrahydrofolic acid, calcium salt [(L-5-MTHF-Ca)]; (6S)-5-methyltetrahydrofolic acid, calcium salt [(6S)-5-MTHF-Ca]; (6S)-5-methyl-5,6,7,8-tetrahydropteroyl-L-glutamic acid, calcium salt, and L-5-methyl-tetrahydrofolic acid (L-5-MTHF) without the cation specified. Structural formula:  **Characteristics** Purity: > 95 % (Dry basis) Water: ≤ 17,0 % Calcium (on anhydrous and solvent free basis): 7,0 – 8,5 % Calcium D-methylfolate (6R, αS isomer): ≤ 1,0 % Other folates and related substances: ≤ 2,5 % Ethanol: ≤ 0,5 % **Contaminants** CFU: colony forming units

▼M85

Authorised Novel Food	Specifications	
	Infants and young children	General population excluding infants and young children
	Lead: ≤ 1 mg/kg	Lead: ≤ 1 mg/kg
	Boron: ≤ 10 mg/kg	Boron: ≤ 10 mg/kg
	Cadmium ≤ 0,5 mg/kg	Cadmium ≤ 0,5 mg/kg
	Mercury ≤ 1,0 mg/kg	Mercury ≤ 1,5 mg/kg
	Arsenic ≤ 1,5 mg/kg	Arsenic ≤ 1,5 mg/kg
	Platinum ≤ 2 mg/kg	Platinum ≤ 10 mg/kg
	Microbiological criteria: Total viable aerobic counts: ≤ 1 000 CFU/g Total yeast and mould count: ≤ 100 CFU/g	

▼M137

Calcidiol monohydrate	**Description/Definition:** The novel food is calcidiol monohydrate (25-hydroxycholecalciferol monohydrate). The novel food contains the monohydrate form of the major circulating metabolite of vitamin D_3 in the body and is a source of 1,25-dihydroxyvitamin D, the biologically active form of vitamin D. Conversion factor: 1 µg calcidiol = 2,5 µg vitamin D_3 for doses up to 10 µg/day. The production process of the novel food starts with a yeast fermentation which results in a mixture of sterols, with trienol being the major sterol obtained. After the fermentation, purification and several chemical steps follow. The chemical steps include saponification and extraction, where the trienol is isolated from the biomass. This is followed by a hydroxylation step to separate the trienol from the other sterols. Trienol is then epoxidised and subsequently reduced to give 25-hydroxydehydrocholesterol. A photoreaction follows, to obtain a mixture of 25-hydroxy-previtamin D_3, 25-hydroxy-tachysterol and 25-hydroxy-lumisterol. Thereafter, the 25-hydroxy-previtamin D_3 is thermally isomerised to '"Calcidiol"' and recrystallized to obtain the novel food of the required purity. The novel food is intended to be placed on the market as a diluted form '"0,25 % w/w"', containing 0,250-0,275 % w/w of calcidiol (anhydrous). The novel food needs to be placed on the market in a preparation guaranteeing its stability. Chemical name according to IUPAC: (1S,3Z)-3-[(*2E*)-2-[(1R,3αS,7αR)-1-[(*2R*)-6-hydroxy-6-methylheptan-2-yl]-7α-methyl-2,3,3α,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidene-cyclohexan-1-ol; hydrate CAS Number: 63283-36-3 (Calcifediol monohydrate) Empirical formula: $C_{27}H_{44}O_2.H_2O$ Molecular weight: 418,7 g/mol

▼M137

Authorised Novel Food	Specifications
	Characteristics/composition: $25(OH)D_3.H_2O$: 97,0-100 % Total related substances: ≤ 1,5 %, of which: Δ^{22}-$25(OH)D_3$: ≤ 0,5 %; Lumisterol ([31]): ≤ 0,5 %; pre-$25(OH)D_3$ ([32]): ≤ 0,5 %; Tachysterol ([33]): ≤ 0,5 %; trans-Vitamin D_3 ([34]): ≤ 0,5 % Other impurities: ≤ 0,10 % Water content: 3,8-5,0 % Acetone: ≤ 1 000 mg/kg Isopropanol: ≤ 10 mg/kg **Heavy metals:** Arsenic: ≤ 1 mg/kg
▼M106 **Dried nuts of *Canarium ovatum* Engl.**	**Description/Definition:** The traditional food consists of the unroasted dried nuts of *Canarium ovatum* Engl. (family: Burseraceae) commonly known as Pili nuts. Pili nuts are produced only by plants of *Canarium ovatum* Engl. varieties Laysa, Magnaye, M. Orolfo, Lanuza and Magayon and can be placed on the market with or without the shell. The edible part of the nut is the kernel. **Typical composition range:** Fat: 57-73 % Protein: 11-15 % Water: 1-5 % Carbohydrates: 8-16,5 % Ash: 2,8-3,4 % **Microbiological criteria:** Moulds and yeasts: ≤ 100 CFU/g Total colony count at 30 °C: ≤ 10 000 CFU/g Coliforms: ≤ 100 CFU/g *Escherichia coli*: ≤ 10 CFU/g *Staphylococcus aureus*: Absence in 25 g *Salmonella* spp.: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g Sulphite reducing anaerobes: ≤ 10 CFU/g CFU: Colony Forming Units

▼M9

Authorised Novel Food	Specifications
▼M109	
***Canarium indicum* L. dried nuts (Kenari) (Traditional food from a third country)**	**Description/Definition:** The traditional food is processed dried kenari nuts. The term 'Kenari Nuts' refers to the kernels of ripe Kenari Fruit, scientifically known as *Canarium indicum* L. (or *Canarium amboinense* Hochr.; family: Burseraceae). **Composition:** Ash: ≤ 5 (g/100 g) Moisture: ≤ 6 (g/100 g) Protein: 12,8 – 14,4 g/100 g Carbohydrates: 11,0 – 16,4 g/100 g Fat: 59,3 – 66,3 g/100 g Dietary fibre: 4,4 – 9,8 g/100 g **Microbiological criteria:** Aerobic Plate Count: ≤ $5{,}0 \times 10^3$ CFU/g Coliforms: < 3 MPN/g E. coli: < 3 MPN/g Yeasts and moulds: < 10 CFU/g *Salmonella*: Absent in 25 g *Staphylococcus aureus* (absent/25 g) *Listeria monocytogenes* (absent/25 g) *Aflatoxins* Aflatoxins B1: ≤ 2 mcg/kg Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 mcg/kg *Dioxins and dioxin like PCBs* Sum of dioxins: ≤ 0,75 pg/g fat Sum of dioxins and dioxin-like PCBs: ≤ 1,5 pg/g fat *Heavy metals* Cadmium (Cd): ≤ 0,02 mg/kg Lead (Pb): ≤ 0,07 mg/kg CFU: Colony Forming Units

▼M9

Authorised Novel Food	Specifications
▼M114	
Cellobiose	**Description/Definition:** Cellobiose is a disaccharide with two glucose monomers linked by a β-(1–4) glucosidic bond, that is produced from sucrose and glucose in a two-step enzymatic reaction, followed by a series of purification steps. **Characteristics/composition:** Cellobiose DM (%): ≥ 99 Moisture (%): < 1 Other identified sugars (%): ≤ 1 Optical rotation $[\alpha]_D$ (c 10, water): +33–36 Ash (g/100 g): < 0,1 Protein content (g/100 g): < 0,01 **Heavy metals:** Arsenic: < 0,1 mg/kg **Microbiological criteria:** Total aerobic count (cfu/g): ≤ 1 000 Yeast and moulds (cfu/g): ≤ 100 Salmonella (in 25 g): n.d. Coliforms (cfu/g): ≤ 10 *E. coli* (in 10 g): n.d. cfu: colony forming units n.d.: not detected

▼M9

Authorised Novel Food	Specifications
▼M82 **Cetylated fatty acids**	**Description/Definition:** The novel food concerns primarily a mixture of cetylated myristic acid and cetylated oleic acid synthesised from cetyl alcohol, myristic acid and oleic acid, and to a lesser degree, other cetylated fatty acids and other compounds from olive oil. **Characteristics/composition:** Ester content: 70-80 %, of which: Cetyl oleate: 22-30 %, Cetyl myristate: 41-56 % Triglycerides: 22-25 % Acid value (mg KOH/g): ≤ 5 Saponification value (mg KOH/g): 130-150 **Microbiological criteria:** Total aerobic microbial count: ≤ 1 000 CFU/g Yeasts and moulds: ≤ 100 CFU/g KOH: potassium hydroxide CFU: colony forming units
▼M9 **Chewing gum base (monomethoxypolyethylene glycol)**	**Description/Definition:** The novel food ingredient is a synthetic polymer (Patent number 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

▼M9

Authorised Novel Food	Specifications
	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 anhydride copolymer)	**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 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

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
	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 *Aspergillus niger*	**Description/Definition:** 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 %

▼M9

Authorised Novel Food	Specifications
	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 (*Agaricus bisporus*; *Aspergillus niger*)	**Description/Definition:** 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

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
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 %

▼M56

Chromium-containing yeast (*Yarrowia lipolytica*) biomass	**Description/Definition:** The novel food is the dried and heat-killed chromium-containing biomass of the yeast *Yarrowia lipolytica*. The novel food is produced by fermentation in the presence of chromium chloride followed by a number of purification steps and a heat-killing step of the yeast to ensure the absence of viable *Yarrowia lipolytica* cells in the novel food. **Characteristics/Composition:** Total chromium: 18–23 µg/g Chromium (VI): < 10 µg/kg (i.e. limit of detection) Protein: 40–50 g/100 g Dietary fibre: 24–32 g/100 g Sugars: < 2 g/100 g Fat: 6–12 g/100 g Total ash: ≤ 15 % Water: ≤ 5 % Dry matter: ≥ 95 % **Heavy metals:** Lead: ≤ 3,0 mg/kg Cadmium: ≤ 1,0 mg/kg Mercury: ≤ 0,1 mg/kg

▼M56

Authorised Novel Food	Specifications
	Microbiological criteria: Total aerobic microbial count: ≤ 5×10^3 CFU/g Total yeast and mould count: ≤ 10^2 CFU/g Viable *Yarrowia lipolytica* cells ([14]): < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g CFU: colony forming units
▼M85 ***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. The novel food consists of the dried and cut aerial parts (young shoots with woody parts) of *Cistus incanus* L. Pandalis
▼M9 **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

▼M9

Authorised Novel Food	Specifications
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

▼M79

Coffea arabica L. and/or *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion (Traditional food from a third country)	**Description/Definition:** The traditional food consists of the dried unroasted coffee cherry pulp of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner (genus: *Coffea* family: Rubiaceae) and its infusion. The infusion can be used as such or concentrated or dried. Ripe coffee cherries are collected, and then the coffee beans are mechanically removed, prior or after a drying process, leaving the dried coffee cherry pulp, which can be milled to a powder. The separated coffee cherry pulp is also known as ‘cascara’, from the Spanish ‘cáscara’, meaning ‘husk’. Typically, the infusion is prepared by mixing up to 6 g of cascara pulp or husk in 100 ml of hot water (> 75 °C) for a few minutes and then pouring through a strainer, or using corresponding amounts in dried or instant infusions. **Composition of the dried coffee cherry pulp:** Water: < 18 % Water activity (a_w): ≤ 0,65 Ash: < 10,4 % DM Protein: < 15 % DM Fat: < 5 % DM Carbohydrates: < 85 % DM **Microbiological criteria:** Aerobic Plate Count: < 10^4 CFU/g Total yeasts and moulds: < 100 CFU/g Enterobacteriaceae: < 50 CFU/g *Salmonella*: Absence in 25 g *Bacillus cereus*: < 100 CFU/g

▼M79

Authorised Novel Food	Specifications
	Mycotoxins: Ochratoxin A: < 5,0 µg/kg Aflatoxin B1: < 2,0 µg/kg Aflatoxin B1, B2, G1, G2 (as sum): < 4,0 µg/kg **Heavy metals:** Cadmium (Cd): < 0,05 mg/kg Lead (Pb): < 1,0 mg/kg Copper: ≤ 50 mg/kg Mercury: ≤ 0,02 mg/kg Arsenic: ≤ 0,2 mg/kg **Impurities:** Benzo(a)pyrene: < 10,0 µg/kg Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: < 50,0 µg/kg **Pesticides:** Pesticide levels in the traditional food shall comply with levels set by Regulation (EC) No 396/2005 for '0639000' for 'Herbal infusions from any other parts of the plant'. CFU: Colony Forming Units DM: Dry Matter
▼M30 **D-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

▼M30

Authorised Novel Food	Specifications
	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 ([8]) 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 ([9])/g Yeast: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Coliforms: ≤ 10 CFU/g *Salmonella* sp: Negative/25 g

▼M9

Authorised Novel Food	Specifications
▼M54	
Dried *Euglena gracilis*	**Description/Definition:** The novel food is dried whole cell Euglena, which is the dried biomass of the microalga *Euglena gracilis*. The novel food is produced by fermentation followed by filtration and a heat-killing step of the microalga to ensure the absence of viable *Euglena gracilis* cells in the novel food. **Characteristics/Composition:** Total carbohydrates: ≤ 75 % β-glucan: > 50 % Protein: ≥ 15 % Fat: ≤ 15 % Ash: ≤ 10 % Moisture: ≤ 6 % **Heavy metals:** Lead: ≤ 0,5 mg/kg Cadmium: ≤ 0,5 mg/kg Mercury: ≤ 0,05 mg/kg Arsenic: ≤ 0,02 mg/kg **Microbiological criteria:** Aerobic plate count: ≤ 10 000 CFU/g Coliforms: ≤ 100 MPN/g Yeast and mould: ≤ 500 CFU/g *Escherichia coli*: Absence in 10 g *Staphylococcus aureus*: Absence in 10 g *Salmonella*: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g CFU: colony forming units. MPN: most probable number

▼M9

Authorised Novel Food	Specifications
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 %
▼M70 Coriander 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. Yellowish to brown colour, bland taste CAS No.: 8008-52-4 Composition of fatty acids: Palmitic acid (C16:0): 2-5 %

▼M70

Authorised Novel Food	Specifications
	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: ≤ 4 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
▼M15	
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 ([3]) ([5]): 55.0-60.0 or
	— BL-DMAC method ([4]) ([5]): 15.0-18.0
	Total phenolics (GAE ([6]), % w/w dry weight) ([5])
	— Folin-Ciocalteau method: > 46.2
	Solubility (water): 100 %, with no visible insoluble particles

▼M15

Authorised Novel Food	Specifications
	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 ([7])/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

▼M9

***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 the

▼M9

Authorised Novel Food	Specifications
	complexant, 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: Cyclohexaamylose CAS 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

▼M9

Authorised Novel Food	Specifications
	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)

▼M9

Authorised Novel Food	Specifications
	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 %
▼M22 **Decorticated 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
▼M9 **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 %

▼M9

Authorised Novel Food	Specifications
	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 %

▼M9

Authorised Novel Food	Specifications
	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 %
▼M13 **Dried 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

▼M13

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
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.
▼M32 ***Echinacea purpurea* extract from cell cultures**	**Description/Definition:** Dried extract of *Echinacea purpurea* from cell cultures EchiPure-PC™
▼M9 ***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

▼M9

Authorised Novel Food	Specifications
▼M52	
***Ecklonia 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 CFU: Colony Forming Units

▼M9

Authorised Novel Food	Specifications

▼M18

Egg membrane hydrolysate

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

Chemical parameters	**Methods**
Total nitrogen-containing compounds (% w/w): ≥ 88	Combustion according to AOAC 990.03 and AOAC 992.15
Collagen (% w/w): ≥ 15	Sircol™ Soluble Collagen Assay
Elastin (% w/w): ≥ 20	Fastin™ Elastin Assay
Total glycosaminoglycans (% w/w): ≥ 5	USP26 (chondroitin sulphate K0032 method)
Calcium: ≤ 1 %	

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

▼M18

Authorised Novel Food	Specifications
	Yeast: ≤ 10 CFU/g Mould: ≤ 200 CFU/g CFU: Colony Forming Units; MPN = Most Probable Number; USP: United States Pharmacopeia.

▼M9

Epigallocatechin gallate as a purified extract from green tea leaves (*Camellia sinensis*)	**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 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

▼M9

Authorised Novel Food	Specifications		
	Chemical purity	≥ 99,5 %	HPLC [Eur. Ph. 2,2.29]
		≥ 99,0 %	1H-NMR
	Identification	Compliant with the structure	1H-NMR
		C: 47,14 ± 0,4 %	Elemental analysis
		H: 6,59 ± 0,4 %	
		N: 18,32 ± 0,4 %	
	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)	≤ 1 x 10^3 CFU/g	[Eur. Ph. 01/2011:50104]
	Total yeast and mould count (TYMC)	≤ 1 x 10^2 CFU/g	
	Escherichia coli	Absence in 1 g	

▼M9

Authorised Novel Food	Specifications
	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° (c = 1, H_2O) b) Analyses conducted on each batch c) Maximum levels in accordance with Regulation (EC) No 1881/2006

▼M108

Roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) (Traditional food from a third country)	**Description/Definition** The traditional food consists of the roasted and popped kernels of the seeds of the fresh plants of *Euryale ferox* Salisb. (family: Nymphaeaceae, commonly referred to also as prickly water lily) to be consumed as a snack. The traditional food is produced via a series of steps involving the collection, washing, and drying of the seeds, a first roasting in oil, tempering at ambient temperatures, a subsequent second roasting in oil to pop the kernels, followed by hitting of the hot seeds to release the popped kernels. The traditional food is also known as makhana or fox nuts. **Typical nutritional components:** Fat: 13,0 g/100 g Carbohydrates: 75,0 g/100 g Fibre: 2,5 g/100 g Protein: 7 g/100 g Moisture (% w/w): < 5,0 Ash: < 0,5 g/100 g **Microbiological criteria:** Total plate count: < 10^3 CFU/g Total yeast and mould count: < 100 CFU/g Total Enterobacteriaceae: < 10 CFU/g *Salmonella* spp.: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g **Heavy metals:** Selenium: ≤ 0,8 mg/kg Copper: ≤ 30,0 mg/kg Lead: ≤ 0,1 mg/kg Arsenic: ≤ 0,1 mg/kg

▼M108

Authorised Novel Food	Specifications
	Cadmium: ≤ 0,1 mg/kg Tin: ≤ 3,5 mg/kg Mercury: ≤ 0,025 mg/kg **Mycotoxins:** Aflatoxin B1: ≤ 2,0 µg/kg Sum of aflatoxins B1, B2, G1, and G2: ≤ 4,0 µg/kg Ochratoxin A: ≤ 1,0 µg/kg Citrinin: ≤ 20,0 µg/kg **Cyanotoxins:** Microcystins: ≤ 0,0015 mg/kg **Pesticides:** Pesticides: ≤ 0,01 mg/kg **Process contaminants:** Acrylamide: ≤ 40,0 µg/kg Sum of PAHs: ≤ 10,0 µg/kg Sum of dioxin-like PCBs: ≤ 0,35 pg/g 3-MCPD: ≤ 20,0 µg/kg Glycidyl fatty acid esters (expressed as glycidol): ≤ 500,0 µg/kg Sum of 3-MCPD and 3-MCPD fatty acid esters: ≤ 750,0 µg/kg CFU: Colony Forming Units; PAHs: Polycyclic Aromatic Hydrocarbons; PCBs: Polychlorinated Biphenyls; 3-MCPD: 3-MonoChloroPropane Diol.

▼M52

Extract 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)

▼M52

Authorised Novel Food	Specifications
	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

▼M9

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: $C_{10}H_{12}FeN_2NaO_8 * 3H_2O$

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
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

▼M42

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 [9]/g Enterobacteriaceae: ≤ 10 cfu/g *Salmonella*: Absence in 25 g

▼M9

Authorised Novel Food	Specifications

▼M74

Frozen, dried and powder forms of *Locusta migratoria* (migratory locust)

Description/Definition:

The novel food consists of the frozen, dried and powder forms of migratory locust. The term 'migratory locust' refers to the adult of *Locusta migratoria*, an insect species that belongs to the Acrididae family (subfamily Locustinae).

The novel food is intended to be marketed in three different forms, namely: (i) thermally processed and frozen *L. migratoria* (LM frozen); (ii) thermally processed and freeze-dried *L. migratoria* (LM dried), and (iii) thermally processed freeze-dried and ground whole *L. migratoria* (whole LM powder). The LM dried may be marketed as such or in powder.

For LM frozen and LM dried, legs and wings must be removed to reduce the risk of intestinal constipation that could be possibly caused by ingestion of the large spines on the insect tibia. The whole LM powder is obtained via mechanical grinding of the insect with legs and wings, and sieving to reduce particle size below 1 mm.

A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the adults to discard their bowel content.

Parameters	**LM frozen**	**LM dried**	**Whole LM powder**
Characteristics/Composition			
Ash (% w/w)	0,6-1,0	2,0-3,1	1,8-1,9
Moisture (% w/w)	67-73	≤ 5	≤ 5
Crude protein (N × 6,25) (% w/w)	11-21	43-53	50 – 60
Fat (% w/w)	7-13	31-41	31-41
Saturated fatty acids (% fat)	35-43	35-43	35-43
Digestible carbohydrates (% w/w)	0,1-2,0	0,1-2,0	1,0-3,5
([18]) Dietary fibre (% w/w)	1,5-3,5	5,5-9,0	5,5-9,0
Chitin (% w/w)	1,7-2,4	6,4-10,4	10,5-13,9
Peroxide value (Meq O_2/kg fat)	≤ 5	≤ 5	≤ 5

▼M74

Authorised Novel Food	Specifications			
	Contaminants			
	Lead (mg/kg)	≤ 0,07	≤ 0,07	≤ 0,07
	Cadmium (mg/kg)	≤ 0,05	≤ 0,05	≤ 0,05
	Aflatoxins (Sum of B1, B2, G1, G2) (µg/kg)	≤ 4	≤ 4	≤ 4
	Aflatoxin B1 (µg/kg)	≤ 2	≤ 2	≤ 2
	Deoxynivalenol (µg/kg)	≤ 200	≤ 200	≤ 200
	Ochratoxin A (µg/kg)	≤ 1	≤ 1	≤ 1
	Sum of dioxins and dioxins-like PCBs UB (([19]) WHO_{2005} PCDD/F-PCB-TEQ) (pg/g fat)	≤ 1,2	≤ 1,2	≤ 1,2
	Microbiological criteria			
	Total aerobic colony count (([7]) CFU/g)	≤ 10^5	≤ 10^5	≤ 10^5
	Enterobacteriaceae (presumptive) (CFU/g)	≤ 100	≤ 100	≤ 100
	Escherichia coli (CFU/g)	≤ 50	≤ 50	≤ 50
	Listeria monocytogenes	Not detected in 25g	Not detected in 25g	Not detected in 25g
	Salmonella spp.	Not detected in 25g	Not detected in 25g	Not detected in 25g
	Bacillus cereus (presumptive) (CFU/g)	≤ 100	≤ 100	≤ 100
	Coagulase positive *Staphylococci* (CFU/g	≤ 100	≤ 100	≤ 100
	Sulfite-reducing Anaerobes (CFU/g)	≤ 30	≤ 30	≤ 30
	Yeasts and moulds (CFU/g)	≤ 100	≤ 100	≤ 100

▼M9

Authorised Novel Food	Specifications
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 %

▼M9

Authorised Novel Food	Specifications
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 %

▼M9

Authorised Novel Food	Specifications
	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 (synthetic)	**Definition:** 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

▼M9

▼M149

Authorised Novel Food	Specifications			
Specifications				Data protection
	Definition: 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			2′-Fucosyllactose produced with a genetically modified strain of *Corynebacterium glutamicum* ATCC 13032 authorised on 16 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: 'Advanced Protein Technologies Corporation', 7th Floor GyeongGi-BioCenter, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-si Gyeonggi-do, 16229 South Korea. During the period of data protection, 2′-Fucosyllactose produced with a genetically modified strain of *Corynebacterium glutamicum* ATCC 13032 is authorised for placing on the market within the Union only by 'Advanced Protein Technologies Corporation' 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 'Advanced Protein Technologies Corporation'. End date of the data protection: 16 May 2028.
2′-Fucosyllactose (microbial source)	**Source:** Genetically modified strain of *Escherichia coli* K-12	**Source:** Genetically modified strain of *Escherichia coli* BL-21	**Source**: Genetically modified strain of *Corynebacterium glutamicum* ATCC 13032	
	Description: 2′-Fucosyllactose is a white to off-white powder that is produced by a microbiological 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 % pH (20 C, 5 % solution): 3,0-7,5 Water: ≤ 9,0 % Sulphated ash: ≤ 2,0 % Acetic acid: ≤ 1,0 % Residual proteins: ≤ 0,01 %	**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 % 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)	**Description:** 2′-Fucosyllactose is a white to off white/ivory powder that is produced by a microbiological process. **Purity:** 2′-Fucosyllactose (w/w dry matter): ≥ 94,0 % D-Lactose (w/w dry matter): ≤ 3,0 % L-Fucose (w/w dry matter): ≤ 3,0 % 3-Fucosyllactose (w/w dry matter): ≤ 3,0 % Difucosyllactose (w/w dry matter): ≤ 2,0 % D-Glucose (w/w dry matter): ≤ 3,0 % D-Galactose (w/w dry matter): ≤ 3,0 % Water: ≤ 9,0 % Ash: ≤ 0,5 % Residual proteins: ≤ 0,005 %	

▼M149

Authorised Novel Food	Specifications			
	Microbiological criteria: Aerobic mesophilic bacteria total count: ≤ 3 000 CFU/g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units	**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: ≤ 10 EU/mg (powder), ≤ 10 EU/µl (liquid) Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid) CFU: Colony Forming Units; EU: Endotoxin Units	**Contaminants**: Arsenic: ≤ 0,03 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg Ethanol: ≤ 1 000 mg/kg **Microbiological criteria**: Total plate count: ≤ 500 CFU/g Yeasts and Moulds: ≤ 100 CFU/g Enterobacteriaceae: absence in 10 g *Salmonella*: absence in 25 g *Cronobacter* spp.: absence in 10 g Endotoxins: ≤ 100 EU/g CFU: Colony Forming Units; EU: Endotoxin Units	

▼M58

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 *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)

▼M58

Authorised Novel Food	Specifications
	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

▼M75

3-Fucosyllactose (‘3-FL’) (microbial source)	**Description:** 3-Fucosyllactose (3-FL) is a purified, white to off-white powder that is produced by microbial fermentation and contains limited levels of D-Lactose, L-Fucose, D-Galactose, and D-Glucose. **Source:** Genetically modified strain of *Escherichia coli* K-12. **Definition:** Chemical formula: $C_{18}H_{32}O_{15}$ Chemical name: β-D-galactopyranosyl-(1→4)[-α-L-fucopyranosyl-(1→3)]-D-glucopyranose Molecular mass: 488,44 Da CAS No 41312-47-4 **Characteristics/Composition:** 3-Fucosyllactose (% of dry matter): ≥ 90,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) L-Fucose (% of dry matter): ≤ 3,0 % (w/w)

▼M75

Authorised Novel Food	Specifications
	Sum of D-Galactose/D-Glucose (% of dry matter): ≤ 3,0 % (w/w) Sum of other carbohydrates[a] (% of dry matter): ≤ 3,0 % (w/w) Moisture: ≤ 5,0 % (w/w) pH (20 °C, 5 % solution): 3,0-7,5 Residual protein: ≤ 0,01 % (w/w) Ash (%): ≤ 0,5 **Heavy metals/Contaminants:** Arsenic: ≤ 0,2 mg/kg Cadmium: ≤ 0,05 mg/kg Lead: ≤ 0,05 mg/kg Mercury: ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg Aflatoxin B1: ≤ 0,1 µg/kg Residual endotoxins: ≤ 0,3 EU/mg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* sp.: Absence in 25 g *Cronobacter (Enterobacter) sakazakii*: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g *Bacillus cereus*: ≤ 10 CFU/g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g CFU: Colony Forming Units; EU: Endotoxin Units; [a]Sum of other carbohydrates: 3-Fucosyllactose isomer, difucosyllactose isomer, and oligomers.
▼M102	
3-Fucosyllactose (‘3-FL’) (produced by a derivative strain of *E. coli* BL21(DE3))	**Description:** 3-Fucosyllactose (3-FL) is a purified, white to off-white powder that is produced by microbial fermentation and contains limited levels of D-Lactose, L-Fucose, D-Galactose, and D-Glucose. **Definition:** Chemical name: β-D-Galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]- D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ Molecular mass: 488,44 Da

▼M102

Authorised Novel Food	Specifications
	CAS No: 41312-47-4 **Source:** A genetically modified strain of *Escherichia coli* BL21(DE3) **Characteristics/Composition:** 3-Fucosyllactose (% of dry matter): ≥ 90,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) D-glucose (% of dry matter): ≤ 3,0 % (w/w) D-galactose (% of dry matter): ≤ 3,0 % (w/w) L-Fucose (% of dry matter): ≤ 3,0 % (w/w) Sum of other carbohydrates (% of dry matter) ([24]): ≤ 5,0 % (w/w) Moisture: ≤ 9,0 % (w/w) Ash: ≤ 1,0 % (w/w) Residual protein: ≤ 0,01 % (w/w) **Heavy metals and contaminants:** Arsenic: ≤ 0,2 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria:** Standard plate count: ≤ 1 000 CFU ([25])/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter* (*Enterobacter*) *sakazakii*.: Absence in 10 g Residual endotoxins: ≤ 10 EU ([26])/mg

▼M125

3-Fucosyllactose ('3-FL') **(produced by derivative strain of *E. coli* K-12 DH1)**	**Description:** 3-Fucosyllactose (3-FL) is a purified and concentrated white to off-white powder produced by microbial fermentation and contains limited levels of D-Lactose, 3-Fucosyllactulose, and L-Fucose. **Definition:** Chemical name: β-D-Galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]- D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ Molecular mass: 488,44 Da CAS No: 41312-47-4 **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1

▼M125

Authorised Novel Food	Specifications
	Characteristics/Composition: 3-Fucosyllactose (% w/w of dry matter): ≥ 90,0 D-Lactose (% w/w): ≤ 5,0 3-Fucosyllactulose (% w/w): ≤ 1,5 L-Fucose (% w/w): ≤ 1,0 Sum of 3-Fucosyllactose, 3-Fucosyllactulose, D-Lactose and L-Fucose, (% w/w dry matter): ≥ 92,0 Sum of other carbohydrates (% w/w): ≤ 5,0 Moisture (% w/w): ≤ 6,0 pH (20 °C, 5 % solution): 3,2 -7,0 Ash (% w/w): ≤ 0,5 Acetic acid (% w/w): ≤ 1,0 Residual protein (% w/w): ≤ 0,01 **Heavy metals and contaminants:** Arsenic: ≤ 0,2 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter* spp.: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g Presumptive *Bacillus cereus*: ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units

▼M9

Authorised Novel Food	Specifications
▼M132	
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* and *Papiliotrema terrestris*. GOS: min. 46 % Dry Matter (DM) Lactose: max. 40 % DM Glucose: max. 22 % DM Ash: max. 4,0 % DM Protein: max. 4,5 % DM Nitrite: max. 2 mg/kg
▼M9	
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°

▼M9

Authorised Novel Food	Specifications
Glucosamine sulphate NaCl from *Aspergillus niger* and genetically modified strain of *E. coli* K-12	White crystalline odourless powder Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl$ Relative molecular mass: 573,31 g/mol D-Glucosamine HCl: 98-102 % of reference standard (HPLC) Specific Optical Rotation: $+52^o$ - $+54^o$
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 ([1]) & 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 ([2]).

▼M9

Authorised Novel Food	Specifications
	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.

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
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 leaves of *Ilex guayusa*	**Description/Definition:** Dark brown liquid. Aqueous extracts of dried leaves of *Ilex guayusa.* **Composition:** 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
▼M49 **Infusion 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).

▼M49

Authorised Novel Food	Specifications
	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
▼M94 **Iron hydroxide adipate tartrate**	**Description/Definition:** Iron hydroxide adipate tartrate (IHAT) is an odourless, engineered nanomaterial in powder form that is insoluble in water and is manufactured by a chemical synthesis involving a series of steps involving acid-base reaction, precipitation, filtration, and drying. The food supplements containing the novel food are manufactured in capsular form. Excess adipate, tartrate and sodium chloride are used at levels resulting from the production process to help stabilise IHAT and ensure the authorised particle size distribution. If other forms of food supplements (e.g. tablets, pastilles, sachets of powders, gummies, syrups, etc.) are used in combination with adipate, tartrate and sodium chloride or in combination with other substances, or if other substances are used in the capsular form food supplements containing the novel food, it must be ensured that the authorised IHAT particle size distribution is maintained.

▼M94

Authorised Novel Food	Specifications	
	Common name	Iron oxo-hydroxide adipate tartrate
	Other names	Iron hydroxide adipate tartrate, Iron oxyhydroxide adipate tartrate
	Trade name	IHAT
	CAS number	2460638-28-0
	Molecular formula (calculated)	$FeO_m(OH)_n(H_2O)_x(C_4H_6O_6)_y(C_6H_{10}O_4)_z$ *where: m and n are undefined as per accepted practice for ferric iron oxohydroxides* (*) x = 0,28-0,88 y = 0,78-1,50 z = 0,04-0,19 Tartaric ($C_4H_6O_6$) and adipic ($C_6H_{10}O_4$) acid are represented in their protonated form.
	Molecular weight	Average molecular weight: 35 803,4 Da (lower-upper bound: 27 670,5-45 319,4 Da)
	Characteristics/Composition: **Physical/chemical** Iron (% dry matter): 24,0-36,0 Adipate: (% dry matter): 1,5-4,5 Tartrate: (% dry matter): 28,0-40,0 Water content (%): 10,0-21,0 Sodium (% dry matter): 9,0-11,0 Chloride (% dry matter): 2,6-4,2	

▼M94

Authorised Novel Food	Specifications
	Phase distribution Soluble (%): 2,0-4,0 Nano (%): 92,0-98,0 Micro (%): 0,0-3,0 **Primary particle size** Median diameter ([20]): 1,5-2,3 nm Mean diameter ([20]): 1,8-2,8 nm Dv(10) ([21]): 1,5-2,5 nm Dv(50) ([21]): 2,5-3,5 nm Dv(90) ([21]): 5,0-6,0 nm **Heavy metals** Arsenic: < 0,80 mg/kg Nickel: < 50,0 mg/kg **Residual solvents** Ethanol: < 500 mg/kg **Microbiological criteria** Total aerobic microbial count: < 10 CFU/g Total yeast and mould count: < 10 CFU/g
▼M116 **Iron milk caseinate**	**Description:** Iron milk caseinate is an iron-casein-phosphate complex in the form of a creamy or beige powder produced by the dissolution of ferric iron salts (ferric sulfate or ferric chloride) in a casein solution obtained from bovine milk in the presence of potassium orthophosphate following a series of steps involving pasteurisation, concentration, and drying. **Characteristics/Composition:** Protein (%): 50,0 – 65,0 Ash (%): 20,0 – 40,0 Moisture (%): < 8,0 Fat (%): < 1,0 Iron (%): 2,0 – 4,0

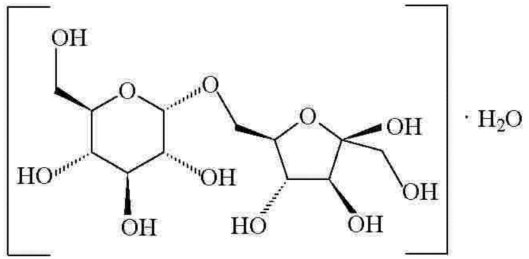
▼M116

Authorised Novel Food	Specifications
	Potassium (%): 5,0 – 15,0Phosphorus (%): 2,0 – 6,0 Sodium (%): < 4,0 **Heavy metals:** Lead: < 0,5 mg/kg Arsenic: ≤ 1,0 mg/kg Cadmium: < 0,5 mg/kg Mercury: < 0,1 mg/kg **Mycotoxins:** Aflatoxin M1: ≤ 0,02 mg/kg **Microbiological criteria:** Aerobic plate count: ≤ 1 000 CFU/g Coliforms: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 10 CFU/g *Escherichia coli:* ≤ 10 CFU/g *Staphylococcus aureus*: Absence in 1 g CFU: Colony Forming Units

▼M9

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

▼M9

Authorised Novel Food	Specifications
	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 taste Chemical 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)

▼M9

Authorised Novel Food	Specifications
	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.

▼M138

Isomaltulose powder	**Description/Definition:** The novel food is isomaltulose powder produced from sucrose by a microbiological process using *Serratia plymuthica*. The dry matter content is a mixture of mono-and disaccharides, mainly composed of isomaltulose (≥ 75 %) and trehalulose (≤ 13 %) and, to a minor extent, glucose, fructose, sucrose and oligosaccharides (traces). **Characteristics/composition:** Isomaltulose (% DM): ≥ 75 Trehalulose (% DM): ≤ 13 Glucose (% DM): ≤ 3 Fructose (% DM): ≤ 4 Sucrose (% DM): ≤ 5 Moisture (%): ≤ 7 Ash (%): ≤ 0,05 Protein (%): < 0,1 **Chemical identity of isomaltulose:** Chemical (IUPAC) name: α-D-glucopyranosyl-(1 → 6)-D-fructofuranose Common name: Isomaltulose CAS number: 13718–94-0 Molecular formula: $C_{12}H_{22}O_{11}$ Molecular weight: 342,30 g/mol **Chemical identity of trehalulose:** Chemical (IUPAC) name: α-D-glucopyranosyl-(1 → 1)-D-fructofuranose Common name: Trehalulose CAS number: 51411–23-5 Molecular formula: $C_{12}H_{22}O_{11}$ Molecular weight: 342,30 g/mol **Heavy metals:** Lead (mg/kg): ≤ 0,1

▼M138

Authorised Novel Food	Specifications
	Microbiological criteria: Total aerobic microbial count: < 100 CFU/g Total yeast and mould count: < 100 CFU/g *E. coli*: < 10 CFU/g Enterobacteriaceae: < 100 CFU/g *Salmonella*: not detected in 25 g CFU: colony forming units DM: dry matter

▼M90

***Jatropha curcas* L. (edible variety) kernels**

Description:

The kernels are obtained from the seeds of the ripe fruits of the edible variety of the *Jatropha curcas* L. plants that produce kernels with non-detectable levels of phorbol esters, following a series of steps involving the cleaning and de-husking of the fruits to obtain the seeds, the drying of the seeds, the cleaning of the seeds to remove debris and other residues, mechanical deshelling of the seeds to obtain the kernels, and the hydrothermal treatment (> 120 °C for 40 minutes) of the kernels to reduce anti-nutrients and the microbiological load.

As the edible variety of the *Jatropha curcas* L. plants, producing kernels that contain non-detectable levels of phorbol esters, are phenotypically undistinguishable from the non-edible variety, only the appropriate edible variety of *Jatropha curcas* L. plants should be used in the production of the novel food. The entire production process must ensure that the mixing of edible and non-edible kernels does not occur.

The absence of mixing of edible with non-edible kernels shall be confirmed by analytical controls for phorbol esters carried on each batch of the seeds after the seed-drying step and before the deshelling step according to the sampling procedure of Table A. Five laboratory samples extracted from each aggregate sample are de-shelled, ground, and analysed for phorbol esters using a validated UHPLC-UV-MS[(b)] method. Only the batches in which phorbol esters are undetectable in all five samples are further processed to the seed deshelling and kernel hydrothermal treatment steps.

Table A

Batch weight (tons)	Weight or number of sublots	Number of incremental samples
≥ 500	100 tons	100
> 100 and < 500	5 sub-lots	100
> 10 and ≤ 100	5 sub-lots	100
> 5,0 and ≤ 10	-	80
> 1 and ≤ 5,0	-	60
> 0,1 and ≤ 1,0	-	30
≤ 0,1	-	10
Each sub-lot shall be sampled separately. Aggregate samples are composed by a minimum of 10 incremental samples. The minimum amount of an aggregate sample shall be 3,5 kg. This amount may increase proportionally according to the number of incremental samples taken.		

▼M90

Authorised Novel Food	Specifications
	Characteristics/Composition: Moisture: ≤ 3,0 % Total fat: 54,0 – 61,0 % Total protein: 21,0 – 32,0 % Total fibre: 6,0 – 10,0 % Ash: 3,0 – 5,0 % **Contaminants:** Phorbol esters (µg TPA eq[(a)]/g kernel)[(b)]: ≤ 0,75 (LOD)[(c)] Lead: ≤ 0,20 mg/kg Cadmium: ≤ 0,20 mg/kg Sum of aflatoxins B1, B2, G1, G2: ≤ 4,0 µg/kg **Microbiological criteria:** Total aerobic microbial count: ≤ 1 000 CFU/g Total yeast/moulds count: ≤ 100 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* sp.: Absent in 25 g *Listeria monocytogenes*: ≤ 100 CFU/g [(a)] TPAeq: 12-O-tetradecanoylphorbol-13-acetate equivalent; [(b)]Validated Ultra-High-Performance Liquid Chromatography coupled to Ultraviolet Spectrophotometry and Mass Spectrometry (UHPLC-UV-MS) method for detection of phorbol ester peaks; [(c)] Limit of Detection (Only batches with concentrations of PEs below the LOD can be fully processed.); CFU: Colony Forming Units

▼M9

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° to + 16° 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

▼M9

Authorised Novel Food	Specifications
	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

▼M144

'Lacto-*N*-fucopentaose I and 2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture (produced using a derivative strain of *E. coli* K-12 DH1)	**Description:** Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture is a purified and concentrated white to off-white powder produced using genetically modified strain of *Escherichia coli* K-12 DH1. **Definition:** **Lacto-*N*-fucopentaose I** Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→3)-2-(acetylamino)-2- deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose Chemical formula: $C_{32}H_{55}NO_{25}$ Molecular mass: 853,77 Da CAS No: 7578-25-8 **2'-Fucosyllactose** Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ Molecular mass: 488,44 Da CAS No: 41263-94-9 **Characteristics/Composition:** Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture (% w/w of dry matter): ≥ 75,0 Lacto-*N*-fucopentaose I (% w/w of dry matter): 50,0 – 75,0 2'-Fucosyllactose (% w/w of dry matter): 15,0 – 35,0 Lacto-*N*-Tetraose (% w/w): ≤ 5,0 3-Fucosyllactose (% w/w): ≤ 1,0 D-Lactose (% w/w): ≤ 10,0 Difucosyllactose (% w/w): ≤ 2,0 Lacto-*N*-fucopentaose I fructose isomer (% w/w): ≤ 1,5 2'-Fucosyl-D-lactulose (% w/w): ≤ 1,0 Sum of L-Fucose and 2′-Fucosyl-D-lactitol[a] (% w/w): ≤ 1,0

▼M144

Authorised Novel Food	Specifications
	Sum of Lacto-*N*-fucopentaose I, 2'-Fucosyllactose, Lacto-*N*-Tetraose, Difucosyllactose, 3-Fucosyllactose, D-Lactose, L-Fucose, 2′-Fucosyl-D-lactitol, Lacto-*N*-fucopentaose I fructose isomer, and 2'-Fucosyl-D-lactulose (% w/w dry matter): ≥ 90,0 Sum of other carbohydrates (% w/w): ≤ 6,0 Moisture (% w/w): ≤ 8,0 pH (20 °C, 5 % solution): 4,0 -7,0 Ash (% w/w): ≤ 0,5 Residual protein (% w/w): ≤ 0,01 **Heavy metals and contaminants:** Arsenic: ≤ 0,2 mg/kg Cadmium: ≤ 0,1 mg/kg Lead: ≤ 0,02 mg/kg Mercury: ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* spp.: Absence in 25 g Yeasts and moulds: ≤ 100 CFU/g *Cronobacter* spp.: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g Presumptive *Bacillus cereus*: ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg [a] L-Fucose and 2′-Fucosyl-D-lactitol peaks on the High Performance Anion Exchange Chromatography with Pulsed Amperometric Detection (HPAEC–PAD) chromatogram overlap. CFU: Colony Forming Units; EU: Endotoxin Units’

▼M9

Authorised Novel Food	Specifications
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

▼M123

Lacto-*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

▼M123

Authorised Novel Food	Specifications
	Description/Source Lacto-*N*-neotetraose is a white to off-white powder that is produced by a microbiological process using genetically modified strain of *Escherichia coli* K-12, and/or of *Escherichia coli* BL21(DE3). An additional optional genetically modified degradation strain of *Escherichia coli* BL21(DE3) may be used in the production process to degrade intermediate carbohydrate by-products and remaining starting carbohydrate substrates. **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 % (% w/w dry matter) pH (20 °C, 5 % solution): 4,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 1,0 % Residual solvents (methanol): ≤ 100 mg/kg Residual proteins: ≤ 0,01 % **Microbiological criteria** Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts and moulds: ≤ 50 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units

▼M45

▼M46

Lacto-*N*-tetraose ('LNT') (microbial source)	**Definition:** Chemical formula: $C_{26}H_{45}NO_{21}$ 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 or agglomerates that is produced by a microbial process.

▼M46

Authorised Novel Food	Specifications
	Source: Genetically modified strain of *Escherichia coli* strain K-12 DH1 **Characteristics/Composition:** Appearance: White to off white powder or agglomerates Sum of lacto-*N*-tetraose, D-Lactose and lacto-*N*-triose 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*-triose 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* spp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units
▼M101 **Lacto-*N*-tetraose ('LNT')** **(produced by derivative strains of *E. coli* BL21(DE3))**	**Description:** Lacto-*N*-tetraose is a purified and concentrated white to off-white powder that is produced by a microbial fermentation process. **Definition:** Chemical name: β-D-Galactopyranosyl-(1→3)-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: 14116-68-8 Molecular mass: 707.63 Da **Source:** Two genetically modified strains (a production strain and an optional degradation strain) of *Escherichia coli* BL21(DE3)

▼M101

Authorised Novel Food	Specifications
	Characteristics/Composition: Lacto-*N*-tetraose (% of dry matter): ≥ 75,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) Lacto-*N*-triose II (% of dry matter): ≤ 5,0 % (w/w) *Para*-lacto-*N*-hexaose (% of dry matter): ≤ 5,0 % (w/w) D-galactose and D-glucose (% of dry matter): ≤ 5,0 % (w/w) Sum of other carbohydrates[a]: ≤ 15,0 % (w/w) Moisture: ≤ 9,0 % (w/w) Ash: ≤ 1,0 % (w/w) Residual protein: ≤ 0,01 % (w/w) **Heavy metals and contaminants:** Arsenic: ≤ 0,2 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria:** Standard plate count: ≤ 1 000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter* (*Enterobacter*) *sakazaki:* Absence in 10 g Residual endotoxins: ≤ 10 EU/mg [a] Sum of other carbohydrates = 100 (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter). CFU: Colony Forming Units; EU: Endotoxin Units

▼M21

***Lonicera caerulea* L. berries (haskap)** **(Traditional food from a third country)**	**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. **Typical nutritional components of haskap berries** (given in fresh berries): Carbohydrates: 12,8 % Fibre: 2,1 % Lipids: 0,6 % Proteins: 0,7 %

▼M21

Authorised Novel Food	Specifications
	Ash: 0,4 % Water: 85,5 %
▼M9 **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

▼M9

Authorised Novel Food	Specifications
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 %

▼M9

Authorised Novel Food	Specifications
▼M52 **Hen 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

▼M9

Authorised Novel Food	Specifications
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 %

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
▼M11	
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

▼M9

Authorised Novel Food	Specifications
(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
Monomethylsilanetriol (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

▼M9

Authorised Novel Food	Specifications
	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)

▼M133

Monosodium salt of L-5-methyl-tetrahydrofolic acid	**Description/Definition:** The novel food is produced by chemical synthesis and consists of L-5-methyltetrahydrofolic acid. **Molecular formula:** $C_{20}H_{24}N_7NaO_6$ **Chemical name:** N-[4-[[(2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-(6S)-pteridinyl)methyl]amino]benzoyl]-l-glutamic acid **CAS number:** 2246974-96-7 **Molecular weight:** 481,44 g/mol **Characteristics/composition:** Appearance: White to yellow or beige powder **Assay & related compounds:** Assay 5-MeTHFA-Na on dry basis: > 95 %; Sum of folate-related substances: ≤ 2,5 Sodium: 4 %–5 % w/w Water: ≤ 1,0 % Residual solvents: Ethanol: ≤ 0,5 %; Isopropanol: ≤ 0,5 % Diastereomeric purity: (6R)-Mefolinate: ≤ 1,0 % area **Elemental impurities:** Boron: ≤ 10 mg/kg Platinum: ≤ 10 mg/kg (for foods intended for infants and young children and food supplements intended for pregnant women then ≤ 2 mg/kg) Arsenic: ≤ 1,5 mg/kg

▼M133

Authorised Novel Food	Specifications
	Cadmium: ≤ 0,5 mg/kg Lead: ≤ 1,0 mg/kg Mercury: ≤ 1,5 mg/kg (for foods intended for infants and young children and food supplements intended for pregnant women then ≤ 1 mg/kg) **Microbiological criteria:** Total aerobic microbial count: ≤ 100 CFU/g Total yeast and moulds count: ≤ 100 CFU/g *E. coli:* Not detected in 10 g Abbreviations: CFU: colony forming unit; IR: infra-red; MeTHFA: methyltetrahydrofolic acid.
▼M87 **Mung bean (*Vigna radiata*) protein**	**Description/Definition:** The novel food is mung bean protein powder extracted from seeds of the plant *Vigna radiata* by several processing steps followed by pasteurization and spray drying. **Characteristics/composition:** Moisture: ≤ 6 % Protein (w/w)[(a)]: ≥ 84 % Ash (w/w): ≤ 6,0 % Fat (w/w): ≤ 5,5 % Carbohydrate (w/w): ≤ 5,0 by calculation **Microbiological criteria:** Aerobic plate count: < 5 000 CFU/g [(b)] Yeasts and moulds: < 100 CFU/g Coliforms: < 100 CFU/g *Escherichia coli*: < 10 CFU/g *Listeria monocytogenes:* Not detected in 25 g *Salmonella* spp.: Not detected in 25 g ([a]) w/w: weight per weight. ([b]) CFU: colony forming units.

▼M9

Authorised Novel Food	Specifications
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
▼M92	
Nicotinamide 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: C11H15N2O5Cl 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 %

▼M92

Authorised Novel Food	Specifications
	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 Mercury*: ≤ 0,1 mg/kg Cadmium*: ≤ 1 mg/kg Lead*: ≤ 0,5 mg/kg **Microbiological criteria:** Total Plate Count: ≤ 1 000 CFU/g Yeast and Mould: ≤ 100 CFU/g *Escherichia coli*: Absence in 10 g CFU: colony forming units (*) only for foods for special medical purposes, total diet replacement for weight control and meal replacements
▼M9 **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

▼M9

Authorised Novel Food	Specifications
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. *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 %

▼M9

Authorised Novel Food	Specifications
	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.

▼M9

Authorised Novel Food	Specifications
	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 %

▼M9

Authorised Novel Food	Specifications
	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 %
▼M126 **Partially 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 %

▼M126

Authorised Novel Food	Specifications
	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*: Not detected in 10 g *Listeria monocytogenes*: Not detected in 25 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

▼M63

Partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L.	**Definition:** The powder is produced from the partially defatted seeds of non-genetically modified *Brassica rapa* L. and *Brassica napus* L. double low (00) cultivars through a series of processing steps to reduce glucosinolates and phytates. **Source:** *Brassica rapa* L. and *Brassica napus* L. seeds **Characteristics/Composition:** Protein (N × 6,25): 33,0-43,0 % Lipids: 14,0 – 22,0 % Total Carbohydrates(*): 33,0 – 40,0 % Total Fibre(**): 33,0 – 43,0 %

▼M63

Authorised Novel Food	Specifications
	Moisture: < 7,0 % Ash: 2,0–5,0 % Total Glucosinolates: < 0,3 mmol/kg (≤ 120 mg/kg) Phytate: < 1,5 % Peroxide value (in novel food weight): ≤ 3,0 mEq O_2/kg **Heavy Metals:** Lead: < 0,2 mg/kg Arsenic (inorganic): < 0,2 mg/kg Cadmium: < 0,2 mg/kg Mercury: < 0,1 mg/kg Aluminium: < 35,0 mg/kg **Microbiological criteria:** Total plate count (30 °C): < 5 000 CFU/g *Enterobacteriaceae*: < 10 CFU/g *Salmonella* sp.: Negative/25 g Yeast and mould: < 100 CFU/g *Bacillus cereus*: < 100 CFU/g (*) By difference: 100 % – [protein % + moisture % + fat % + ash %] (**) AOAC 2011.25 (Enzymatic gravimetry) CFU: Colony Forming Units, AOAC: Association of Official Agricultural Chemists

▼M55

Extract from *Panax notoginseng* and *Astragalus membranaceus*	**Description/Definition:** The novel food contains two extracts. One is an ethanol extract of the roots of *Astragalus membranaceus* (Fisch.) Bunge. The other is a hot water extract of the roots of *Panax notoginseng* (Burkill) F.H. Chen that is further concentrated using absorption on a resin and subsequent elution with 60 % ethanol. At the end of the manufacturing process both extracts are mixed (45–47,5 % of each extract) with maltodextrin (5–10 %). **Characteristics/Composition:** Total saponins: 1,5-5 % Ginsenoside Rb1: 0,1-0,5 % Astragaloside I: 0,01-0,1 %

▼M55

Authorised Novel Food	Specifications		
	Carbohydrates: ≥ 90 % Protein: ≤ 4,5 % Ash: ≤ 1 % Moisture: ≤ 5 % Fat: ≤ 1,5 % **Heavy metals:** Arsenic: ≤ 0,3 mg/kg **Microbiological criteria:** Total plate count: ≤ 5 000 CFU/g Total yeast and mould count: ≤ 500 CFU/g Enterobacteriaceae: < 10 CFU/g *Escherichia coli*: Absence in 25 g *Salmonella*: Absence in 375 g *Staphylococcus aureus*: Absence in 25 g CFU: colony forming units		
▼M9 **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

▼M9

Authorised Novel Food	Specifications
▼M100	
Pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia	**Description:** The novel food is produced from the fermentation of a mixture of 65 % pea and 35 % rice protein concentrates by the mycelia of the Shiitake mushroom (*Lentinula edodes*) followed by heat treatment to terminate the fermentation and a series of drying steps to form a powder. **Characteristics/Composition:** Protein (% dry weight, N x 6,25): ≥ 75,0 Moisture: ≤ 7,0 Total fat (% dry weight): ≤ 10,0 Ash (% dry weight): ≤ 10,0 Carbohydrates (% by calculation): ≤ 15,0 **Mycotoxins**: Aflatoxin B1 (µg/kg): < 1,0 Aflatoxin B2 (µg/kg): < 1,0 Aflatoxin G1 (µg/kg): < 1,0 Aflatoxin G2 (µg/kg): < 1,0 Aflatoxin total (B1+B2+G1+G2) (µg/kg): < 3,0 **Heavy metals:** Arsenic (µg/g): < 0,1 Cadmium (µg/g): < 0,1 Lead (µg/g): < 0,3 Mercury (µg/g): < 0,1 **Microbiological criteria:** Total aerobic microbial count: < 1 000 CFU/g Total yeast/moulds count: < 100 CFU/g Coliforms: ≤ 10 CFU/g *Salmonella* spp.: Absent in 25 g *Escherichia coli*: < 10 CFU/g *Listeria monocytogenes*: Absent in 25 g *CFU: Colony Forming Units

▼M9

Authorised Novel Food	Specifications
▼M37	
Phenylcapsaicin	**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

▼M9

Authorised Novel Food	Specifications
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

▼M112

Phosphated wheat starch

Description:

Phosphated distarch phosphate produced from wheat starch (phosphated wheat starch) is a chemically modified resistant starch derived from wheat starch by combining chemical treatments to create phosphate cross-links within and between individual starch molecules.

The novel food ingredient is a white or near white free flowing powder.

Characteristic/Composition:

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

Parameter	Powder form 1	Powder form 2
Phosphated Distarch Phosphate (Dry basis)	≥ 85 %	≥ 75 %
Unmodified Wheat Starch (Dry basis)	≤ 15 %	≤ 25 %
Moisture	9-12 %	

▼M112

Authorised Novel Food	Specifications		
	Total dietary fibre (dry matter basis)	≥ 76,0 %	≥ 66,0 %
	Ash	≤ 3 %	
	Protein	≤ 0,5 %	
	Total fat	≤ 0,50 %	≤ 0,34 %
	Residual bound phosphorus	≤ 0,4 % (as phosphorus)	
	pH (25 % slurry)	4,5 – 6,5	
	Heavy metals: Arsenic: ≤ 1 mg/kg Lead: ≤ 2 mg/kg Mercury: ≤ 0,1 mg/kg **Microbiological criteria:** Total viable aerobic counts: ≤ 10^4 CFU/g Total yeast and mould count: ≤ 200 CFU/g *Escherichia coli*: Negative to test *Salmonella* spp.: Negative to test CFU: Colony Forming Units		

▼M9

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

▼M9

Authorised Novel Food	Specifications
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 %

▼M9

Authorised Novel Food	Specifications
	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 %

▼M9

Authorised Novel Food	Specifications
	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 hydrolysates thereof	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 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

▼M9

Authorised Novel Food	Specifications
	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: Absent Mycotoxins: 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

▼M9

Authorised Novel Food	Specifications
▼M136	
Protein concentrate from *Lemna gibba* and *Lemna minor*	**Description/Definition:**The novel food is a protein concentrate produced from the *Lemna gibba* (70–100 %) and *Lemna minor* (0–30 %) plant species. The manufacturing process of the protein concentrate involves mechanical separation of the protein fraction from insoluble fibres, followed by precipitation under acidic conditions, pasteurisation and spray drying. The cultivation is carried out in basins in greenhouses under controlled conditions. The water used for the cultivation is filtered and UV-treated. The cultivation conditions are monitored to control the growth of algae, yeast and fungi. The pH is maintained between 5,5 and 6,5. **Characteristics/composition:** Appearance: green powder Moisture: 1,5-8 % Protein (Nx6,25): 60-75 % Ash: 4-12 % Fat: 2-11 % Fibre: 6-17 % Ash: 4-12 % Vitamins: β-Carotene: < 755 mg/kg Vitamin K_1 (Phylloquinone): < 16 mg/100 g Minerals: Boron: < 10 mg/kg Copper: < 12 mg/kg Molybdenum: < 40 mg/kg Iron: < 670 mg/kg Zinc: < 50 mg/kg Manganese: < 100 mg/kg **Antinutritional factors:** Oxalic acid: < 1 900 mg/kg

▼M136

Authorised Novel Food	Specifications
	Heavy metals: Lead (mg/kg): ≤ 0,3 Cadmium (mg/kg): ≤ 0,2 Mercury (mg/kg): ≤ 0,1 Arsenic (mg/kg): ≤ 0,2 Cyanotoxins: Microcystins-/Nodularin: < 0,19 mg/kg **Other contaminants:** Lysino-alanine (bound): < 500 mg/kg Lysino-alanine (free): < 10 mg/kg Nitrate: < 3 000 mg/kg **Pesticides:** Pesticide levels in accordance with Code number 0254000 (‘Subgroup (d) watercresses’ in the group of Leaf vegetables, herbs and edible flowers) set out in Regulation (EC) No 396/2005. **Microbiological criteria:** Total colony count: < 10^4 CFU/g *Bacillus cereus*: < 100 CFU/g *Clostridium perfringens*: < 100 CFU/g Coagulase-positive Staphylococci: < 100 CFU/g *Escherichia coli*: < 10 CFU/g *Enterobacteriaceae*: < 10 CFU/g *Listeria monocytogenes*: Not detected in 25 g *Salmonella* spp.: Not detected in 25 g Yeasts and moulds: < 10 CFU/g CFU: colony forming units.

▼M9

Authorised Novel Food	Specifications	
▼M143		
Protein 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 protein extract from pig kidney is formulated in appropriate forms and dosage to reach the active sites of digestion. **Basic product:** Specification: Protein extract from pig kidney 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 Radio Extraction Assay)) **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/10 g Bile salt resistant enterobacteriaceae: < 10^4 CFU/g **Final product:** Specification protein extract from pig kidney with natural content of DAO (E.C. 1.4.3.22) in appropriate forms and dosage to reach the active sites of digestion:	**Description/Definition:** The protein extract is obtained from homogenised pig kidneys through a series of steps involving a number of acetone washes to defat and dehydrate the homogenized pig kidneys, followed by draining, drying, milling, and sieving to produce a powder containing essentially proteins with a 7-9 % (on average) content of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22). The protein extract from pig kidney is formulated in appropriate forms and dosage to reach the active sites of digestion. **Basic product:** Specification: Protein extract from pig kidney with natural content of diamine oxidase (DAO): Physical condition: powder Colour: pale brown Enzymatic activity: ≥ 0,10 mU/mg (ultra-high performance liquid chromatography linked with fluorescent detection) Humidity: < 10 % **Residual solvents:** Acetone: < 5 000 mg/kg **Microbiological criteria:** *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/10 g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g *Listeria monocytogenes*: absence in 25 g

▼M143

Authorised Novel Food	Specifications	
	Physical condition: solid Colour: yellow grey Enzymatic activity: 110-220 kHDU DAO/g (DAO REA (DAO Radio Extraction Assay)) Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 68 kHDU DAO/g (DAO REA (DAO Radio Extraction Assay)) Humidity: < 10 % **Microbiological criteria:** *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/10 g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g PCR: Polymerase Chain Reaction; HDU (Histamine Degrading Units)	**Final product:** Specification protein extract from pig kidney with natural content of DAO (E.C. 1.4.3.22) in appropriate forms and dosage to reach the active sites of digestion: Physical condition: solid Colour: pale brown Enzymatic activity: 2,29-4,6 mU/g (ultra-high performance liquid chromatography linked with fluorescent detection). Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 1,4 mU DAO/g (ultra-high performance liquid chromatography linked with fluorescent detection) Humidity: < 10 % **Microbiological criteria:** *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/10 g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g *Listeria monocytogenes*: absence in 25 g mU: milliUnit (expressed in mU/mg) measures nanomols (nmol) of histamine degraded by the DAO per minute using ultra-high performance liquid chromatography linked with fluorescent fetection (O. Comas-Basté et al. Analytical and Bioanalytical Chemistry 411:7595-7602 (2019)). 1 mU corresponds to 48 000 HDU of the DAO Radio Extraction Assay (REA) method.

▼M9

Authorised Novel Food	Specifications
▼M10	
Pyrroloquinoline 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

▼M9

Authorised Novel Food	Specifications
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.

▼M9

Authorised Novel Food	Specifications
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

▼M9

Authorised Novel Food	Specifications
▼M17	
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

▼M9

Authorised Novel Food	Specifications
▼M86	
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 Trans-resveratrol content: Min. 98 % w/w (dry weight basis) Ash: Max. 0,5 % w/w Moisture: Max. 3 % w/w
▼M9	
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.

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
	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 %

▼M9

Authorised Novel Food	Specifications
	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
▼M147 ***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: ≥ 15 % EPA content: ≥ 10 %
▼M27 ***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 %

▼M9

Authorised Novel Food	Specifications
▼M148	
***Schizochytrium* sp. (CABIO-A-2) oil**	**Description/Definition:** The novel food is an oil produced from the strain CABIO-A-2 of the microalgae *Schizochytrium* sp. **Composition:** DHA content: ≥ 35,0 % Acid value: ≤ 0,5 mg KOH/g Peroxide value: ≤ 5,0 meq/kg Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 3,5 % Trans-fatty acids: ≤ 2,0 % Free fatty acids: ≤ 0,4 % *p*-Anisidine value: ≤ 10
▼M71	
Schizochytrium sp. (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/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % Docosahexaenoic acid (DHA): ≥ 32,0 % p-anisidine value: ≤ 10
▼M9	
***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 %

▼M9

Authorised Novel Food	Specifications
▼M44	
***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 %
▼M65	
***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/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % Docosahexaenoic acid (DHA): ≥ 32,0 % p-anisidine value: ≤ 10
▼M145	
***Schizochytrium limacinum* (TKD-1) oil**	**Description/Definition:** The novel food is an oil produced from the strain TKD-1 of the microalgae species *Schizochytrium limacinum*. **Composition:** DHA content: ≥ 35,0 % Acid value: ≤ 0,5 mg KOH/g Peroxide value: ≤ 5,0 meq/kg Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 3,5 % Trans-fatty acids: ≤ 2,0 % Free fatty acids: ≤ 0,4 % *p*-Anisidine value: ≤ 10

▼M9

Authorised Novel Food	Specifications
▼M23	
Syrup from *Sorghum bicolor* (L.) Moench. **(Traditional food from a third country)**	**Description/Definition** The traditional food is syrup from *Sorghum bicolor* (L.) Moench (genus, *Sorghum*; family, *Poaceae* (alt. *Gramineae*)). 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
▼M9	
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: ConfirmableCondition: 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).

▼M9

Authorised Novel Food	Specifications
▼M142	
Seeds and seed flour of *Vigna subterranea* (L.) Verdc. (traditional food from a third country)	**Description/Definition:** The traditional food consists of de-shelled whole dried seeds of *Vigna subterranea* (L.) Verdc. [Family: Fabaceae (alt. Leguminosae)] or the flour obtained by several steps, including heat treatment and milling of the seeds. Synonyms: *Cryptolobus subterraneus* (L.) Spreng., *Glycine subterranea* L., *Tetrodea subterranea* (L.) Raf., *Voandzeia subterranea* (L.) Thouars. Common names: Bambara groundnut, Bambara nut, Bambara bean, Bambara pea, Nyimo bean. **Dried seeds** **Typical composition range:** Moisture: 7-11 % Protein : > 15 % Carbohydrates: 32-65 % Sugar: < 6,0 % Fat: 4-7 % Fiber: 7-31 % **Heavy metals:** Arsenic: < 0,05 mg/kg Cadmium: < 0,02 mg/kg Lead: < 0,05 mg/kg Mercury: < 0,01 mg/kg **Mycotoxins:** Sum of Aflatoxins (B1+B2+G1+G2): < 4 µg/kg Aflatoxin B1: < 2 µg/kg Sum of Fumonisin (B1+B2+B3): < 60 µg/kg Deoxynivalenol: < 0,1 mg/kg Ochratoxin A: < 0,5 µg/kg Zearalenone: < 0,1 mg/kg **Other contaminants or anti-nutrient factors:** Hydrocyanic acid (including hydrocyanic acid bound in cyanogenic glycosides): < 15 mg/kg

▼M142

Authorised Novel Food	Specifications
	Microbiological criteria: Aerobic mesophilic spores: < 1 Spore/g *Alicyclobacillus*: Not detected in 10 g Presumptive *Bacillus cereus*: < 10 cfu/g Coliforms: < 10 cfu/g *E. coli*: < 10 cfu/g *Salmonella*: Not detected in 25 g *Staphylococcus aureus*: < 10 cfu/g Total Plate Count: < 5 000 cfu/g Yeast & Moulds: < 100 cfu/g **Dried seed flour** **Typical composition range:** Moisture: 4-7 % Protein : > 15 % Carbohydrates: 55-75 % Sugar: < 20 % Fat: 4-9 % Fiber: 10-30 % **Heavy metals:** Arsenic: < 0,05 mg/kg Cadmium: < 0,02 mg/kg Lead: < 0,05 mg/kg Mercury: < 0,01 mg/kg **Mycotoxins:** Sum of Aflatoxins (B1+B2+G1+G2): < 4 µg/kg Aflatoxin B1: < 2 µg/kg Sum of Fumonisin (B1+B2+B3): < 60 µg/kg Deoxynivalenol: < 0,1 mg/kg Ochratoxin A: < 0,5 µg/kg Zearalenone: < 0,1 mg/kg

▼M142

Authorised Novel Food	Specifications
	Other contaminants or anti-nutrient factors: Hydrocyanic acid (including hydrocyanic acid bound in cyanogenic glycosides): < 10 mg/kg Phytic acid: < 0,01 g/100 g **Microbiological criteria:** Aerobic mesophilic spores: < 1 Spore/g *Alicyclobacillus*: Not detected in 10 g Presumptive *Bacillus cereus*: < 10 cfu/g Coliforms: < 10 cfu/g *E. coli*: < 10 cfu/g *Salmonella*: Not detected in 25 g *Staphylococcus aureus*: < 10 cfu/g Total Plate Count: < 1 000 cfu/g Yeast & Moulds: < 100 cfu/g cfu: colony forming units
▼M57 **Selenium-containing yeast (*Yarrowia lipolytica*) biomass**	**Description/Definition:** The novel food is the dried and heat-killed selenium-containing biomass of the yeast *Yarrowia lipolytica*. The novel food is produced by fermentation in the presence of sodium selenite followed by a number of purification steps including a heat-killing step of the yeast to ensure the absence of viable *Yarrowia lipolytica* cells in the novel food. **Characteristics/Composition:** Total selenium: 165–200 µg/g Se-methionine ([13]): 100–140 µg/g Protein: 40–50 g/100 g Dietary fibre: 24–32 g/100 g Sugars: < 1 g/100 g Fat: 6–12 g/100 g Total ash: ≤ 15 % Water: ≤ 5 % Dry matter: ≥ 95 %

▼M57

Authorised Novel Food	Specifications
	Heavy metals: Lead: ≤ 3,0 mg/kg Cadmium: ≤ 1,0 mg/kg Mercury: ≤ 0,1 mg/kg **Microbiological criteria:** Total aerobic microbial count: ≤ 5×10^3 CFU/g Total yeast and mould count: ≤ 10^2 CFU/g Viable *Yarrowia lipolytica* cells ([14]): < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g CFU: colony forming units

▼M61

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)

▼M61

Authorised Novel Food	Specifications
	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.

▼M105

3′-Sialyllactose (‘3′-SL’) sodium salt **(produced by derivative strains of *E. coli* BL21(DE3))**	**Description:** 3'-Sialyllactose (3′-SL) sodium salt is a purified, white to off-white powder or agglomerate produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid. **Definition:** Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Chemical formula: $C_{23}H_{38}NO_{19}Na$ Molecular mass: 655,53 Da CAS No: 128596-80-5 **Source:** Two genetically modified strains (a production strain and an optional degradation strain) of *Escherichia coli* BL21(DE3) **Characteristics/Composition:** 3′-Sialyllactose sodium salt (% of dry matter): ≥ 88,0 % (w/w) 3′-Sialyl-lactulose (% of dry matter): ≤ 5,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) Sialic acid (% of dry matter): ≤ 1,5 % (w/w) N-acetyl-D-glucosamine (% of dry matter): ≤ 1,0 % (w/w) Sum of other carbohydrates (% of dry matter)[a]: ≤ 5,0 % (w/w) Moisture: ≤ 9,0 % (w/w) Ash: ≤ 8,5 % (w/w) Residual protein: ≤ 0,01 % (w/w) Sodium: ≤ 4,2 % (w/w) **Microbiological criteria:** Standard plate count: ≤ 1 000 *CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g

▼M105

Authorised Novel Food	Specifications
	Yeast and mould: ≤ 100 CFU/g *Cronobacter* (*Enterobacter*) *sakazakii*: Absence in 10 g Residual endotoxins: ≤ 10 **EU/mg [a] Sum of other carbohydrates = 100 (% (w/w) of dry matter) – 3'-Sialyllactose sodium salt (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter); * CFU: Colony Forming Units; ** EU: Endotoxin Units
▼M135	
3′-Sialyllactose (3′-SL) sodium salt (produced using a derivative strain of *E. coli* W (ATCC 9637))	**Description:** 3′-Sialyllactose (3′-SL) sodium salt is a purified, concentrated, white to off-white powder that is produced by a microbial process. It contains limited levels of Sialic acid, D-Lactose, D-Glucose, and 3′-Sialyllactulose and 6′-Sialyllactose sodium salts. **Source:** Genetically modified strain of *Escherichia coli* W (ATCC 9637) **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 N°: 128596-80-5 **Characteristics/Composition:** 3′-Sialyllactose sodium salt (% w/w of dry matter): ≥ 82,0 Sialic acid (% w/w of dry matter): ≤ 6,0 D-Lactose (% w/w of dry matter): ≤ 3,0 D-Glucose (% w/w of dry matter): ≤ 3,0 Sum of 3′- Sialyllactulose and 6′-Sialyllactose sodium salts (% w/w of dry matter): ≤ 5,0 Sum of other carbohydrates[a] (% w/w of dry matter): ≤ 12,0 Moisture (% w/w): ≤ 10,5 Sodium (% w/w): ≤ 5,0 pH (25 °C, 5 % solution): 4,5 -7,5 Residual protein (% w/w): ≤ 0,01 **Heavy metals and contaminants:** Arsenic (mg/kg): ≤ 0,2 Lead (mg/kg): ≤ 0,2 Cadmium (mg/kg): ≤ 0,2

▼M135

Authorised Novel Food	Specifications
	Mercury (mg/kg): ≤ 0,1 Aflatoxin M1: < 0,025 (µg/kg) **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g *Enterobacteriaceae*: Absence in 10 g *Cronobacter* spp.: Absence in 10 g *Salmonella* spp.: Absence in 25 g Yeasts and moulds: ≤ 100 CFU/g *Listeria monocytogenes*: Absence in 25 g Presumptive *Bacillus cereus:* ≤ 50 CFU/g Residual endotoxins: ≤ 10 EU/mg [a]Sum of other carbohydrates = 100 % w/w of dry matter – 3′-Sialyllactose (acid, % w/w of dry matter) –quantified carbohydrates ((% w/w of dry matter), Sialic acid + D-Lactose + D-Glucose + (3′- Sialyllactulose and 6′-Sialyllactose (acids)) – sodium (w/w of dry matter); CFU: Colony Forming Units; EU: Endotoxin Units

▼M60

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)

▼M60

Authorised Novel Food	Specifications
	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.

▼M115

6'-**Sialyllactose ('6'-SL') sodium salt** **(produced by derivative strains of *E. coli* BL21(DE3))**	**Description:** 6'-Sialyllactose (6′-SL) sodium salt is a purified, white to off-white powder or agglomerate produced by a microbial process and contains limited levels of lactose, 6'-sialyl-lactulose, and sialic acid. **Definition:** Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Chemical formula: $C_{23}H_{38}NO_{19}Na$ Molecular mass: 655,53 Da CAS No: 157574-76-0 **Source:** Two genetically modified strains (a production strain and an optional degradation strain) of *Escherichia coli* BL21(DE3) **Characteristics/Composition:** 6′-Sialyllactose sodium salt (% of dry matter): ≥ 90,0 % (w/w) 6′-Sialyl-lactulose (% of dry matter): ≤ 3,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) Sialic acid (% of dry matter): ≤ 2,0 % (w/w) N-acetyl-D-glucosamine (% of dry matter): ≤ 3,0 % (w/w) Sum of other carbohydrates (% of dry matter) ([28]): ≤ 5,0 % (w/w) Moisture: ≤ 9,0 % (w/w) Ash: ≤ 8,5 % (w/w) Residual protein: ≤ 0,01 % (w/w) Sodium: ≤ 4,2 % (w/w) **Contaminants:** Arsenic: ≤ 0,2 (mg/kg) Aflatoxin M1: ≤ 0,025 (µg/kg)

▼M115

Authorised Novel Food	Specifications
	Microbiological criteria: Standard plate count: ≤ 1 000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter spp.*: Absence in 10 g Residual endotoxins: ≤ 10 EU/mg

▼M127

6′ -Sialyllactose (6′-SL) sodium salt (produced by derivative strain of *E. coli* W (ATCC 9637))	**Description:** 6′-Sialyllactose (6′-SL) sodium salt is a purified, white to off-white powder that is produced by a microbial process, is further isolated, purified and concentrated. It contains limited levels of Sialic acid, D-Lactose, D-Glucose, 6′-Sialyllactulose, and 3′-Sialyllactose sodium salt. **Source:** Genetically modified strain of *Escherichia coli* W (ATCC 9637) **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:** 6′-Sialyllactose sodium salt (% w/w of dry matter): ≥ 82,0 Sialic acid (% w/w of dry matter): ≤ 6,0 D-Lactose (% w/w of dry matter): ≤ 3,0 D-Glucose (% w/w of dry matter): ≤ 3,0 Sum of 6′- Sialyllactulose and 3′-Sialyllactose sodium salt (% w/w of dry matter): ≤ 5,0 Sum of other carbohydrates[a] (% w/w of dry matter): ≤ 13,0 Moisture (% w/w): ≤ 10,5 Sodium (% w/w): ≤ 5,0 pH (25 °C, 5 % solution): 4,5–7,5 Residual protein (% w/w): ≤ 0,01 **Heavy metals and contaminants:** Arsenic (mg/kg): ≤ 0,2 Aflatoxin M1: < 0,025 (µg/kg)

▼M127

Authorised Novel Food	Specifications
	Microbiological criteria: Total plate count: ≤ 1 000 CFU/g *Enterobacteriaceae*: Absence in 10 g *Cronobacter* spp.: Absence in 10 g *Salmonella* spp.: Absence in 25 g Yeasts and moulds: ≤ 100 CFU/g *Listeria monocytogenes*: Absence in 25 g Presumptive *Bacillus cereus:* ≤ 50 CFU/g Residual endotoxins: ≤ 10 EU/mg [a] Sum of other carbohydrates = 100 % w/w of dry matter – 6′-Sialyllactose (acid, % w/w of dry matter) –quantified carbohydrates ((% w/w of dry matter), Sialic acid + D-Lactose + D-Glucose + (6′- Sialyllactulose and 3′-Sialyllactose (acids)) – sodium (w/w of dry matter); CFU: Colony Forming Units; EU: Endotoxin Units
▼M43 **Spermidine-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
▼M9 **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 %

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
▼M53	
Sugars 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

▼M9

Authorised Novel Food	Specifications
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 %

▼M73

***Synsepalum dulcificum* dried fruits**	**Description/Definition:** The novel food is lyophilised pulp and skin of pitted fruits of *Synsepalum dulcificum* (Schumach. & Thonn.) Daniell that belongs to the Sapotaceae family. The resulting dried cake is milled into a powder. **Characteristics/Composition:** Moisture (g/100 g): < 6 Ash (g/100 g): 3,5-8,5 Total carbohydrates (g/100 g): 70-87 Sugars (g/100 g): 50-75 Fibre (g/100 g): 1-6,5 Total protein (g/100 g): 3,5-6,0 Miraculin ([16]) (g/100 g): 1,5-2,5 Total fat (g/100 g): 0,50-3,50 **Microbiological criteria:** Total aerobic colony count: < 10^4 CFU ([7])/g *Bacillus cereus* (presumptive): < 100 CFU/g Sulfite-reducing *Clostridia*: ≤ 30 CFU/g Total Enterobacteriaceae: < 100 CFU/g Yeasts and moulds: < 500 CFU/g

▼M73

Authorised Novel Food	Specifications
	Pesticides: Pesticide levels in accordance with Code number 0820990 (‘others’ in the group of fruit spices) set out in Regulation (EC) No 396/2005 ([17])

▼M66

Dried *Tenebrio molitor* larva (yellow mealworm)	**Description/Definition:** The novel food is the whole, thermally dried yellow mealworm, either whole (blanched, oven-dried larva) or in the form of a powder (blanched, oven-dried, ground larva). The term ‘mealworm’ refers to the larval form of *Tenebrio molitor*, an insect species that belongs to the family of *Tenebrionidae* (darkling beetles). The entire mealworms are meant for human consumption and no parts are removed. A minimum 24 hours fasting period is required before the thermal drying step, to allow the larvae to discard their bowel content. **Characteristics/Composition:** Ash (% w/w): 3,5 – 4,5 Moisture (% w/w): 1-8 Crude protein (N x 6,25) (% w/w): 56–61 Digestible Carbohydrates ([15]) (% w/w): 1–6 Fat (% w/w): 25–30 of which saturated (% w/w): 4–9 Peroxide value (Meq O_2/kg fat): ≤ 5 Dietary fibre (% w/w): 4–7 Chitin (% w/w): 4–7 **Heavy metals:** Lead: ≤ 0,075 mg/kg Cadmium: ≤ 0,1 mg/kg **Mycotoxins:** Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1: ≤ 2 µg/kg Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg

▼M66

Authorised Novel Food	Specifications
	Microbiological criteria: Total aerobic colony count: ≤ 10^5 CFU (^{7})/g Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: ≤ 50 CFU/g *Salmonella* spp.: Not detected in 25 g *Listeria monocytogenes*: Not detected in 25 g Sulfite-reducing Anaerobes: ≤ 30 CFU/g *Bacillus cereus* (presumptive): ≤ 100 CFU/g Enterobacteriaceae (presumptive): < 10 CFU/g Coagulase-positive *staphylococci*: ≤ 100 CFU/g

▼M81

Frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva)

Description/Definition:

The novel food are frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva). The term 'mealworm' refers to the larval form of *Tenebrio molitor*, an insect species that belongs to the family of Tenebrionidae (darkling beetles). Another identified scientific synonym is *Tenebrio molitor* Linnaeus.

The entire mealworms are meant for human consumption, no parts are removed.

A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the larvae to discard their bowel content.

The novel food is intended to be placed on the market in three different forms, namely: whole, blanched and frozen *T. molitor* larva (frozen); whole, blanched and freeze-dried *T. molitor* larva (dried) which may be in powder form (powder).

Parameters	Frozen	Dried or powder
Characteristics/Composition		
Ash	0,9-1,10	3,6-4,1
Moisture (% w/w)	69-75	≤ 5
Crude protein (N x 6,25) (% w/w)	14-19	54-60

▼M81

Authorised Novel Food	Specifications		
	Fat (% w/w) — of which saturated fatty acids (% fat)	7-12,5 20-29	27-30 20-29
	Digestible carbohydrates (% w/w)	1-2	4-8
	Dietary fibre (% w/w)	1,2-3,5	4-6
	Chitin(*) (% w/w)	≤ 3	4-9
	Peroxide value (Meq O_2/kg fat)	≤ 5	≤ 5
	Contaminants		
	Heavy metals		
	Lead (mg/kg)	≤ 0,01	≤ 0,075
	Cadmium (mg/kg)	≤ 0,05	≤ 0,1
	Mycotoxins		
	Aflatoxins (Sum of B1, B2, G1, G2) (µg/kg)	≤ 4	≤ 4
	Aflatoxin B1 (µg/kg)	≤ 2	≤ 2
	Deoxynivalenol (µg/kg)	≤ 200	≤ 200
	Ochratoxin A (µg/kg)	≤ 1	≤ 1
	Dioxins and PCBs		
	Sum of dioxins and dl-PCBs (UB, WHO-TEQ2005)(**) (pg/g fat)	≤ 0,75	≤ 0,75

▼M81

Authorised Novel Food	Specifications		
	Microbiological criteria		
	Total aerobic colony count (CFU/g)	≤ 10^5	≤ 10^5
	Enterobacteriaceae (presumptive) (CFU/g)	≤ 100	≤ 100
	Escherichia coli (CFU/g)	≤ 50	≤ 50
	Listeria monocytogenes	Absence in 25g	Absence in 25g
	Salmonella spp.	Absence in 25g	Absence in 25g
	Bacillus cereus (presumptive) (CFU/g)	≤ 100	≤ 100
	Coagulase positive Staphylococci (CFU/g	≤ 100	≤ 100
	Sulfite-reducing Anaerobes (CFU/g)	≤ 30	≤ 30
	Yeasts and moulds (CFU/g)	≤ 100	≤ 100
	(*) Chitin calculated as the difference between the Acid Detergent Fibre fraction and the Acid Detergent Lignin fraction (ADF-ADL), as described by Hahn et al. (2018).		
	(**) Upper bound sum of polychlorinated dibenzo-para-dioxins (PCDDs)-polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) expressed as World Health Organization toxic equivalent (using WHO-TEFs of 2005)).		
	CFU: colony forming units.		

▼M89

Tetrahydrocurcuminoids	**Description:**
	The tetrahydrocurcuminoids are produced via a series of steps involving the extraction of curcuminoids from the dried, pulverised rhizomes of turmeric (*Curcuma longa* L.), hydrogenation (using palladium on carbon (Pd/C) as a catalyst), concentration, crystallisation, drying, and milling into a powder.
	Characteristics/Composition:
	Total tetrahydrocurcuminoids (dry basis) (% w/w): > 95,0
	Moisture (% w/w): ≤ 1,0
	Ash (% w/w): ≤ 1,0
	Palladium (mg/kg): < 5,0

▼M89

Authorised Novel Food	Specifications
	Microbiological criteria: Total aerobic microbial count: ≤ 5 000 CFU/g Total yeast/moulds count: ≤ 100 CFU/g *Escherichia coli*: < 10 CFU/g *Staphylococcus aureus*: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Coliforms: ≤ 10 CFU/g CFU: Colony Forming Units
▼M9 **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

▼M9

Authorised Novel Food	Specifications
***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

▼M9

Authorised Novel Food	Specifications
	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° (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
►M52 **Taxifolin-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. ►M52 **Definition:** 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

▼M9

Authorised Novel Food	Specifications
	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 %.

▼M9

Authorised Novel Food	Specifications
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:

▼M9

Authorised Novel Food	Specifications
	% trehalose = 100 × (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° (5 % aqueous solution, dihydrate), +199° (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
▼M52 **UV-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.

▼M9

Authorised Novel Food	Specifications
▼M84	
UV-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_2 (ergocalciferol). Vitamin D_2 content in the yeast concentrate varies between 800 000 – 3 500 000 IU vitamin D/100 g (200-875 µg/g). The yeast shall be inactivated for use in infant formula and follow-on formula, processed cereal-based food and foods for special medical purposes as defined by Regulation (EU) No 609/2013, while for use in other foods the yeast may or may not be inactivated. 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_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 **Microbiological criteria for the yeast concentrate** Coliforms: $\leq 10^3$/g *Escherichia coli*: $\leq$ 10/g *Salmonella*: Absence in 25 g
▼M9	
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.

▼M9

Authorised Novel Food	Specifications
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

▼M51

Vitamin 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 ([12]) Moisture: ≤ 10,0 % Ash: ≤ 13,5 %

▼M51

Authorised Novel Food	Specifications
	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 (7)/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
▼M76 **Vitamin D_2 mushroom powder**	**Description/Definition:** The novel food is mushroom powder produced from the dried whole *Agaricus bisporus* mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to UV irradiation. UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under Regulation (EU) 2015/2283. **Characteristics/composition:** Vitamin D_2 content: 580-595 µg/g of mushroom powder Ash: ≤ 13,5 % Water activity: < 0,5 Moisture content: ≤ 7,5 % Carbohydrates: ≤ 35,0 %

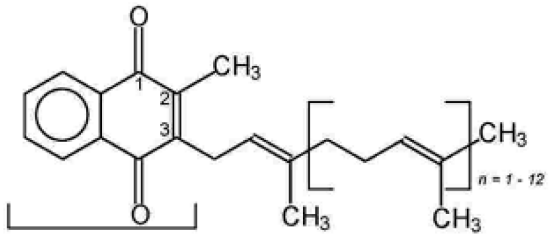
▼M76

Authorised Novel Food	Specifications
	Total Dietary Fibre: ≥ 15 % Crude protein (N × 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: ≤ 0,10 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria:** Total plate count: ≤ 5 000 CFU ([17]) Total yeast and mould count: < 100 CFU/g *E. 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
▼M98 **Vitamin D_2 mushroom powder**	**Description/Definition:** The novel food is produced by controlled exposure of sliced/diced *Agaricus bisporus* mushrooms to UV irradiation followed by dehydration and grinding into a powder. UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under Regulation (EU) 2015/2283. **Characteristics/composition:** Vitamin D_2 content: 125–375 µg/g Moisture: ≤ 7 %

▼M98

Authorised Novel Food	Specifications
	Ash: ≤ 13,5 % Water activity: < 0,5 Fat: ≤ 4,5 % Total carbohydrates: ≤ 60 % Protein: ≤ 40 % **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: ≤ 2 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria:** Total aerobic microbial count: ≤ 5 000 CFU/g Total yeast and mould count: < 100 CFU/g Coliforms: < 100 MPN/g *Salmonella* spp.: Absence in 25 g *Staphylococcus aureus*: Absence in 10 g *Escherichia coli*: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g CFU: colony forming units. MPN: most probable number.
▼M9 **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: $C_{46}H_{64}O_2$

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
	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
▼M78 *Wolffia arrhiza* and/or *Wolffia globosa* fresh plants (Traditional food from a third country)	**Description/Definition:** The traditional food consists of fresh plants of *Wolffia arrhiza* (L.) Horkel ex Wimm. and/or of *Wolffia globosa* (Roxb.) Hartog & Plas (family: Araceae). **Microbiological criteria:** Total plate count: < 10^3 CFU/g Total yeast and mould count: < 100 CFU/g Total Enterobacteriaceae: < 100 CFU/g *Escherichia coli*: < 100 CFU/g *Salmonella*: Absence in 25 g *Listeria monocytogenes*: Absence in 25 g *Staphylococcus aureus*: Absence/10 g **Heavy metals:** Lead: < 0,3 mg/kg Arsenic (inorganic): < 0,10 mg/kg Cadmium: < 0,2 mg/kg Chromium: < 1 mg/kg Mercury: < 0,10 mg/kg **Trace elements:** Copper: < 0,8 mg/kg Molybdenum: < 0,3 mg/kg Zinc: < 5 mg/kg

▼M78

Authorised Novel Food	Specifications
	Boron: < 5 mg/kg Manganese: < 6 mg/kg **Cyanotoxins:** Microcystins: 0,006 µg/g **Pesticides:** Pesticide levels in accordance with Code number 0254000 ('Subgroup (d) watercresses' in the group of Leaf vegetables, herbs and edible flowers) set out in Regulation (EC) No 396/2005 ([17]).

▼M19
▼M20

Xylo-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	-
Dry material (%)	-	-	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

▼M20

Authorised Novel Food	Specifications			
	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		
	[a] Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose. [b] Maltodextrin content is calculated according to the amount added in the process. DP: Degree of polymerization [c] CFU: Colony Forming Units [d] MPN: Most Probable Number			

▼M9

Authorised Novel Food	Specifications
▼M140	
***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 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 lipolytic*a cells[(a)]: < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g Salmonella spp.: Not detected in 25 g **Contaminants**: Lead: ≤ 0,1 mg/kg Mercury: ≤ 0,1 mg/kg Cadmium: ≤ 0,1 mg/kg Arsenic: ≤ 0,15 mg/kg Abbreviations: CFU, colony forming units (a) To be tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable Y. lipolytica cells during packaging and/or storage of the novel food
▼M9	
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.

▼M9

Authorised Novel Food	Specifications
	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

▼M9

Authorised Novel Food	Specifications
	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:* ►**M32** 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

▼M9

Authorised Novel Food	Specifications
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°- 22,8° 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

▼M9

Authorised Novel Food	Specifications
	Microbiological criteria: Total viable mesophilic count: ≤ 1 000 CFU/g Yeasts and moulds: ≤ 100 CFU/g Pathogen: Absence

(*) Cornell RM and Schwertmann U, 2003. The Iron Oxides: Structure, Properties, Reactions, Occurrences and Uses. 2nd Edition. Wiley. https://doi.org/10.1002/3527602097

(1) 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).

(2) 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).

►M15 (3) OSC-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.

(4) 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.

(5) The different values for these three parameters are due to the different methods used.

(6) GAE: Gallic Acid Equivalents.

(7) CFU: Colony Forming Units. ◄

►M30 (8) HPLC/RI: High-performance liquid chromatography coupled with refractive index detection.

(9) CFU: Colony-forming unit. ◄

(10) To 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.

(11) 2′-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates.

►M51 (12) Converted from International Units (IU) using the conversion factor of 0,025 µg = 1 IU. ◄

(13) Expressed as selenium.

(14) Applicable at all stages after the heat-treatment step to guarantee the absence of viable *Yarrowia lipolytica* cells and to be first 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 novel food.

(15) Digestible carbohydrates = 100 – (crude protein + fat + dietary fibre + ash + moisture).

(16) Miraculin is part of the total protein content.

(17) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

(18) Dietary fibre may not include chitin due to different analytical methods.

(19) Upper bound sum of polychlorinated dibenzo-para-dioxins (PCDDs)-polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) expressed as World Health Organization toxic equivalent (using WHO-TEFs of 2005)).

(20) Number-based (by Transmission Electron Microscopy (TEM)).

(21) Volume-based (hydrodynamic diameter by Dynamic Light Scattering (DLS)); CFU: Colony Forming Units.

(22) Chitin calculated as the difference between the Acid Detergent Fibre fraction and the Acid Detergent Lignin fraction (ADF-ADL), as described by Hahn et al. (2018).

(23) Upper bound sum of polychlorinated dibenzo-para-dioxins (PCDDs)-polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) expressed as World Health Organization Toxic Equivalent Factors (using WHO-TEFs of 2005)).
CFU: Colony Forming Units.

(24) Sum of other carbohydrates = 100 (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter).

(25) CFU: Colony Forming Units.

▼M9

([26]) EU: Endotoxin Units.
([27]) Chitin calculated as Acid Detergent Fibre.
([28]) Sum of other carbohydrates = 100 (% (w/w) of dry matter) – 6'-Sialyllactose sodium salt (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter); CFU: Colony Forming Units; EU: Endotoxin Units.
([29]) Other carbohydrates (g/100g) = 100 (Dry residue) – Ash – Protein (Nitrogen × 6,25) – Total fat – Succinic acid – L-malic acid – Dietary fibre
([30]) Expressed as total dietary fibre.
([31]) 9b,10a-Cholesta-5,7-diene-3b,25-diol (25(OH)).
([32]) Cholesta-5,7-diene-3b,25-diol.
([33]) (6E)-9,10-Secocholesta-5(10),6,8-triene-3b,25-diol (iso-25(OH)).
([34]) (5E,7E)-9,10-Secocholesta-5,7,10(19)-triene-3b,25-diol.