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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

This issue closes the L series for 2017.

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2017/2466

of 18 December 2017

amending Regulation (EU) No 1388/2013 opening and providing for the management of autonomous tariff quotas of the Union for certain agricultural and industrial products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 31 thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) In order to ensure the sufficient and uninterrupted supply of certain goods insufficiently produced in the Union and to avoid disturbances on the market for certain agricultural and industrial products, autonomous tariff quotas were opened by Council Regulation (EU) No 1388/2013 ([1]). Products within those tariff quotas can be imported into the Union at reduced or zero duty rates.

(2) For those reasons, it is necessary to open, with effect from 1 January 2018, tariff quotas at zero duty rates for an appropriate volume as regards 12 new products. In the case of five additional products, the quota volumes should be increased, as an increase is in the interests of economic operators of the Union.

(3) In the case of one additional product, the quota volume should be decreased, as the production capacity of the Union producers has been increased.

(4) In the case of five products, the quota period and the quota volume should be adapted, as they had been opened for a period of 6 months only.

(5) In the case of another product, its description should be amended.

(6) In the case of 12 other products, the autonomous tariff quotas of the Union should be closed with effect from 1 January 2018, as it is not in the Union's interest to maintain those quotas as from that date.

(7) Regulation (EU) No 1388/2013 should therefore be amended accordingly.

(8) In order to avoid any interruption of the application of the quota scheme and to comply with the guidelines set out in the Communication from the Commission concerning autonomous tariff suspensions and quotas ([2]), the changes provided for in this Regulation regarding the quotas for the products concerned have to apply from 1 January 2018. This Regulation should therefore enter into force as a matter of urgency,

([1]) Council Regulation (EU) No 1388/2013 of 17 December 2013 opening and providing for the management of autonomous tariff quotas of the Union for certain agricultural and industrial products, and repealing Regulation (EU) No 7/2010 (OJ L 354, 28.12.2013, p. 319).
([2]) OJ C 363, 13.12.2011, p. 6.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 1388/2013 is amended as follows:

(1) the rows for the tariff quotas with order numbers 09.2872, 09.2874, 09.2878, 09.2880, 09.2886, 09.2876, 09.2888, 09.2866, 09.2906, 09.2909, 09.2910 and 09.2932 set out in Annex I to this Regulation are inserted into the table according to the order of the CN codes indicated in the second column;

(2) in the table, the rows for the tariff quotas with order numbers 09.2828, 09.2929, 09.2704, 09.2842, 09.2844, 09.2671, 09.2846, 09.2723, 09.2848, 09.2870, 09.2662, 09.2850 and 09.2868 are replaced by the corresponding rows set out in Annex II to this Regulation;

(3) in the table, the rows for the tariff quotas with order numbers 09.2703, 09.2691, 09.2692, 09.2680, 09.2977, 09.2693, 09.2712, 09.2714, 09.2666, 09.2687, 09.2689 and 09.2669 are deleted;

(4) endnote (*) containing the text 'A newly introduced measure or a measure with amended conditions.' is deleted.

Article 2

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

It shall apply from 1 January 2018.

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

Done at Brussels, 18 December 2017.

For the Council
The President
K. SIMSON

ANNEX I

In the table in the Annex to Regulation (EU) No 1388/2013, the following rows are inserted according to the order of the CN codes indicated in the second column of that table:

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
'09.2872	ex 2833 29 80	40	Cesium sulphate (CAS RN 10294-54-9) in solid form or as aqueous solution containing by weight 48 % or more but not more than 52 % of cesium sulphate	1.1.-31.12.	160 tonnes	0
09.2874	ex 2924 29 70	87	Paracetamol (INN) (CAS RN 103-90-2)	1.1.-31.12.	20 000 tonnes	0
09.2878	ex 2933 29 90	85	Enzalutamide INN (CAS RN 915087-33-1)	1.1.-31.12.	1 000 kg	0
09.2880	ex 2933 59 95	39	Ibrutinib (INN) (CAS RN 936563-96-1)	1.1.-31.12.	5 tonnes	0
09.2886	ex 2934 99 90	51	Canagliflozin (INN) (CAS RN 928672-86-0)	1.1.-31.12.	10 tonnes	0
09.2876	ex 3811 29 00	55	Additives consisting of reaction products of diphenylamine and branched nonenes with: — by weight more than 28 %, but not more than 35 % of 4-monononyldiphenylamine, and — by weight more than 50 % but not more than 65 % of 4,4′-dinonyldiphenylamine, — by weight a total percentage of 2, 4-dinonyldiphenylamine and 2, 4′-dinonyldiphenylamine of not more than 5 %, used for the manufacture of lubricating oils [2]	1.1.-31.12.	900 tonnes	0
09.2888	ex 3824 99 92	89	Mixture of tertiary alkyldimethyl amines containing by weight: — 60 % or more but not more than 80 % of dodecyldimethylamine (CAS RN 112-18-5), and — 20 % or more but not more than 30 % of dimethyl(tetradecyl)amine (CAS RN 112-75-4)	1.1.-31.12.	16 000 tonnes	0
09.2866	ex 7019 12 00 ex 7019 12 00	06 26	S glass stratifils (rovings): — composed of continuous glass filaments of 9 µm (± 0,5 µm), — measuring 200 tex or more but not more than 680 tex, — not containing any calcium oxide, and — with a breaking strength of more than 3 550 Mpa determined by ASTM D2343-09 for use in the manufacture of aeronautics [2]	1.1.-31.12.	1 000 tonnes	0

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
09.2906	ex 7609 00 00	20	Aluminium tube or pipe fittings for affixing to radiators of motor bikes (2)	1.1.-31.12.	3 000 000 pieces	0
09.2909	ex 8481 80 85	40	Exhaust valve for use in the manufacture of motorcycle exhaust gas systems (2)	1.1.-31.12.	1 000 000 pieces	0
09.2910	ex 8708 99 97	75	Aluminium alloy support bracket, with mounting holes, whether or not with fixation nuts, for indirect connection of the gearbox to the car body for use in the manufacture of goods of Chapter 87 (2)	1.1.-31.12.	200 000 pieces	0
09.2932	ex 9027 10 90	20	Lambda sensors for permanent incorporation into motor cycle exhaust systems (2)	1.1.-31.12.	1 000 000 pieces	0’.

(2) Suspension of duties is subject to end-use customs supervision in accordance with Article 254 of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

ANNEX II

In the table in the Annex to Regulation (EU) No 1388/2013, the rows for the tariff quotas with order numbers 09.2828, 09.2929, 09.2704, 09.2842, 09.2844, 09.2671, 09.2846, 09.2723, 09.2848, 09.2870, 09.2662, 09.2850 and 09.2868 are replaced by the following:

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
'09.2828	2712 20 90		Paraffin wax containing by weight less than 0,75 % of oil	1.1.-31.12.	120 000 tonnes	0
09.2929	2903 22 00		Trichloroethylene (CAS RN 79-01-6)	1.1.-31.12.	15 000 tonnes	0
09.2704	ex 2909 49 80	20	2,2,2′,2′-Tetrakis(hydroxymethyl)-3,3′-oxy-dipropan-1-ol (CAS RN 126-58-9)	1.1.-31.12.	500 tonnes	0
09.2842	2932 12 00		2-Furaldehyde (furfuraldehyde)	1.1.-31.12.	10 000 tonnes	0
09.2844	ex 3824 99 92	71	Mixtures containing by weight: — 60 % or more but not more than 90 % of 2-chloropropene (CAS RN 557-98-2), — 8 % or more but not more than 14 % of (Z)-1-chloropropene (CAS RN 16136-84-8), — 5 % or more but not more than 23 % of 2-chloropropane (CAS RN 75-29-6), — not more than 6 % of 3-chloropropene (CAS RN 107-05-1), and — not more than 1 % of ethyl chloride (CAS RN 75-00-3)	1.1.-31.12.	6 000 tonnes	0
09.2671	ex 3905 99 90	81	Poly(vinyl butyral)(CAS RN 63148-65-2): — containing by weight 17,5 % or more, but not more than 20 % of hydroxyl groups, and — with a median particle size (D50) of more than 0,6 mm	1.1.-31.12.	12 500 tonnes	0
09.2846	ex 3907 40 00	25	Polymer blend of polycarbonate and poly(methyl methacrylate) with a poly-carbonate content of not less than 98,5 % by weight, in the form of pellets or granules, with a luminous transmittance of not less than 88,5 %, measured using a test sample with a thickness of 4 mm at a wavelength of λ = 400 nm (according to ISO 13468-2)	1.1.-31.12.	2 000 tonnes	0
09.2723	ex 3911 90 19	10	Poly(oxy-1,4-phenylenesulphonyl-1,4-phenyl-eneoxy-4,4′-biphenylene)	1.1.-31.12.	3 500 tonnes	0

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
09.2848	ex 5505 10 10	10	Waste of synthetic fibres (including noils, yarn waste, and garnetted stock) of nylon or other polyamides (PA6 and PA66)	1.1.-31.12.	10 000 tonnes	0
09.2870	ex 7019 40 00 ex 7019 52 00	70 30	E-fibre glass fabrics: — having a weight of 20 g/m² or more, but not more than 214 g/m², — impregnated with silane, — in rolls, — having a humidity content by weight of 0,13 % or less, and — having not more than 3 hollow fibres out of 100 000 fibres, for the exclusive use in the manufacture of prepregs and copper clad laminates (2)	1.1.-31.12.2018	6 000 000 m	0
09.2662	ex 7410 21 00	55	Plates: — consisting of at least one layer of fibre-glass fabric impregnated with epoxide resin, — covered on one or both sides with copper foil with a thickness of not more than 0,15 mm, — with a dielectric constant (DK) of less than 5,4 at 1 MHz, as measured according to IPC-TM-650 2.5.5.2, — with a loss tangent of less than 0,035 at 1 MHz, as measured according to IPC-TM-650 2.5.5.2, — with a comparative tracking index (CTI) of 600 or more	1.1.-31.12.	80 000 m²	0
09.2850	ex 8414 90 00	70	Aluminium alloy compressor wheel with: — a diameter of 20 mm or more, but not more than 130 mm, and — a weight of 5 g or more, but not more than 800 g for use in the manufacture of combustion engines (2)	1.1.-31.12.	5 900 000 pieces	0
09.2868	ex 8714 10 90	60	Pistons for suspension systems, having a diameter of not more than 55 mm, of sintered steel	1.1.-31.12.	2 000 000 pieces	0'.

(2) Suspension of duties is subject to end-use customs supervision in accordance with Article 254 of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

COUNCIL REGULATION (EU) 2017/2467

of 21 December 2017

amending Regulation (EU) No 1387/2013 suspending the autonomous Common Customs Tariff duties on certain agricultural and industrial products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 31 thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Union production of 67 products that are not listed in the Annex to Council Regulation (EU) No 1387/2013 ([1]) is not sufficient to cover the needs of the Union industry. It is therefore in the interest of the Union to suspend the autonomous Common Customs Tariff ('CCT') duties on those products.

(2) It is necessary to modify the conditions for the suspension of autonomous CCT duties for 49 products listed in the Annex to Regulation (EU) No 1387/2013 in order to take into account technical product developments and economic trends on the market. Certain product classifications have been amended in order to allow industry to fully benefit from the suspensions in force. Moreover, the Annex to Regulation (EU) No 1387/2013 should be updated in order to align or clarify texts in some cases. The modified conditions relate to changes in the product description, classification, duty rates or end-use requirements.

(3) The end dates for the mandatory review provided for in the Annex to Regulation (EU) No 1387/2013 should be revised for 188 suspensions.

(4) It is no longer in the interest of the Union to maintain the suspension of autonomous CCT duties for 92 products listed in the Annex to Regulation (EU) No 1387/2013. Suspensions for those products should therefore be deleted from that Annex.

(5) In the interests of clarity, the entries for the suspensions that are modified or newly introduced by this Regulation should be marked with an asterisk, whereas the asterisk should be removed from the entries for the suspensions that are not modified by this Regulation.

(6) Regulation (EU) No 1387/2013 should therefore be amended accordingly.

(7) In order to avoid any interruption of the application of the autonomous suspension scheme and to comply with the guidelines set out in the Communication from the Commission concerning autonomous tariff suspensions and quotas ([2]), the changes provided for in this Regulation regarding the suspensions for the products concerned have to apply from 1 January 2018. This Regulation should therefore enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 1387/2013 is amended as follows:

(1) in the table, the rows for the products for which the CN and TARIC codes are set out in Annex I to this Regulation are deleted;

(2) all asterisks in the table and endnote (*), containing the text 'A newly introduced measure or a measure with amended conditions.', are deleted;

(3) the rows for the products listed in Annex II to this Regulation are inserted into the table according to the order of the CN codes indicated in the first column of that table.

([1]) Council Regulation (EU) No 1387/2013 of 17 December 2013 suspending the autonomous Common Customs Tariff duties on certain agricultural and industrial products and repealing Regulation (EU) No 1344/2011 (OJ L 354, 28.12.2013, p. 201).

([2]) OJ C 363, 13.12.2011, p. 6.

Article 2

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

It shall apply from 1 January 2018.

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

Done at Brussels, 21 December 2017.

For the Council
The President
M. MAASIKAS

ANNEX I

In the table set out in the Annex to Regulation (EU) No 1387/2013, the rows relating to suspensions for the products identified by the following CN and TARIC codes are deleted:

CN code	TARIC
ex 1511 90 19	20
ex 1511 90 91	20
ex 1513 11 10	20
ex 1513 19 30	20
ex 1513 21 10	20
ex 1513 29 30	20
ex 2007 99 50	81
ex 2007 99 50	82
ex 2007 99 50	83
ex 2007 99 50	84
ex 2007 99 50	85
ex 2007 99 50	91
ex 2007 99 50	92
ex 2007 99 50	93
ex 2007 99 50	94
ex 2007 99 50	95
ex 2007 99 93	10
ex 2008 93 91	20
ex 2008 99 49	70
ex 2008 99 99	11
ex 2804 50 90	10
ex 2805 19 90	20
ex 2811 19 80	30
ex 2811 22 00	70
ex 2816 40 00	10
ex 2823 00 00	10
ex 2823 00 00	20
ex 2825 10 00	10
ex 2825 60 00	10
ex 2835 10 00	10
ex 2837 20 00	20
ex 2839 19 00	10
ex 2841 80 00	10
ex 2841 90 85	10
ex 2850 00 20	30
ex 2850 00 20	50
2903 39 31	
ex 2903 39 35	10
ex 2903 89 80	50

CN code	TARIC
ex 2904 99 00	40
ex 2905 19 00	70
ex 2905 19 00	80
ex 2905 39 95	20
ex 2905 39 95	40
ex 2906 29 00	30
ex 2907 29 00	55
ex 2908 99 00	40
ex 2909 60 00	40
ex 2912 29 00	50
ex 2912 49 00	20
ex 2914 19 90	20
ex 2914 19 90	30
ex 2914 19 90	40
ex 2914 39 00	30
ex 2914 39 00	70
ex 2914 39 00	80
ex 2914 50 00	45
ex 2914 50 00	60
ex 2914 50 00	70
ex 2914 79 00	20
ex 2915 60 19	10
ex 2915 90 70	30
ex 2915 90 70	75
ex 2916 12 00	70
ex 2916 13 00	10
ex 2916 39 90	55
ex 2916 39 90	75
ex 2916 39 90	85
ex 2917 19 10	20
ex 2917 39 95	70
ex 2918 29 00	35
ex 2918 30 00	50
ex 2918 99 90	15
ex 2920 29 00	50
ex 2920 29 00	60
ex 2920 90 10	60
ex 2920 90 70	40
ex 2920 90 70	50
2921 13 00	
ex 2921 19 99	70
ex 2921 30 99	40
ex 2921 42 00	86
ex 2921 42 00	87
ex 2921 42 00	88

CN code	TARIC
ex 2921 43 00	80
ex 2921 49 00	85
ex 2921 59 90	30
ex 2921 59 90	60
ex 2922 19 00	20
ex 2922 19 00	25
ex 2922 49 85	20
ex 2922 49 85	60
ex 2924 19 00	80
ex 2924 29 70	51
ex 2924 29 70	53
ex 2924 29 70	86
ex 2924 29 70	87
ex 2925 19 95	20
ex 2925 19 95	30
ex 2927 00 00	80
ex 2928 00 90	60
ex 2929 10 00	20
ex 2929 10 00	55
ex 2929 10 00	80
ex 2930 20 00	10
ex 2930 90 98	65
ex 2930 90 98	66
ex 2930 90 98	68
ex 2930 90 98	83
ex 2931 39 90	08
ex 2931 39 90	25
ex 2932 14 00	10
ex 2932 20 90	20
ex 2932 20 90	40
ex 2932 99 00	25
ex 2932 99 00	80
ex 2933 19 90	80
ex 2933 19 90	85
ex 2933 29 90	80
ex 2933 39 99	12
ex 2933 39 99	18
ex 2933 39 99	50
ex 2933 39 99	57
ex 2933 49 10	30
ex 2933 49 90	25
ex 2933 59 95	77
ex 2933 59 95	88
ex 2933 79 00	30
ex 2933 99 80	18

CN code	TARIC
ex 2933 99 80	24
ex 2933 99 80	28
ex 2933 99 80	43
ex 2933 99 80	47
ex 2933 99 80	51
ex 2934 10 00	15
ex 2934 10 00	25
ex 2934 10 00	35
ex 2934 20 80	40
ex 2934 30 90	10
ex 2934 99 90	14
ex 2934 99 90	18
ex 2934 99 90	22
ex 2934 99 90	35
ex 2934 99 90	37
ex 2934 99 90	38
ex 2934 99 90	74
ex 2935 90 90	73
ex 2940 00 00	40
ex 3204 11 00	30
ex 3204 11 00	70
ex 3204 11 00	80
ex 3204 12 00	20
ex 3204 12 00	30
ex 3204 13 00	20
ex 3204 13 00	30
ex 3204 13 00	40
ex 3204 17 00	12
ex 3204 17 00	60
ex 3204 17 00	75
ex 3204 17 00	80
ex 3204 17 00	85
ex 3204 17 00	88
ex 3204 19 00	52
ex 3204 19 00	84
ex 3204 19 00	85
ex 3205 00 00	20
ex 3207 40 85	40
ex 3208 90 19	25
ex 3208 90 19	35
ex 3208 90 19	75
ex 3208 90 91	20
ex 3215 11 90	10
ex 3215 19 90	10
ex 3215 19 90	20

CN code	TARIC
ex 3402 13 00	20
ex 3707 90 29	50
ex 3802 90 00	11
ex 3808 91 90	60
ex 3808 93 15	10
ex 3811 21 00	30
ex 3811 21 00	50
ex 3811 21 00	60
ex 3811 21 00	70
ex 3811 21 00	85
ex 3811 29 00	20
ex 3811 29 00	30
ex 3811 29 00	40
ex 3811 29 00	50
ex 3811 29 00	55
ex 3811 90 00	40
ex 3812 39 90	80
ex 3815 19 90	87
ex 3815 90 90	16
ex 3815 90 90	18
ex 3815 90 90	71
ex 3815 90 90	85
ex 3824 99 92	22
ex 3824 99 92	35
ex 3824 99 92	39
ex 3824 99 92	44
ex 3824 99 92	47
ex 3824 99 92	48
ex 3824 99 92	49
ex 3824 99 92	50
ex 3824 99 92	80
ex 3824 99 92	83
ex 3824 99 92	86
ex 3824 99 93	57
ex 3824 99 93	63
ex 3824 99 93	77
ex 3824 99 93	83
ex 3824 99 93	88
ex 3824 99 96	50
ex 3824 99 96	79
ex 3824 99 96	85
ex 3824 99 96	87
ex 3902 10 00	10
ex 3902 10 00	50
ex 3903 90 90	15

CN code	TARIC
ex 3904 69 80	85
ex 3905 30 00	10
ex 3905 91 00	30
ex 3906 90 90	27
ex 3907 20 20	20
ex 3907 30 00	60
ex 3907 69 00	50
ex 3907 99 80	25
ex 3907 99 80	60
ex 3907 99 80	70
ex 3908 90 00	60
ex 3909 40 00	30
ex 3910 00 00	50
ex 3911 90 19	30
ex 3911 90 99	53
ex 3911 90 99	57
ex 3919 10 80	40
ex 3919 10 80	45
ex 3919 10 80	47
ex 3919 10 80	53
ex 3919 10 80	55
ex 3919 90 80	25
ex 3919 90 80	32
ex 3919 90 80	34
ex 3919 90 80	36
ex 3919 90 80	38
ex 3919 90 80	40
ex 3919 90 80	42
ex 3919 90 80	43
ex 3919 90 80	44
ex 3919 90 80	45
ex 3919 90 80	47
ex 3919 90 80	53
ex 3919 90 80	60
ex 3920 10 28	93
ex 3920 10 40	30
ex 3920 10 89	50
ex 3920 20 29	55
ex 3920 20 29	94
ex 3920 20 80	93
ex 3920 20 80	95
ex 3920 49 10	95
ex 3920 62 19	60
ex 3920 99 28	55
ex 3921 13 10	20

CN code	TARIC
ex 3921 90 60	95
ex 3926 90 92	40
ex 3926 90 97	20
ex 3926 90 97	77
ex 4104 41 19	10
ex 5407 10 00	10
ex 5603 11 10	20
ex 5603 11 90	20
ex 5603 12 90	50
ex 6909 19 00	15
ex 7005 10 30	10
ex 7009 10 00	50
ex 7019 12 00	05
ex 7019 12 00	25
ex 7019 19 10	15
ex 7019 19 10	50
ex 7409 19 00	10
ex 7410 21 00	70
ex 7601 20 20	10
ex 7607 20 90	10
ex 7616 99 90	75
ex 8102 10 00	10
ex 8105 90 00	10
ex 8108 20 00	50
ex 8108 90 30	20
ex 8108 90 50	10
ex 8108 90 50	15
ex 8108 90 50	30
ex 8108 90 50	35
ex 8108 90 50	50
ex 8108 90 50	60
ex 8108 90 50	75
ex 8113 00 90	10
ex 8207 30 10	10
ex 8407 33 20	10
ex 8407 33 80	10
ex 8407 90 80	10
ex 8407 90 90	10
ex 8408 90 43	40
ex 8408 90 45	30
ex 8408 90 47	50
ex 8409 91 00	20
ex 8409 91 00	30
ex 8409 99 00	50
ex 8411 99 00	60

CN code	TARIC
ex 8411 99 00	65
ex 8414 59 25	30
ex 8415 90 00	50
ex 8431 20 00	30
ex 8481 80 69	60
ex 8482 10 10	30
ex 8482 10 90	20
ex 8483 30 38	40
ex 8501 10 99	60
ex 8501 31 00	25
ex 8501 31 00	33
ex 8501 31 00	35
ex 8501 32 00	70
ex 8501 62 00	30
ex 8503 00 99	40
ex 8504 31 80	20
ex 8504 31 80	40
ex 8504 40 82	40
ex 8504 50 95	50
ex 8505 11 00	35
ex 8505 11 00	50
ex 8505 11 00	60
ex 8506 90 00	10
ex 8507 60 00	25
ex 8507 60 00	50
ex 8507 60 00	53
ex 8507 60 00	55
ex 8507 60 00	57
ex 8511 30 00	50
ex 8512 90 90	10
ex 8516 90 00	70
ex 8518 29 95	30
ex 8522 90 80	15
ex 8522 90 80	96
ex 8525 80 19	45
ex 8529 90 65	75
ex 8529 90 92	70
ex 8536 69 90	51
ex 8536 69 90	81
ex 8536 69 90	88
ex 8536 90 95	30
ex 8537 10 91	30
ex 8537 10 98	92
ex 8544 20 00	20
ex 8544 30 00	35

CN code	TARIC
ex 8544 30 00	80
ex 8544 42 90	30
ex 8544 42 90	60
ex 8548 10 29	10
ex 8548 90 90	50
ex 8704 23 91	20
ex 8708 40 20	10
ex 8708 40 50	20
ex 8708 50 20	30
ex 8708 50 99	20
ex 8708 93 10	20
ex 8708 93 90	20
ex 8708 99 10	20
ex 8708 99 97	70
ex 9001 20 00	10
ex 9001 20 00	40
ex 9001 50 41	30
ex 9001 50 49	30
ex 9001 90 00	25
ex 9001 90 00	60
ex 9001 90 00	75
ex 9002 11 00	20
ex 9002 11 00	30
ex 9002 11 00	40
ex 9002 11 00	70
ex 9002 11 00	80
ex 9002 90 00	40
ex 9032 89 00	40

ANNEX II

In the table set out in the Annex to Regulation (EU) No 1387/2013, the following rows are inserted according to the order of the CN codes indicated in the first column of that table:

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 1511 90 19 *ex 1511 90 91 *ex 1513 11 10 *ex 1513 19 30 *ex 1513 21 10 *ex 1513 29 30	20 20 20 20 20 20	Palm oil, coconut (copra) oil, palm kernel oil, for the manufacture of: — industrial monocarboxylic fatty acids of subheading 3823 19 10, — methyl esters of fatty acids of heading 2915 or 2916, — fatty alcohols of subheadings 2905 17, 2905 19 and 3823 70 used for the manufacture of cosmetics, washing products or pharmaceutical products, — fatty alcohols of subheading 2905 16, pure or mixed, used for the manufacture of cosmetics, washing products or pharmaceutical products, — stearic acid of subheading 3823 11 00, — goods of heading 3401, or — fatty acids with high purity of heading 2915 (2)	0 %	—	31.12.2018
*ex 2007 99 50 *ex 2007 99 50 *ex 2007 99 93	83 93 10	Mango puree concentrate, obtained by cooking: — of the Genus *Mangifera* spp., — with a sugar content by weight of not more than 30 % for use in the manufacture of products of food and drink industry (2)	6 % (3)	—	31.12.2022
*ex 2007 99 50 *ex 2007 99 50	84 94	Papaya puree concentrate, obtained by cooking: — of the Genus *Carica* spp., — with a sugar content by weight of more than 13 % but not more than 30 % for use in the manufacture of products of food and drink industry (2)	7,8 % (3)	—	31.12.2022
*ex 2007 99 50 *ex 2007 99 50	85 95	Guava puree concentrate, obtained by cooking: — of the Genus *Psidium* spp., — with a sugar content by weight of more than 13 % but not more than 30 % for use in the manufacture of products of food and drink industry (2)	6 % (3)	—	31.12.2022

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*ex 2008 93 91	20	Sweetened dried cranberries, excluding packing alone as processing, for the manufacture of products of food processing industries (4)	0 %	—	31.12.2022
*ex 2008 99 49 *ex 2008 99 99	70 11	Blanched vine leaves of the genus *Karakishmish*, in brine, containing by weight: — more than 6 % of salt concentration, — 0,1 % or more but not more than 1,4 % of acidity expressed as citric acid monohydrate and — whether or not but not more than 2 000 mg/kg of sodium benzoate according CODEX STAN 192-1995 for use in the manufacture of stuffed vine leaves with rice (2)	0 %	—	31.12.2022
*ex 2106 90 92	50	Casein protein hydrolysate consisting of: — by weight 20 % or more but not more than 70 % free amino acids, and — peptones of which by weight more than 90 % having a molecular weight of not more than 2 000 Da	0 %	kg	31.12.2022
*ex 2804 50 90	40	Tellurium (CAS RN 13494-80-9) of a purity by weight of 99,99 % or more, but not more than 99,999 %, based on metallic impurities measured by ICP analysis	0 %	—	31.12.2018
*ex 2805 19 90	20	Lithium metal (CAS RN 7439-93-2) of a purity by weight of 98,8 % or more	0 %	—	31.12.2022
*ex 2811 22 00	15	Amorphous silicon dioxide (CAS RN 60676-86-0), — in the form of powder — of a purity by weight of 99,0 % or more — with a median grain size of 0,7 µm or more, but not more than 2,1 µm — where 70 % of the particles have a diameter of not more than 3 µm	0 %	—	31.12.2020
*ex 2811 29 90	10	Tellurium dioxide (CAS RN 7446-07-3)	0 %	—	31.12.2022
*ex 2816 40 00	10	Barium hydroxide (CAS RN 17194-00-2)	0 %	—	31.12.2022
*ex 2823 00 00	10	Titanium dioxide (CAS RN 13463-67-7): — of a purity by weight of 99,9 % or more, — with an average grain-size of 0,7 µm or more but not more than 2,1 µm	0 %	—	31.12.2022

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*ex 2825 10 00	10	Hydroxylammonium chloride (CAS RN 5470-11-1)	0 %	—	31.12.2022
*ex 2825 60 00	10	Zirconium dioxide (CAS RN 1314-23-4)	0 %	—	31.12.2022
*ex 2835 10 00	10	Sodium hypophosphite monohydrate (CAS RN 10039-56-2)	0 %	—	31.12.2022
*ex 2837 20 00	20	Ammonium iron (III) hexacyanoferrate (II) (CAS RN 25869-00-5)	0 %	—	31.12.2022
*ex 2839 19 00	10	Disodium disilicate (CAS RN 13870-28-5)	0 %	—	31.12.2022
*ex 2841 50 00	10	Potassium dichromate (CAS RN 7778-50-9)	0 %	—	31.12.2022
*ex 2841 80 00	10	Diammonium wolframate (ammonium para-tungstate) (CAS RN 11120-25-5)	0 %	—	31.12.2022
*ex 2841 90 30	10	Potassium metavanadate (CAS RN 13769-43-2)	0 %	kg	31.12.2022
*ex 2841 90 85	10	Lithium cobalt(III) oxide (CAS RN 12190-79-3) with a cobalt content of at least 59 %	0 %	—	31.12.2022
*ex 2850 00 20	30	Titanium nitride (CAS RN 25583-20-4) with a particle size of not more than 250 nm	0 %	—	31.12.2022
*ex 2850 00 20	60	Disilane (CAS RN 1590-87-0)	0 %	—	31.12.2022
*ex 2903 39 19	20	5-Bromopent-1-ene (CAS RN 1119-51-3)	0 %	—	31.12.2022
*2903 39 31		2,3,3,3-Tetrafluoroprop-1-ene (2,3,3,3-tetrafluoropropene) (CAS RN 754-12-1)	0 %	—	31.12.2022
*ex 2903 39 35	20	*Trans*-1,3,3,3-tetrafluoroprop-1-ene (*Trans*-1,3,3,3-tetrafluoropropene) (CAS RN 29118-24-9)	0 %	—	31.12.2018
*ex 2903 39 39	40	1,1,2,3,4,4-hexafluorobuta-1,3-diene (CAS RN 685-63-2)	0 %	—	31.12.2022
*ex 2903 89 80	50	Chlorocyclopentane (CAS RN 930-28-9)	0 %	—	31.12.2022
*ex 2903 89 80	60	Octafluorocyclobutane (CAS RN 115-25-3)	0 %	—	31.12.2022
*ex 2904 99 00	40	4-Chlorobenzenesulphonyl chloride (CAS RN 98-60-2)	0 %	—	31.12.2022
*ex 2905 19 00	70	Titanium tetrabutanolate (CAS RN 5593-70-4)	0 %	—	31.12.2022
*ex 2905 19 00	80	Titanium tetraisopropoxide (CAS RN 546-68-9)	0 %	—	31.12.2022
*ex 2905 39 95	20	Butane-1,2-diol (CAS RN 584-03-2)	0 %	—	31.12.2022
*ex 2905 39 95	40	Decane-1,10-diol (CAS RN 112-47-0)	0 %	—	31.12.2022
*ex 2906 29 00	30	2-Phenylethanol (CAS RN 60-12-8)	0 %	—	31.12.2022

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*ex 2908 99 00	40	4,5-Dihydroxynaphthalene-2,7-disulphonic acid (CAS RN 148-25-4)	0 %	—	31.12.2018
*ex 2912 29 00	35	Cinnamaldehyde (CAS RN 104-55-2)	0 %	kg	31.12.2022
*ex 2912 29 00	50	4-Isobutylbenzaldehyde (CAS RN 40150-98-9)	0 %	—	31.12.2018
*ex 2912 49 00	20	4-Hydroxybenzaldehyde (CAS RN 123-08-0)	0 %	—	31.12.2022
*ex 2914 19 90	20	Heptan-2-one (CAS RN 110-43-0)	0 %	—	31.12.2022
*ex 2914 19 90	30	3-Methylbutanone (CAS RN 563-80-4)	0 %	—	31.12.2022
*ex 2914 19 90	40	Pentan-2-one (CAS RN 107-87-9)	0 %	—	31.12.2022
*ex 2914 39 00	30	Benzophenone (CAS RN 119-61-9)	0 %	—	31.12.2022
*ex 2914 39 00	70	Benzil (CAS RN 134-81-6)	0 %	—	31.12.2022
*ex 2914 39 00	80	4′-Methylacetophenone (CAS RN 122-00-9)	0 %	—	31.12.2022
*ex 2914 50 00	45	3,4-Dihydroxybenzophenone (CAS RN 10425-11-3)	0 %	—	31.12.2022
*ex 2914 50 00	60	2,2-Dimethoxy-2-phenylacetophenone (CAS RN 24650-42-8)	0 %	—	31.12.2022
*ex 2914 79 00	20	2,4′-Difluorobenzophenone (CAS RN 342-25-6)	0 %	—	31.12.2022
*ex 2915 60 19	10	Ethyl butyrate (CAS RN 105-54-4)	0 %	—	31.12.2022
*ex 2915 90 70	30	3,3-Dimethylbutyryl chloride (CAS RN 7065-46-5)	0 %	—	31.12.2022
*ex 2916 12 00	70	2-(2-Vinyloxyethoxy)ethyl acrylate (CAS RN 86273-46-3)	0 %	—	31.12.2022
*ex 2916 13 00	30	Zinc monomethacrylate powder (CAS RN 63451-47-8) whether or not containing not more than 17 % by weight of manufacturing impurities	0 %	—	31.12.2020
*ex 2916 39 90	55	4-*tert*-Butylbenzoic acid (CAS RN 98-73-7)	0 %	—	31.12.2022
*ex 2916 39 90	75	*m*-Toluic acid (CAS RN 99-04-7)	0 %	—	31.12.2022
*ex 2916 39 90	85	(2,4,5-Trifluorophenyl)acetic acid (CAS RN 209995-38-0)	0 %	—	31.12.2022
*ex 2917 19 10	20	Diethyl malonate (CAS RN 105-53-3)	0 %	—	31.12.2022
*ex 2918 29 00	35	Propyl 3,4,5-trihydroxybenzoate (CAS RN 121-79-9)	0 %	—	31.12.2022
*ex 2918 30 00	50	Ethyl acetoacetate (CAS RN 141-97-9)	0 %	—	31.12.2022
*ex 2918 99 90	15	Ethyl 2,3-epoxy-3-phenylbutyrate (CAS RN 77-83-8)	0 %	—	31.12.2022

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*ex 2918 99 90	27	Ethyl 3-ethoxypropionate (CAS RN 763-69-9)	0 %	—	31.12.2022
*ex 2920 29 00	15	Phosphorous acid 3,3′,5,5′-tetrakis(1,1-dimethylethyl)-6,6′-dimethyl[1,1′-biphenyl]-2,2′-diyl tetra-1-naphthalenyl ester (CAS RN 198979-98-5)	0 %	—	31.12.2022
*ex 2920 29 00	50	Fosetyl-aluminium (CAS RN 39148-24-8)	0 %	—	31.12.2018
*ex 2920 29 00	60	Fosetyl-sodium (CAS RN 39148-16-8) in form of an aqueous solution with a content by weight of fosetyl-sodium of 35 % or more but not more than 45 % for use in the manufacture of pesticides (2)	0 %	—	31.12.2021
*ex 2920 90 10	60	2,4-Di-*tert*-butyl-5-nitrophenyl methyl carbonate (CAS RN 873055-55-1)	0 %	—	31.12.2022
*2921 13 00		2-(*N*,*N*-Diethylamino)ethyl chloride hydrochloride (CAS RN 869-24-9)	0 %	—	31.12.2022
*ex 2921 19 99	70	*N*,*N*-Dimethyloctylamine – boron trichloride (1:1) (CAS RN 34762-90-8)	0 %	—	31.12.2022
*ex 2921 30 99	40	Cyclopropylamine (CAS RN 765-30-0)	0 %	—	31.12.2022
*ex 2921 42 00	86	2,5-Dichloroaniline (CAS RN 95-82-9)	0 %	—	31.12.2022
*ex 2921 42 00	87	*N*-Methylaniline (CAS RN 100-61-8)	0 %	—	31.12.2022
*ex 2921 42 00	88	3,4-Dichloroaniline-6-sulphonic acid (CAS RN 6331-96-0)	0 %	—	31.12.2022
*ex 2921 43 00	80	6-Chloro-α,α,α-trifluoro-m-toluidine (CAS RN 121-50-6)	0 %	—	31.12.2018
*ex 2921 45 00	60	1-Naphthylamine (CAS RN 134-32-7)	0 %	—	31.12.2022
*ex 2921 45 00	70	8-Aminonaphthalene-2-sulphonic acid (CAS RN 119-28-8)	0 %	—	31.12.2022
*ex 2921 59 90	30	3,3′-Dichlorobenzidine dihydrochloride (CAS RN 612-83-9)	0 %	—	31.12.2022
*ex 2921 59 90	60	(2R,5R)-1,6-Diphenylhexane-2,5-diamine dihydrochloride (CAS RN 1247119-31-8)	0 %	—	31.12.2022
*ex 2922 19 00	20	2-(2-Methoxyphenoxy)ethylamine hydrochloride (CAS RN 64464-07-9)	0 %	—	31.12.2022
*ex 2922 49 85	20	3-Amino-4-chlorobenzoic acid (CAS RN 2840-28-0)	0 %	—	31.12.2022
*ex 2922 49 85	60	Ethyl-4-dimethylaminobenzoate (CAS RN 10287-53-3)	0 %	—	31.12.2022
*ex 2922 49 85	75	L-alanine isopropyl ester hydrochloride (CAS RN 62062-65-1)	0 %	—	31.12.2022

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*ex 2922 50 00	15	3,5-Diiodothyronine (CAS RN 1041-01-6)	0 %	—	31.12.2022
*ex 2924 19 00	25	Isobutylidenediurea (CAS RN 6104-30-9)	0 %	—	31.12.2022
*ex 2924 19 00	80	Tetrabutylurea (CAS RN 4559-86-8)	0 %	—	31.12.2022
*ex 2924 29 70	53	4-Amino-*N*-[4-(aminocarbonyl)phenyl]benzamide (CAS RN 74441-06-8)	0 %	—	31.12.2022
*ex 2924 29 70	86	Anthranilamide (CAS RN 88-68-6) of a purity by weight of 99,5 % or more	0 %	—	31.12.2022
*ex 2925 19 95	20	4,5,6,7-Tetrahydroisoindole-1,3-dione (CAS RN 4720-86-9)	0 %	—	31.12.2022
*ex 2925 19 95	30	*N*,*N*′-(*m*-Phenylene)dimaleimide (CAS RN 3006-93-7)	0 %	—	31.12.2022
*ex 2927 00 00	80	4-[(2,5-Dichlorophenyl)azo]-3-hydroxy-2-naphthoic acid (CAS RN 51867-77-7)	0 %	—	31.12.2022
*ex 2929 10 00	20	Butyl isocyanate (CAS RN 111-36-4)	0 %	—	31.12.2022
*ex 2929 10 00	55	2,5 (and 2,6)-Bis(isocyanatomethyl)bicyclo [2.2.1]heptane (CAS RN 74091-64-8)	0 %	—	31.12.2022
*ex 2929 10 00	80	1,3-Bis(isocyanatomethyl)benzene (CAS RN 3634-83-1)	0 %	—	31.12.2022
*ex 2930 20 00	10	Prosulfocarb (ISO) (CAS RN 52888-80-9)	0 %	—	31.12.2022
*ex 2930 90 98	65	Pentaerythritol tetrakis(3-mercaptopropionate) (CAS RN 7575-23-7)	0 %	—	31.12.2022
*ex 2930 90 98	68	Clethodim (ISO) (CAS RN 99129-21-2)	0 %	—	31.12.2022
*ex 2931 39 90	08	Sodium diisobutyldithiophosphinate (CAS RN 13360-78-6) in an aqueous solution	0 %	—	31.12.2022
*ex 2931 39 90	25	(*Z*)-Prop-1-en-1-ylphosphonic acid (CAS RN 25383-06-6)	0 %	—	31.12.2022
*ex 2931 90 00	20	Ferrocene (CAS RN 102-54-5)	0 %	—	31.12.2022
*ex 2932 14 00	10	1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4 deoxy-α-D-galactopyranoside (CAS RN 56038-13-2)	0 %	—	31.12.2019
*ex 2932 20 90	40	(*S*)-(–)-α-Amino-γ-butyrolactone hydrobromide (CAS RN 15295-77-9)	0 %	—	31.12.2022
*ex 2932 20 90	50	L-Lactide (CAS RN 4511-42-6) or D-Lactide (CAS RN 13076-17-0) or dilactide (CAS RN 95-96-5)	0 %	t	31.12.2022
*ex 2932 99 00	25	1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxylic acid (CAS RN 862574-88-7)	0 %	—	31.12.2022

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*ex 2932 99 00	80	1,3:2,4-*bis*-*O*-(4-Methylbenzylidene)-*D*-glucitol (CAS RN 81541-12-0)	0 %	—	31.12.2018
*ex 2933 19 90	80	3-(4,5-Dihydro-3-methyl-5-oxo-1*H*-pyrazol-1-yl)benzenesulphonic acid (CAS RN 119-17-5)	0 %	—	31.12.2022
*ex 2933 29 90	80	Imazalil (ISO) (CAS RN 35554-44-0)	0 %	—	31.12.2022
*ex 2933 39 99	12	2,3-Dichloropyridine (CAS RN 2402-77-9)	0 %	—	31.12.2022
*ex 2933 39 99	36	1-[2-[5-Methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]acetyl]piperidine-4-carbothioamide (CAS RN 1003319-95-6)	0 %	—	31.12.2022
*ex 2933 39 99	57	*Tert*-butyl 3-(6-amino-3-methylpyridin-2-yl) benzoate (CAS RN 1083057-14-0)	0 %	—	31.12.2022
*ex 2933 49 10	30	Ethyl 4-oxo-1,4-dihydroquinoline-3-carboxylate (CAS RN 52980-28-6)	0 %	—	31.12.2022
*ex 2933 49 90	25	Cloquintocet-mexyl (ISO) (CAS RN 99607-70-2)	0 %	—	31.12.2021
*ex 2933 59 95	77	3-(Trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4] triazolo[4,3-a]pyrazine hydrochloride (1:1) (CAS RN 762240-92-6)	0 %	—	31.12.2022
*ex 2933 79 00	30	5-Vinyl-2-pyrrolidone (CAS RN 7529-16-0)	0 %	—	31.12.2022
*ex 2933 99 80	24	1,3-Dihydro-5,6-diamino-2*H*-benzimidazol-2-one (CAS RN 55621-49-3)	0 %	—	31.12.2022
*ex 2933 99 80	41	5-[4′-(bromomethyl)biphenyl-2-yl]-1-trityl-1H-tetrazole (CAS RN 124750-51-2)	0 %	—	31.12.2022
*ex 2933 99 80	46	(S)-indoline-2-carboxylic acid (CAS RN 79815-20-6)	0 %	—	31.12.2022
*ex 2933 99 80	47	Paclobutrazol (ISO) (CAS RN 76738-62-0)	0 %	—	31.12.2022
*ex 2933 99 80	51	Diquat dibromide (ISO) (CAS RN 85-00-7) in aqueous solution for use in the manufacture of herbicides [2]	0 %	—	31.12.2021
*ex 2934 10 00	15	4-Nitrophenyl thiazol-5-ylmethyl carbonate (CAS RN 144163-97-3)	0 %	—	31.12.2022
*ex 2934 10 00	25	(S)-Ethyl-2-(3-((2-isopropylthiazol-4-yl) methyl)-3-methylureido)-4-morpholino-butanoate oxalate (CAS RN 1247119-36-3)	0 %	—	31.12.2022
*ex 2934 10 00	35	(2-Isopropylthiazol-4-yl)-*N*-methylmethanamine dihydrochloride (CAS RN 1185167-55-8)	0 %	—	31.12.2022
*ex 2934 20 80	15	Benthiavalicarb-isopropyl (ISO) (CAS RN 177406-68-7)	0 %	kg	31.12.2022
*ex 2934 20 80	40	1,2-Benzisothiazol-3(2*H*)-one (Benzisothiazolinone (BIT)) (CAS RN 2634-33-5)	0 %	—	31.12.2022

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*ex 2934 30 90	10	2-Methylthiophenothiazine (CAS RN 7643-08-5)	0 %	—	31.12.2022
*ex 2934 99 90	37	4-Propan-2-ylmorpholine (CAS RN 1004-14-4)	0 %	—	31.12.2022
*ex 2934 99 90	52	Epoxiconazole (ISO) (CAS RN 133855-98-8)	0 %	—	31.12.2022
*ex 2934 99 90	54	2-benzyl-2-dimethylamino-4′-morpholinobutyrophenone (CAS RN 119313-12-1)	0 %	kg	31.12.2022
*ex 2934 99 90	56	1-[5-(2,6-Difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]ethanone (CAS RN 1173693-36-1)	0 %	—	31.12.2022
*ex 2934 99 90	57	(6R,7R)-7-Amino-8-oxo-3-(1-propenyl)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (CAS RN 120709-09-3)	0 %	—	31.12.2022
*ex 2934 99 90	58	Dimethenamide-P (CAS RN 163515-14-8)	0 %	—	31.12.2018
*ex 2934 99 90	74	2-Isopropylthioxanthone (CAS RN 5495-84-1)	0 %	—	31.12.2022
*ex 2935 90 90	73	(2S)-2-Benzyl-*N*,*N*-dimethylaziridine-1-sulfonamide (CAS RN 902146-43-4)	0 %	—	31.12.2022
*ex 2938 90 90	30	Rebaudioside A (CAS RN 58543-16-1)	0 %	—	31.12.2022
*ex 2938 90 90	40	Purified steviol glycoside with a rebaudioside M (CAS RN 1220616-44-3) content of 80 % or more but not more than 90 % by weight for use in the manufacture of non-alcoholic beverages [2]	0 %	—	31.12.2022
*ex 3204 11 00	35	Colourant C.I Disperse Yellow 232 (CAS RN 35773-43-4) and preparations based thereon with a colourant C.I Disperse Yellow 232 content of 50 % or more	0 %	—	31.12.2022
*ex 3204 11 00	45	Preparation of dispersion dyes, containing: — C.I. Disperse Orange 61 or Disperse Orange 288, — C.I. Disperse Blue 291:1, — C.I. Disperse Violet 93:1, — whether or not containing C.I. Disperse Red 54	0 %	—	31.12.2020
*ex 3204 13 00	30	Colourant C.I. Basic Blue 7 (CAS RN 2390-60-5) and preparations based thereon with a colourant C.I. Basic Blue 7 content of 50 % or more by weight	0 %	—	31.12.2018
*ex 3204 13 00	40	Colourant C.I. Basic Violet 1 (CAS RN 603-47-4 or CAS RN 8004-87-3) and preparations based thereon with a colourant C.I. Basic Violet 1 content of 90 % or more by weight	0 %	—	31.12.2022

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*ex 3204 15 00	80	Colourant C.I. Vat Blue 1 (CAS RN 482-89-3) and preparations based thereon with a colourant C.I. Vat Blue 1 content of 94 % or more by weight	0 %	—	31.12.2022
*ex 3204 17 00	26	Colourant C.I. Pigment Orange 13 (CAS RN 3520-72-7) and preparations based thereon with a colourant C.I. Pigment Orange 13 content of 80 % or more by weight	0 %	—	31.12.2022
*ex 3204 17 00	75	Colourant C.I. Pigment Orange 5 (CAS RN 3468-63-1) and preparations based thereon with a colourant C.I. Pigment Orange 5 content of 80 % or more by weight	0 %	—	31.12.2022
*ex 3204 17 00	80	Colourant C.I. Pigment Red 207 (CAS RN 71819-77-7) and preparations based thereon with a colourant C.I. Pigment Red 207 content of 50 % or more by weight	0 %	—	31.12.2022
*ex 3204 17 00	85	Colourant C.I. Pigment Blue 61 (CAS RN 1324-76-1) and preparations based thereon with a colourant C.I. Pigment Blue 61 content of 35 % or more by weight	0 %	—	31.12.2022
*ex 3204 17 00	88	Colourant C.I. Pigment Violet 3 (CAS RN 1325-82-2 or CAS RN 101357-19-1) and preparations based thereon with a colourant C.I. Pigment Violet 3 content of 90 % or more by weight	0 %	—	31.12.2022
*ex 3204 19 00	16	Colourant C.I Solvent Yellow 133 (CAS RN 51202-86-9) and preparations based thereon with a colourant C.I. Solvent Yellow 133 content of 97 % or more by weight	0 %	—	31.12.2022
*ex 3204 19 00	84	Colourant C.I. Solvent Blue 67 (CAS RN 12226-78-7) and preparations based thereon with a colourant C.I. Solvent Blue 67 content of 98 % or more by weight	0 %	—	31.12.2022
*ex 3204 90 00	20	Preparations of colourant C.I. Solvent Red 175 (CAS RN 68411-78-6) in petroleum distillates, hydrotreated light naphthenic (CAS RN 64742-53-6), containing by weight 40 % or more but not more than 60 % C.I. Solvent Red 175	0 %	—	31.12.2022
*ex 3206 49 70	30	Colourant C.I. Pigment Black 12 (CAS RN 68187-02-0) and preparations based thereon with a colourant C.I. Pigment Black 12 content of 50 % or more by weight	0 %	—	31.12.2022
*ex 3207 40 85	40	Glass flakes (CAS RN 65997-17-3): — of a thickness of 0,3 μm or more but not more than 10 μm, and — coated with titanium dioxide (CAS RN 13463-67-7) or iron oxide (CAS RN 18282-10-5)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3208 90 19 *ex 3208 90 91	25 20	Tetrafluoroethylene copolymer in butylacetate solution with a content of solvent of 50 % (± 2 %) by weight	0 %	—	31.12.2022
*ex 3208 90 19	65	Silicones containing 50 % by weight or more of xylene and not more than 25 % by weight of silica, of a kind used for the manufacture of long term surgical implants	0 %	—	31.12.2018
*ex 3208 90 19	75	Acenaphthalene copolymer in ethyl lactate solution	0 %	—	31.12.2022
*ex 3215 11 00 *ex 3215 19 00	10 10	Printing ink, liquid, consisting of a dispersion of a vinyl acrylate copolymer and colour pigments in isoparaffins, containing by weight not more than 13 % of vinyl acrylate copolymer and colour pigments	0 %	—	31.12.2018
*ex 3215 19 00	20	Ink: — consisting of a polyester polymer and a dispersion of silver (CAS RN 7440-22-4) and silver chloride (CAS RN 7783-90-6) in methyl propyl ketone (CAS RN 107-87-9), — with a total solid content by weight of 55 % or more, but not more than 57 %, and — with a specific gravity of 1,40 g/cm³ or more, but not more than 1,60 g/cm³, for use in the manufacture of electrodes (2)	0 %	l	31.12.2022
*ex 3402 13 00	20	Surfactant containing 1,4-dimethyl-1,4-*bis*(2-methylpropyl)-2-butyne-1,4-diyl ether, polymerised with oxirane, methyl terminated	0 %	—	31.12.2022
*ex 3506 91 90	60	Temporary wafer-bonding adhesive material in the form of a suspension of a solid polymer in D-limonene (CAS RN 5989-27-5) with a polymeric content by weight of 65 % or more but not more than 75 %	0 %	l	31.12.2022
*ex 3506 91 90	70	Temporary wafer-bonding release in form of a suspension of a solid polymer in cyclopentanone (CAS RN 120-92-3) with a polymeric content of not more than 10 % by weight	0 %	l	31.12.2022
*ex 3603 00 60	10	Igniters for gas generators with an overall maximum length of 20,34 mm or more but not more than 25,25 mm and a pin length of 6,68 mm (± 0,3 mm) or more but not more than 6,9 mm (± 0,3 mm)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3707 90 29	50	Dry ink powder or toner blend, consisting of: — styrene acrylate/butadiene copolymer — either carbon black or an organic pigment — whether or not containing polyolefin or amorphous silica for use as a developer in the manufacturing of ink/toner filled bottles or cartridges for facsimile machines, computer printers and copiers (2)	0 %	—	31.12.2022
*ex 3801 90 00	20	Pitch coated graphite based powder with: — an average particle size of 10,8 μm or more but not more than 13,0 μm, — an iron content of less than 40 ppm, — a copper content of less than 5 ppm, — a nickel content of less than 5 ppm, — an average surface area (N2 atmosphere) of 3,0 m^2/g or more but not more than 4,36 m^2/g, and — a magnetic metal impurity of less than 0,3 ppm	0 %	kg	31.12.2022
*ex 3808 91 90	60	Spinetoram (ISO) (CAS RN 935545-74-7), preparation of two spinosyn components (3′-ethoxy-5,6-dihydro spinosyn J) and (3′-ethoxy- spinosyn L)	0 %	—	31.12.2022
*ex 3811 21 00	30	Additives for lubricating oils, containing mineral oils, consisting of calcium salts of reaction products of polyisobutylene substituted phenol with salicylic acid and formaldehyde, used as a concentrated additive for the manufacture of engine oils through a blending process	0 %	—	31.12.2022
*ex 3811 21 00	50	Additives for lubricating oils, — based on calcium C16-24 alkylbenzene-sulphonates (CAS RN 70024-69-0), — containing mineral oils, used as a concentrated additive for the manufacture of engine oils through a blending process	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3811 21 00	60	Additives for lubricating oils, containing mineral oils, — based on calcium polypropylenyl substituted benzenesulphonate (CAS RN 75975-85-8) with a content by weight of 25 % or more but not more than 35 %, — with a total base number (TBN) of 280 or more but not more than 320, used as a concentrated additive for the manufacture of engine oils through a blending process	0 %	—	31.12.2022
*ex 3811 21 00	70	Additives for lubricating oils, — containing polyisobutylene succinimide derived from reaction products of polyethylenepolyamines with polyisobutenyl succinic anhydride (CAS RN 84605-20-9), — containing mineral oils, — with a chlorine content by weight of 0,05 % or more but not more than 0,25 %, — with a total base number (TBN) of more than 20, used as a concentrated additive for the manufacture of engine oils through a blending process	0 %	—	31.12.2022
*ex 3811 21 00	85	Additives, — containing more than 20 % or more but not more than 45 % by weight of mineral oils, — based on a mixture of branched dodecylphenol sulfide calcium salts, whether or not carbonated, of a kind used in the manufacture of blends of additives for lubricating oils	0 %	—	31.12.2022
*ex 3811 29 00	20	Additives for lubricating oils, consisting of reaction products of bis(2-methylpentan-2-yl) dithiophosphoric acid with propylene oxide, phosphorus oxide, and amines with C12-14 alkyl chains, used as a concentrated additive for the manufacture of lubricating oils	0 %	—	31.12.2022
*ex 3811 29 00	30	Additives for lubricating oils, consisting of reaction products of butyl-cyclohex-3-enecarboxylate, sulphur and triphenyl phosphite (CAS RN 93925-37-2), used as a concentrated additive for the manufacture of engine oils through a blending process	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3811 29 00	40	Additives for lubricating oils, consisting of reaction products of 2-methyl-prop-1-ene with sulphur monochloride and sodium sulphide (CAS RN 68511-50-2), with a chlorine content by weight of 0,01 % or more but not more than 0,5 %, used as a concentrated additive for the manufacture of lubricating oils	0 %	—	31.12.2022
*ex 3811 29 00	50	Additives for lubricating oils, consisting of a mixture of *N,N*-dialkyl -2-hydroxyacetamides with alkyl chain lengths between 12 and 18 carbon atoms (CAS RN 866259-61-2), used as a concentrated additive for the manufacture of engine oils through a blending process	0 %	—	31.12.2022
*ex 3811 90 00	40	Solution of a quaternary ammonium salt based on polyisobutenyl succinimide, containing by weight 20 % or more but not more than 29,9 % of 2-ethylhexanol	0 %	—	31.12.2022
*ex 3812 39 90	80	UV-stabilizer, consisting of: — a hindered amine: *N,N′*-bis(1,2,2,6,6-pentamethyl-4-piperidinyl)-1,6-hexanediamine, polymer with 2,4-dichloro-6-(4-morpholinyl)-1,3,5-triazine (CAS RN 193098-40-7) and — either an o-hydroxyphenyl triazine UV light absorber or — a chemically modified phenolic compound	0 %	—	31.12.2022
*ex 3815 19 90 *ex 8506 90 00	87 10	Cathode, in rolls, for air zinc button cell batteries (hearing aid batteries) [2]	0 %	—	31.12.2018
*ex 3815 90 90	16	Initiator based on dimethylaminopropyl urea	0 %	—	31.12.2022
*ex 3815 90 90	18	Oxidation catalyst with an active ingredient of di[manganese (1+)], 1,2-bis(octahydro-4,7-dimethyl-1*H*-1,4,7-triazonine-1-yl-*k*N^{1}, *k*N^{4}, *k*N^{7})ethane-di-*μ*-oxo-*μ*-(ethanoato-*k*O, *k*O′)-, di[chloride(1-)],(CAS RN 1217890-37-3) used to accelerate chemical oxidation or bleaching	0 %	—	31.12.2022
*ex 3815 90 90	22	Catalyst in powder form consisting by weight of 95 % (± 1 %) titanium dioxide and 5 % (± 1 %) silicon dioxide	0 %	—	31.12.2022
*ex 3815 90 90	85	Catalyst based on aluminosilicate (zeolite), for the alkylation of aromatic hydrocarbons, for the transalkylation of alkylaromatic hydrocarbons or for the oligomerization of olefins [2]	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3824 99 92	26	Preparation containing by weight: — 60 % or more but not more than 75 % of Solvent naphtha (petroleum), heavy aromatic (CAS RN 64742-94-5) — 15 % or more but not more than 25 % of 4-(4-nitrophenylazo)-2,6-di-sec-butyl-phenol (CAS RN 111850-24-9), and — 10 % or more but not more than 15 % of 2-sec-butylphenol (CAS RN 89-72-5)	0 %	—	31.12.2022
*ex 3824 99 92	28	Aqueous solution containing by weight — 10 % or more but not more than 42 % of 2-(3-chloro-5-(trifluoromethyl)pyridin-2-yl)ethanamine (CAS RN 658066-44-5), — 10 % or more but not more than 25 % of sulphuric acid (CAS RN 7664-93-9) and — 0,5 % or more but not more than 2,9 % of methanol (CAS RN 67-56-1)	0 %	—	31.12.2020
*ex 3824 99 92	29	Preparation containing by weight: — 85 % or more but not more than 99 % of polyethylene glycol ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate, and — 1 % or more but not more than 15 % of polyoxyethylene (20) sorbitan trioleate	0 %	—	31.12.2020
*ex 3824 99 92	35	Preparations containing not less than 92 % or more but not more than 96,5 % by weight of 1,3:2,4-*bis*-O-(4-methylbenzylidene)-*D*-glucitol and also containing carboxylic acid derivatives and an alkyl sulphate	0 %	—	31.12.2018
*ex 3824 99 92	39	Preparation containing not less than 47 % by weight of 1,3:2,4-bis-O-benzylidene-D-glucitol	0 %	—	31.12.2018
*ex 3824 99 92	47	Preparation, containing: — trioctylphosphine oxide (CAS RN 78-50-2), — dioctylhexylphosphine oxide (CAS RN 31160-66-4), — octyldihexylphosphine oxide (CAS RN 31160-64-2) and — trihexylphosphine oxide (CAS RN 3084-48-8)	0 %	—	31.12.2022
*ex 3824 99 92	49	Preparation based on 2,5,8,11-tetramethyl-6-dodecyn-5,8-diol ethoxylate (CAS RN 169117-72-0)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3824 99 92	50	Alkyl carbonate-based preparation, also containing a UV absorber, for use in the manufacture of spectacle lenses (2)	0 %	—	31.12.2022
*ex 3824 99 92	80	Diethylene glycol propylene glycol triethanolamine titanate complexes (CAS RN 68784-48-5) dissolved in diethylene glycol (CAS RN 111-46-6)	0 %	—	31.12.2022
*ex 3824 99 93	30	Powder Mixture containing by weight: — 85 % or more of zinc diacrylate (CAS RN 14643-87-9), — not more than 5 % of 2,6-di-*tert*-butyl-alpha-dimethylamino-p-cresol (CAS RN 88-27-7), and — not more than 10 % of zinc stearate (CAS RN 557-05-1)	0 %	—	31.12.2018
*ex 3824 99 93	63	Mixture of phytosterols, not in the form of powder, containing by weight: — 75 % or more of sterols, — not more than 25 % of stanols, for use in the manufacture of stanols/sterols or stanol/sterol esters (2)	0 %	—	31.12.2022
*ex 3824 99 93 *ex 3824 99 96	83 85	Preparation containing: — C,C′-azodi(formamide) (CAS RN 123-77-3), — magnesium oxide (CAS RN 1309-48-4) and — zinc bis(p-toluene sulphinate) (CAS RN 24345-02-6) in which the gas formation from C,C′-azodi(formamide) occurs at 135 °C	0 %	—	31.12.2018
*ex 3824 99 93	88	Mixture of phytosterols derived from wood and wood based oils (tall oil), in the form of powder, containing by weight: — 60 % or more, but not more than 80 % of sitosterols, — not more than 15 % of campesterols, — not more than 5 % of stigmasterols and — not more than 15 % of betasitostanols	0 %	—	31.12.2022
*ex 3824 99 96	45	Lithium nickel cobalt aluminum oxide powder (CAS RN 177997-13-6) with: — a particle size of less than 10 μm, — a purity by weight of more than 98 %	0 %	kg	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3824 99 96	50	Nickel hydroxide, doped with 12 % or more but not more than 18 % by weight of zinc hydroxide and cobalt hydroxide, of a kind used to produce positive electrodes for accumulators	0 %	—	31.12.2022
*ex 3824 99 96	87	Platinum oxide (CAS RN 12035-82-4) fixed on a porous support of aluminium oxide (CAS RN 1344-28-1), containing by weight: — 0,1 % or more but not more than 1 % of platinum, and — 0,5 % or more but not more than 5 % of ethylaluminium dichloride (CAS RN 563-43-9)	0 %	—	31.12.2022
*ex 3903 90 90	15	Copolymer in the form of granules containing by weight: — 78 (± 4 %) of styrene, — 9 (± 2 %) of n-butyl acrylate, — 11 (± 3 %) of n-butyl methacrylate, — 1,5 (± 0,7 %) of methacrylic acid and — 0,01 % or more but not more than 2,5 % of polyolefinic wax	0 %	—	31.12.2018
*ex 3904 69 80	85	Copolymer of ethylene with chlorotrifluoroethylene, whether or not modified with hexafluoroisobutylene, in powder, whether or not with fillers	0 %	—	31.12.2022
*ex 3905 30 00	10	Viscous preparation, essentially consisting of poly(vinyl alcohol) (CAS RN 9002-89-5), an organic solvent and water for use as protective coating of wafers during the manufacturing of semiconductors (2)	0 %	—	31.12.2022
*ex 3905 91 00	40	Water soluble copolymer of ethylene and vinyl alcohol (CAS RN 26221-27-2), containing by weight not more than 38 % of the monomer unit ethylene	0 %	—	31.12.2022
*ex 3906 90 90	27	Copolymer of stearyl methacrylate, isooctyl acrylate and acrylic acid, dissolved in isopropyl palmitate	0 %	—	31.12.2022
*ex 3907 20 20	20	Polytetramethylene ether glycol with a weight average molecular weight (Mw) of 2 700 or more but not more than 3 100 (CAS RN 25190-06-1)	0 %	—	31.12.2022
*ex 3907 20 20	60	Polypropylene glycol monobutyl ether (CAS RN 9003-13-8) of an alkalinity of not more than 1 ppm of sodium	0 %	—	31.12.2022
*ex 3907 20 99	80	Isoamyl alcohol polyoxyethylene ether (CAS RN 62601-60-9)	0 %	kg	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3907 30 00	60	Polyglycerol polyglycidyl ether resin (CAS RN 118549-88-5)	0 %	—	31.12.2022
*ex 3907 99 80	25	Copolymer, containing 72 % by weight or more of terephthalic acid and/or isomers thereof and cyclohexanedimethanol	0 %	—	31.12.2022
*ex 3907 99 80	70	Copolymer of poly(ethylene terephthalate) and cyclohexane dimethanol, containing more than 10 % by weight of cyclohexane dimethanol	3.5 %	—	31.12.2019
*ex 3910 00 00	50	Silicone based pressure sensitive adhesive in solvent containing copoly (dimethylsiloxane/diphenylsiloxane) gum	0 %	—	31.12.2022
*ex 3911 90 19	30	Copolymer of ethyleneimine and ethyleneimine dithiocarbamate, in an aqueous solution of sodium hydroxide	0 %	—	31.12.2022
*ex 3911 90 99	53	Hydrogenated polymer of 1,2,3,4,4a,5,8,8a-octahydro-1,4:5,8-dimethanonaphthalene with 3a,4,7,7a-tetrahydro-4,7-methano-1H-indene and 4,4a,9,9a-tetrahydro-1,4-methano-1H-fluorene (CAS RN 503442-46-4)	0 %	—	31.12.2022
*ex 3911 90 99	57	Hydrogenated polymer of 1,2,3,4,4a,5,8,8a-octahydro-1,4:5,8-dimethanonaphthalene with 4,4a,9,9a-tetrahydro-1,4-methano-1H-fluorene (CAS RN 503298-02-0)	0 %	—	31.12.2022
*ex 3919 10 80 *ex 3919 90 80	40 43	Black poly(vinyl chloride) film: — with a gloss of more than 30 degrees according to ASTM D2457, — whether or not covered on one side with a protective poly(ethyleneterephthalate) film, and on the other side with a pressure sensitive adhesive with channels and a release liner	0 %	—	31.12.2022
*ex 3919 10 80 *ex 3919 90 80	45 45	Reinforced polyethylene foam tape, coated on both sides with an acrylic micro channelled pressure sensitive adhesive and on one side a liner, with an application thickness of 0,38 mm or more but not more than 1,53 mm	0 %	—	31.12.2022
*ex 3919 10 80 *ex 3919 90 80	55 53	Acrylic foam tape, covered on one side with a heat activatable adhesive or an acrylic pressure sensitive adhesive and on the other side with an acrylic pressure sensitive adhesive and a release sheet, of a peel adhesion at an angle of 90° of more than 25 N/cm (as determined by the ASTM D 3330 method)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3919 90 80	82	Reflecting film consisting of: — a polyurethane layer, — a glass microspheres layer, — a metallised aluminium layer, and — an adhesive, covered on one or both sides with a release liner, — whether or not a poly(vinyl chloride) layer, — a layer whether or not incorporating security imprints against counterfeiting, alteration or substitution of data or duplication, or an official mark for an intended use	0 %	—	31.12.2020
*ex 3919 90 80 *ex 9001 90 00	83 33	Reflector or diffuser sheets, in rolls, — for protection against ultraviolet or infrared heat radiation, to be affixed to windows or — for equal transmission and distribution of light, intended for LCD modules	0 %	—	31.12.2022
*ex 3920 20 29	94	Co-extruded trilayer film, — each layer containing a mixture of polypropylene and polyethylene, — containing not more than 3 % by weight of other polymers, — whether or not containing titanium dioxide in the core layer, — of an overall thickness of not more than 70 µm	0 %	—	31.12.2022
*ex 3920 62 19	60	Poly(ethylene terephthalate) film: — of a thickness of not more than 20 µm, — coated on at least one side with a gas barrier layer consisting of a polymeric matrix in which silica or aluminium oxide has been dispersed and of a thickness of not more than 2µm	0 %	—	31.12.2022
*ex 3920 99 28	55	Thermoplastic polyurethane film extruded, with: — not self-adhesive, — an index of yellow lower of more than 1,0 but not more than 2,5 for 10 mm stacked films (as determined by test method ASTM E 313-10), — a light transmission higher to 87 % for 10 mm stacked films (as determined by test method ASTM D 1003-11),	0 %	—	31.12.2018

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— a total thickness of 0,38 mm or more, but not more than 7,6 mm, — a width of 99 cm or more, but not more than 305 cm, of a kind used in the production of laminated safety glass			
*ex 3921 13 10	20	Rolls of open-cell polyurethane foam: — with a thickness of 2,29 mm (± 0,25 mm), — surface-treated with a foraminous adhesion promoter, and — laminated to a polyester film and a layer of textile material	0 %	—	31.12.2022
*ex 3921 19 00	60	Multi-porous multilayer separator foil with: — one microporous polyethylene layer between two microporous polypropylene layers and whether or not containing a coating of aluminium oxide on both sides, — a width of 65 mm or more but not more than 170 mm, — a total thickness of 0,01 mm or more but not more than 0,03 mm, — a porosity of 0,25 or more but not more than 0,65	0 %	m^2	31.12.2022
*ex 3921 19 00	70	Microporous membranes of expanded Polytetrafluoroethylene (ePTFE) in rolls, having: — a width of 1 600 mm or more but not more than 1 730 mm, and — a membrane thickness of 15 μm or more, but not more than 50 μm for use in the manufacture of a bi-component ePTFE membrane (2)	0 %	—	31.12.2022
*ex 3921 19 00	80	Microporous monolayer film of polypropylene or a microporous trilayer film of polypropylene, polyethylene and polypropylene, each film with — zero transversal production direction (TD) shrinkage, — a total thickness of 10 μm or more but not more than 50 μm, — a width of 15 mm or more but not more than 900 mm, — a length of more than 200 m but not more than 3 000 m, and — an average pore size between 0,02 μm and 0,1 μm	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 3926 30 00 *ex 3926 90 97	30 34	Electroplated interior or exterior decorative parts consisting of: — a copolymer of acrylonitrile-butadiene-styrene (ABS), whether or not mixed with polycarbonate, — layers of copper, nickel and chromium for use in the manufacturing of parts for motor vehicles of heading 8701 to 8705 (2)	0 %	p/st	31.12.2022
*ex 3926 90 97	33	Housings, housing parts, drums, setting wheels, frames, covers and other parts of acrylonitrile-butadiene-styrene or polycarbonate, of a kind used for the manufacture of remote controls	0 %	p/st	31.12.2019
*ex 3926 90 97	77	Silicone decoupling ring, with an inner diameter of 15,4 mm (+ 0,0 mm/– 0,1 mm), of a kind used in car parking aid sensor systems	0 %	p/st	31.12.2021
*ex 4104 41 19	10	Buffalo leather, split, chrome tanned synthetic retanned ('crust'), dry	0 %	—	31.12.2022
*ex 5407 10 00	10	Textile fabric, consisting of warp filament yarns of polyamide-6,6 and weft filament yarns of polyamide-6,6, polyurethane and a copolymer of terephthalic acid, *p*-phenylenediamine and 3,4′–oxybis (phenyleneamine)	0 %	—	31.12.2022
*ex 5603 12 90	50	Non-woven: — weighing 30 g/m^2 or more, but not more than 60 g/m^2, — containing fibres of polypropylene or of polypropylene and polyethylene, — whether or not printed, with: — on one side, 65 % of the total surface area having circular bobbles of 4 mm in diameter, consisting of anchored, elevated un-bonded curly fibres, suitable for the engagement of extruded hook materials, and the remaining 35 % of the surface area being bonded, — and on other side a smooth untextured surface, for use in the manufacture of napkins and napkin liners for babies and similar sanitary articles (2)	0 %	m^2	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 7009 10 00	50	Unfinished electro-chromic auto-dimming mirror for motor vehicle rear-view mirrors: — whether or not equipped with plastic backing plate, — whether or not equipped with a heating element, — whether or not equipped with Blind Spot Module (BSM) display	0 %	—	31.12.2022
*ex 7019 12 00 *ex 7019 12 00	05 25	Rovings ranging from 1 980 to 2 033 tex, composed of continuous glass filaments of 9 μm (± 0,5 μm)	0 %	—	31.12.2022
*ex 7019 19 10	15	S-glass yarn of 33 tex or a multiple of 33 tex (± 13 %) made from continuous spun-glass filaments with fibres of a diameter of 9 μm (– 1 μm / + 1,5 μm)	0 %	—	31.12.2022
*ex 7019 19 10	50	Yarn of 11 tex or a multiple thereof (± 7,5 %), obtained from continuous spun-glass filaments, containing 93 % by weight or more of silicon dioxide, of a nominal diameter of 6 μm or 9 μm, other than those treated	0 %	—	31.12.2022
*ex 7020 00 10	20	Raw material for optical elements of fused silicon dioxide with: — a thickness of 10 cm or more but not more than 40 cm and — a weight of 100 kg or more	0 %	—	31.12.2022
*ex 7315 11 90	10	Roller type steel timing chain with a fatigue limit of 2 kN at 7 000 rpm or more for use in the manufacture of engines of motor vehicles (2)	0 %	—	31.12.2022
*ex 7601 20 20	10	Slabs and billets of aluminium alloy containing lithium	0 %	—	31.12.2022
*ex 7608 20 20 *ex 8708 91 99	30 40	Assembly for supplying compressed air, whether or not with a resonator, comprising at least: — one solid aluminium tube whether or not with mounting bracket, — one flexible rubber hose, and — one metal clip for use in the manufacture of goods of Chapter 87 (2)	0 %	—	31.12.2022
*ex 8101 96 00	20	Tungsten wire — containing by weight 99,95 % or more of tungsten, and — with a maximum cross-sectional dimension of not more than 1,02 mm	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 8102 10 00	10	Molybdenum powder with: — a purity by weight of 99 % or more and — a particle size of 1,0 μm or more, but not more than 5,0 μm	0 %	—	31.12.2022
*ex 8105 90 00	10	Bars or wires made of cobalt alloy containing, by weight: — 35 % (± 2 %) cobalt, — 25 % (± 1 %) nickel, — 19 % (± 1 %) chromium and — 7 % (± 2 %) iron conforming to the material specifications AMS 5842, of a kind used in the aerospace industry	0 %	—	31.12.2018
*ex 8108 20 00	55	Titanium alloy ingot, — with a height of 17,8 cm or more, a length of 180 cm or more, a width of 48,3 cm or more — a weight of 680 kg or more, containing alloy elements by weight of: — 3 % or more but not more than 7 % of aluminium, — 1 % or more but not more than 5 % of tin, — 3 % or more but not more than 5 % of zirconium, — 4 % or more but not more than 8 % of molybdenum	0 %	—	31.12.2020
*ex 8108 20 00	70	Titanium alloy slab, with — a height of 20,3 cm or more, but not more than 23,3 cm, — a length of 246,1 cm or more, but not more than 289,6 cm, — a width of 40,6 cm or more, but not more than 46,7 cm, — a weight of 820 kg or more but not more than 965 kg, containing alloy elements by weight of: — 5,2 % or more but not more than 6,2 % of aluminium, — 2,5 % or more but not more than 4,8 % of vanadium	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 8108 90 30	15	Rods and wire of an alloy of titanium with: — a uniform solid cross-section in a form of a cylinder, — with a diameter of 0,8 mm or more, but not more than 5 mm, — an aluminium content by weight of 0,3 % or more, but not more than 0,7 %, — a silicon content by weight of 0,3 % or more, but not more than 0,6 %, — a niobium content by weight of 0,1 or more, but not more than 0,3 %, and — an iron content by weight of not more than 0,2 %	0 %	kg	31.12.2022
*ex 8108 90 50	45	Cold or hot rolled plates, sheets and strips of non-alloyed titanium with: — a thickness of 0,4 mm or more, but not more than 100 mm, — a length of not more than 14 m, and — a width of not more than 4 m	0 %	kg	31.12.2022
*ex 8108 90 50	55	Plates, sheets, strip and foil of an alloy of titanium	0 %	—	31.12.2021
*ex 8108 90 60	30	Seamless tubes and pipes of a titanium or an alloy of titanium with: — a diameter of 19 mm or more but not more than 159 mm, — a wall thickness of 0,4 mm or more but not more than 8 mm, and — a maximum length of 18 m	0 %	kg	31.12.2022
*ex 8113 00 90	10	Carrier plate of aluminium silicon carbide (AlSiC-9) for electronic circuits	0 %	—	31.12.2022
*ex 8207 30 10	10	Set of transfer and/or tandem press tools for cold-forming, pressing, drawing, cutting, punching, bending, calibrating, bordering and throating of metal sheets, for use in the manufacture of frame parts of motor vehicles (2)	0 %	p/st	31.12.2022
*ex 8407 33 20 *ex 8407 33 80 *ex 8407 90 80 *ex 8407 90 90	10 10 10 10	Spark-ignition reciprocating or rotary internal combustion piston engines, having a cylinder capacity of not less than 300 cm^3 and a power of not less than 6 kW but not exceeding 20,0 kW, for the manufacture of: — self-propelled lawn mowers, with a seat of subheading 8433 11 51, and hand-operated lawn mowers of heading 8433 11 90, — tractors of subheading 8701 91 90, whose main function is that of a lawn mower,	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— four stroke mowers with motor of a cylinder capacity of not less than 300 cc of subheading 8433 20 10 or — snowploughs and snow blowers of subheading 8430 20 (2)			
*ex 8408 90 43 *ex 8408 90 45 *ex 8408 90 47	40 30 50	4 Cylinder, 4 cycle, liquid cooled, compression-ignition engine having: — a capacity of not more than 3 850 cm^3, and — a rated output of 15 kW or more but not more than 85 kW, for use in the manufacture of vehicles of heading 8427 (2)	0 %	—	31.12.2022
*ex 8409 91 00	40	Fuel injector with solenoid valve for optimized atomization in the combustion chamber for use in the manufacture of spark-ignition internal combustion piston engines of motor vehicles (2)	0 %	—	31.12.2021
*ex 8409 91 00 *ex 8409 99 00	50 55	exhaust manifold with turbine housing of turbochargers with: — a heat-resistance of not more than 1 050 °C, and — a hole to insert a turbine wheel, whereby the hole has a diameter of 28 mm or more, but not more than 130 mm	0 %	p/st	31.12.2018
*ex 8409 99 00	60	Intake manifold for air supply to the engine cylinders, comprising at least: — a throttle, — a boost pressure sensor for use in the manufacture of compression ignition engines of motor vehicles (2)	0 %	—	31.12.2022
*ex 8409 99 00	70	Metal alloy intake and exhaust valve with a Rockwell hardness HRC 20 or more, but not more than HRC 50 for use in the manufacture of compression ignition engines of motor vehicles (2)	0 %	—	31.12.2021
*ex 8409 99 00	80	High pressure oil jet for engine piston cooling and lubrication with: — an opening pressure of 1 bar or more, but not more than 3 bar, — a closing pressure of more than 0,7 bar, — a one-way valve for use in the manufacture of compression ignition engines of motor vehicles (2)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 8411 99 00	20	Wheel-shaped gas turbine component with blades, of a kind used in turbochargers: — of a precision-cast nickel based alloy complying with standard DIN G- NiCr13Al6-MoNb or DIN G- NiCr13Al16MoNb or DIN G- NiCo10W10Cr9AlTi or DIN G- NiCr12Al6MoNb or AMS AISI:686, — with a heat-resistance of not more than 1 100 °C, — with a diameter of 28 mm or more, but not more than 180 mm, — with a height of 20 mm or more, but not more than 150 mm	0 %	p/st	31.12.2022
*ex 8411 99 00	30	Turbine housing of turbochargers with: — a heat-resistance of not more than 1 050 °C, and — a hole to insert a turbine wheel, whereby the hole has a diameter of 28 mm or more, but not more than 130 mm	0 %	p/st	31.12.2021
*ex 8414 80 22 *ex 8414 80 80	20 20	Air membrane compressor with: — a flow of 4,5 l/min or more, but not more than 7 l/min, — power input of not more than 8,1 W, and — a gauge pressure capacity not exceeding 400 hPa (0,4 bar) of a kind used in the production of motor vehicle seats	0 %	—	31.12.2022
*ex 8415 90 00	55	Aluminium arc-welded removable receiver dryer with polyamide and ceramic elements with: — a length of 143 mm or more but not more than 292 mm, — a diameter of 31 mm or more but not more than 99 mm, — a spangle length of not more than 0,2 mm and a thickness of not more than 0,06 mm, and — a solid particle diameter of not more than 0,06 mm of a kind used in car air-conditioning systems	0 %	p/st	31.12.2020
*ex 8431 20 00	30	Drive axle assembly containing differential, reduction gears, crown wheel, drive shafts, wheel hubs, brakes and mast mounting arms for use in the manufacture of vehicles in heading 8427 [2]	0 %	p/st	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 8481 80 69	60	Four-way reversing valve for refrigerants, consisting of: — a solenoid pilot valve — a brass valve body including valve slider and copper connections with a working pressure up to 4,5 MPa	0 %	p/st	31.12.2022
*ex 8482 10 10 *ex 8482 10 90	40 30	Ball bearings: — with an internal diameter of 3 mm or more, — with an external diameter of not more than 100 mm, — with a width of not more than 40 mm, — whether or not equipped with a duster, for use in the manufacture of belt drive steering systems of motor, electric power steering systems or steering gears or assembly ball screw for steering gears (2)	0 %	p/st	31.12.2019
*ex 8483 30 32 *ex 8483 30 38	20 50	Bearing housing of a kind used in turbochargers: — of precision-cast grey cast iron complying with standard DIN EN 1561, — with oil chambers, — without bearings, — with a diameter of 50 mm or more, but not more than 250 mm, — with a height of 40 mm or more, but not more than 150 mm, — whether or not with water chambers and connectors	0 %	p/st	31.12.2022
*ex 8483 40 90	20	Hydrostatic transmission with: — measurements (without shafts) of not more than 154 mm × 115 mm × 108 mm, — a weight of not more than 3,3 kg, — a maximum rotation speed of the input shaft of 2 700 rpm or more, but not more than 3 200 rpm, — a torque of the output shaft of not more than 10,4 Nm, — a rotation speed of the output shaft of not more than 930 rpm at 2 800 rpm input speed, and — an operating temperature range of – 5 °C or more, but not more than + 40 °C for use in the manufacture of hand-operated lawn mowers of heading 8433 11 90 (2)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 8483 40 90	30	Hydrostatic transmission with — a reduction of 20,63:1 or more, but not more than 22,68:1, — an input speed of 1 800 rpm or more when loaded and of not more than 3 000 rpm when unloaded, — a continuous output torque of 142 Nm or more, but not more than 156 Nm, — an intermittent output torque of 264 Nm or more, but not more than 291 Nm, and — an axle shaft diameter of 19,02 mm or more, but not more than 19,06 mm, — whether or not equipped with a fan impeller or with a pulley with integrated fan impeller for use in the production of self-propelled lawn mowers with a seat of subheading 8433 11 51, and tractors of subheading 8701 91 90, whose main function is that of a lawn mower (2)	0 %	—	31.12.2022
*ex 8501 10 99	60	DC motor: — with a rotor speed of 3 500 rpm or more but not more than 5 000 rpm loaded and not more than 6 500 rpm when not loaded — with a power supply voltage of 100 V or more but not more than 240 V for use in the manufacture of electric fryers (2)	0 %	—	31.12.2022
*ex 8501 20 00	30	Universal AC/DC motor with — a rated output of 1,2 kW, — a supply voltage of 230 V, and — engine brake, — assembled to a reduction gear with output shaft, which is contained in a plastic housing for use as electric drive of lawnmower blades (2)	0 %	—	31.12.2022
*ex 8501 31 00	25	DC motors, brushless, with: — an external diameter of 80 mm or more, but not more than 100 mm,	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— a supply voltage of 12 V, — an output at 20 °C of 300 W or more, but not more than 750 W, — a torque 20 °C of 2,00 Nm or more, but not more than 7,00 Nm, — a rated speed at 20 °C of 600 rpm or more, but not more than 3 100 rpm, — with or without the rotor angle position sensor of resolver type or Hall effect type, of the kind used in power steering systems for cars			
*ex 8501 31 00	75	Brushless DC motor assembly comprised of a motor and transmission, with: — electronic control operating by Hall Effect position sensors, — voltage input 9V or more but not more than 16 V, — external diameter of the motor 70 mm or more but not more than 80 mm, — output motor power 350 W or more but not more than 550 W, — maximum output torque 50 Nm or more but not more than 52 Nm, — maximum output rotation speed 280 rpm or more but not more than 300 rpm, — coaxial male spline outputs of outer diameter 20 mm (± 1 mm), 17 teeth and minimum length of teeth 25 mm (± 1 mm), and — with distance between root of splines 119 mm (± 1 mm) for use in the manufacture of all-terrain or utility task vehicles (2)	0 %	—	31.12.2021
*ex 8501 31 00 *ex 8501 32 00	78 75	Automotive-ready, brushless and permanently excited direct current motor with: — a specified speed of not more than 4 100 rpm, — a minimum output of 400 W, but not more than 1,3 kW (at 12 V), — a flange diameter of 90 mm or more, but not more than 150 mm, — a maximum length of 200 mm, measured from the beginning of the shaft to the outer ending,	0 %	—	31.12.2020

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— a housing length of not more than 160 mm, measured from the flange to the outer ending, — a maximum of two-piece (basic housing including electric components and flange with minimum 2 and maximum 6 bore holes) aluminium diecast housing whether or not with a sealing compound (groove with an O-ring and grease), — a stator with single T-tooth design and single coil windings in 12/8 topology, and — surface magnets			
*ex 8501 62 00	30	Fuel cell system — consisting of at least phosphoric acid fuel cells, — in a housing with integrated water management and gas treatment, — for permanent, stationary energy supply	0 %	—	31.12.2022
*ex 8503 00 99	40	Fuel cell membrane, in rolls or sheets, with a width of not more than 150 cm, of a kind used for manufacture of fuel cells in heading 8501	0 %	p/st	31.12.2022
*ex 8504 31 80	40	Electrical transformers: — with a capacity of 1 kVA or less — without plugs or cables, for internal use in the manufacture of set top boxes and TVs (2)	0 %	—	31.12.2022
*ex 8504 40 82	40	Printed circuit board equipped with a bridge rectifier circuit and other active and passive components: — with two output connectors — with two input connectors which are available and useable in parallel — able to switch between bright and dimmed operation mode — with an input voltage of 40 V (+ 25 % -15 %) or 42 V (+ 25 % -15 %) in bright operation mode, with an input voltage of 30 V (± 4 V) in dimmed operation mode, or — with an input voltage of 230 V (+ 20 % -15 %) in bright operation mode, with an input voltage of 160 V (± 15 %) in dimmed operation mode, or	0 %	p/st	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— with an input voltage of 120 V (15 % -35 %) in bright operation mode, with an input voltage of 60 V (± 20 %) in dimmed operation mode — with an input current reaching 80 % of its nominal value within 20 ms — with an input frequency of 45 Hz or more, but not more than 65 Hz for 42 V and 230 V, and 45-70 Hz for 120 V versions — with an maximum inrush current overshoot of not more than 250 % of the input current — with a period of the inrush current overshoot of not more than 100 ms — with an input current undershoot of not less than 50 % of the input current — with a period of the inrush current undershoot of not more than 20 ms — with a presettable output current — with an output current reaching 90 % of its nominal pre-set value within 50 ms — with an output current reaching zero within 30 ms after removal of the input voltage — with an defined failure status in case of no-load or too-high load (end-of-life function)			
*ex 8504 40 82	50	Electric rectifier: — with an input AC voltage of 100-240 V at frequency of 50-60 Hz, — with two output DC voltages of 9 V or more but not more than 12 V and 396 V or more but not more than 420 V, — output cables without connectors, and — in a plastic enclosure with dimensions 110 mm (± 0,5 mm) × 60 mm (± 0,5 mm) × 38 mm (± 1 mm) for use in the manufacture of products using IPL (Intensive Pulse Light) [2]	0 %	p/st	31.12.2022
*ex 8504 50 95	50	Solenoid coil with — a power consumption of not more than 6 W,	0 %	p/st	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— an insulation resistance of more than 100 M ohms, and — an insert hole of 11,4 mm or more, but not more than 11,8 mm			
*ex 8505 11 00	50	Bars specifically shaped, intended to become permanent magnets after magnetisation, containing neodymium, iron and boron, with dimensions: — a length of 15 mm or more but not more than 52 mm, — a width of 5 mm or more but not more than 42 mm, of a kind to be used in the manufacture of electric servomotors for industrial automation	0 %	p/st	31.12.2022
*ex 8505 11 00	60	Rings, tubes, bushings or collars made from an alloy of neodymium, iron and boron, with — a diameter of not more than 45 mm, — a height of not more than 45 mm, of a kind used in the manufacture of permanent magnets after magnetisation	0 %	—	31.12.2022
*ex 8505 19 90	50	Article of agglomerated ferrite in the shape of a rectangular prism to become permanent magnet after magnetisation — whether or not with bevelled edges — of a length of 27 mm or more but not more than 32 mm (± 0,15 mm), — of a width of 8,5 mm or more but not more than 9,5 mm (+ 0,05 mm/ – 0,09 mm), — of a thickness of 5,5 mm or more but not more than 5,8 mm (+ 0/– 0,2 mm), and — of a weight of 6,1 g or more but not more than 8,3 g	0 %	—	31.12.2022
*ex 8507 60 00	25	Rectangular modules for incorporation in lithium-ion rechargeable batteries, with: — a width of 352,5 mm (± 1 mm) or 367,1 mm (±1mm) — a depth of 300 mm (± 2 mm) or 272,6 mm (± 1 mm) — a height of 268,9 mm (± 1,4 mm) or 229,5 mm (± 1mm)	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— a weight of 45,9 kg or 46,3 kg — a rating of 75 Ah and — a nominal voltage of 60 V			
*ex 8507 60 00	50	Modules for the assembly of batteries of ion lithium electric accumulators with: — a length of 298 mm or more, but not more than 408 mm, — a width of 33,5 mm or more, but not more than 209 mm, — a height of 138 mm or more, but not more than 228 mm, — a weight of 3,6 kg or more, but not more than 17 kg, and — a power of 458 Wh or more, but not more than 2 158 Wh	0 %	—	31.12.2022
*ex 8507 60 00	53	Batteries of lithium-ion electric accumulators or rechargeable module: — a length of 1 203 mm or more, but not more than 1 297 mm, — a width of 282 mm or more, but not more than 772 mm, — a height of 792 mm or more, but not more than 839 mm, — a weight of 253 kg or more, but not more than 293 kg, — power of 22 kWh or 26 kWh, and — constituted of 24 or 48 modules	0 %	—	31.12.2022
*ex 8511 30 00	55	Ignition coil: — with a length of 50 mm or more, but not more than 200 mm, — with an operating temperature of – 40 °C or more, but not more than 140 °C, and — with a voltage of 9 V or more, but not more than 16 V, — with or without connection cable, for use in the manufacture of engines of motor vehicles (2)	0 %	—	31.12.2021
*ex 8516 90 00	70	Inner pot: — containing side and central openings, — of annealed aluminium, — with a ceramic coating, heat resistant to more than 200 °C for use in the manufacture of an electric fryer (2)	0 %	p/st	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 8518 29 95	30	Loudspeakers of: — an impedance of 3 Ohm or more, but not more than 16 Ohm, — a nominal power of 2 W or more, but not more than 20 W, — with or without plastic bracket, and — with or without electric cable fitted with connectors, of a kind used for TV sets and video monitors manufacture as well as home entertainment systems	0 %	—	31.12.2022
*ex 8526 91 20	30	Control unit of the emergency call system containing GSM and GPS module, for use in the manufacture of goods of Chapter 87 (2)	0 %	—	31.12.2019
*ex 8529 90 65	75	Modules comprising at least semiconductor chips for: — the generation of driving signals for pixel addressing, or — driving addressing pixels	0 %	p/st	31.12.2022
*ex 8529 90 92	70	Rectangular fastening and covering frame: — of an aluminium alloy containing silicon and magnesium, — with a length of 500 mm or more but not more than 2 200 mm, — with a width of 300 mm or more but not more than 1 500 mm, of a kind used for the production of TV sets	0 %	p/st	31.12.2022
*ex 8536 69 90	51	SCART type connectors, built into a plastic or metal housing, with 21 pins in 2 rows, for use in the manufacture of products falling within headings 8521 and 8528 (2)	0 %	p/st	31.12.2022
*ex 8536 69 90	88	Secure Digital (SD), CompactFlash, 'Smart Card' and 'Common interface modules (cards)' female connectors and interfaces, of a kind used for soldering on printed circuit boards, for connecting electrical apparatus and circuits and switching or protecting electrical circuits with a voltage of not more than 1 000 V	0 %	p/st	31.12.2022
*ex 8536 90 95	40	Rivet contacts — of copper — plated with silver nickel alloy AgNi10 or with silver containing by weight 11,2 % (± 1,0 %) of tin oxide and of indium oxide taken together	0 %	p/st	31.12.2020

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— with a thickness of the plating of 0,3 mm (– 0/+ 0,015 mm) — whether or not gilded			
*ex 8537 10 91	70	Programmable memory controller for a voltage not exceeding 1 000 V, of a kind used for the operation of a combustion motor and/or various actuators working with a combustion motor, comprising at least — a printed circuit with active and passive components, — an aluminium housing, and — multiple connectors	0 %	—	31.12.2022
*ex 8544 20 00	30	Antenna connecting cable for the transmission of radio (AM/FM) signal and whether or not GPS signal, containing: — a coaxial cable, — two or more connectors, and — 3 or more plastic clips for attachment to the dashboard of a kind used in the manufacture of goods of Chapter 87	0 %	—	31.12.2021
*ex 8544 30 00	35	Wire harness: — with an operation voltage of 12 V, — wrapped in tape or covered in plastic convoluted tubing, — with 16 or more strands, with all terminals to be tin plated or equipped with connectors, for use in the manufacture of all-terrain or utility task vehicles (2)	0 %	—	31.12.2021
*ex 8544 30 00 *ex 8544 42 90	85 65	extension two-core cable with two connectors, containing at least: — a rubber grommet, — a metal attachment bracket of a kind used to connect vehicle speed sensors in the manufacture of vehicles of Chapter 87	0 %	p/st	31.12.2020
*ex 8548 10 29	10	Spent lithium-ion or nickel metal hydride electric accumulators	0 %	—	31.12.2018
*ex 8708 40 20	30	Automatic gearbox with a hydraulic torque converter with: — at least eight gears,	0 %	—	31.12.2022

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— an engine torque of 300 Nm or more, and — transverse or longitudinal installation for use in the manufacture of motor vehicles of heading 8703 (2)			
*ex 8708 40 20 *ex 8708 40 50	40 30	Gear box assembly with one or two inputs and at least three outputs in cast aluminium housing with overall dimensions (excluding the shafts) of not more than 455 mm (width) × 462 mm (height), 680 mm length, equipped with at least: — one exterior-splined output shaft, — a rotary switch to indicate gear position, — the potential for a differential for use in the manufacture of all-terrain or utility task vehicles (2)	0 %	—	31.12.2021
*ex 8708 50 20 *ex 8708 50 99 *ex 8708 99 10 *ex 8708 99 97	40 30 70 80	Single input, dual output gearcase (transmission) in cast aluminium housing, with overall dimensions not exceeding 148 mm (± 1 mm) × 213 mm (± 1 mm) × 273 mm (± 1 mm) comprising at least: — two electro-magnetic one direction clutches in one cage, working in both directions, — an input shaft with outer diameter of 24 mm (± 1 mm), ended with spline of 22, — a coaxial output bushing with inner diameter of 22 mm or more but not more than 30 mm, ended with spline of 22 teeth or more but not more than 28 teeth for use in the manufacture of all-terrain or utility task vehicles (2)	0 %	—	31.12.2021
*ex 8708 93 10 *ex 8708 93 90	30 30	Mechanically operated centrifugal clutch for use with an elastomeric belt in a dry environment in a continuously variable transmission (CVT), equipped with: — elements that activate the clutch at given rotation and generate (in this way) centrifugal force, — shaft ended with 5 or more but not more than 6 degree taper,	0 %	—	31.12.2021

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
		— 3 weights, and — 1 compression spring for use in the manufacture of all-terrain or utility task vehicles (2)			
*ex 8708 99 97	85	Electroplated interior or exterior parts consisting of: — a copolymer of acrylonitrile-butadiene-styrene (ABS), whether or not mixed with polycarbonate, — layers of copper, nickel and chromium for use in the manufacturing of parts for motor vehicles of heading 8701 to 8705 (2)	0 %	p/st	31.12.2022
*ex 9001 20 00	10	Material consisting of a polarising film, whether or not on rolls, supported on one or both sides by transparent material, whether or not with an adhesive layer, covered on one side or on both sides with a release film	0 %	—	31.12.2022
*ex 9001 50 41 *ex 9001 50 49	40 40	Organic uncut corrective eyeglass lens, finished on both sides, to undergo a coating, colouring, edging, mounting or any other substantial process for use in the manufacture of corrective glasses (2)	0 %	—	31.12.2022
*ex 9001 90 00	25	Unmounted optical elements made from moulded infrared transmitting chalcogenide glass, or a combination of infrared transmitting chalcogenide glass and another lens material	0 %	—	31.12.2018
*ex 9002 11 00	20	Lenses — measuring not more than 80 mm × 55 mm × 50 mm, — with a resolution of 160 lines/mm or better, and — with a zoom ratio of 18 times, of a kind used for the production of visualizers or live image cameras	0 %	—	31.12.2022
*ex 9002 11 00	40	Lenses — measuring not more than 125 mm × 65 mm × 65 mm, — with a resolution of 125 lines/mm or better, and — with a zoom ratio of 16 times of a kind used for the production of visualizers or live image cameras	0 %	—	31.12.2018

CN code	TARIC	Description	Rate of autonomous duty	Supplementary Unit	Date foreseen for mandatory review
*ex 9002 11 00	85	Lens assembly with: — a horizontal field of view range of 50 deg or more, but not more than 200 deg, — a focal length of 1,16 mm or more, but not more than 5,45 mm, — a relative aperture of F/2,0 or more but not more than F/2,6, and — a diameter of 5 mm or more but not more than 18,5 mm, for use in the manufacture of CMOS automotive cameras (2)	0 %	—	31.12.2019
*ex 9002 90 00	40	Mounted lenses made from infrared transmitting chalcogenide glass, or a combination of infrared transmitting chalcogenide glass and another lens material	0 %	p/st	31.12.2022
*ex 9032 89 00	40	Digital valve controller for controlling liquids and gases	0 %	p/st	31.12.2022

(2) Suspension of duties is subject to end-use customs supervision in accordance with Article 254 of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

(3) Only the *ad valorem* duty is suspended. The specific duty shall continue to apply.

(4) A surveillance of imports of goods covered by this tariff suspension shall be established in accordance with the procedure laid down in Articles 55 and 56 of Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

* A newly introduced measure or a measure with amended conditions.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2468

of 20 December 2017

laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 20 and Article 35(3) thereof,

Whereas:

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

(2) Pursuant to Article 20 of Regulation (EU) 2015/2283 the Commission has to adopt implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries.

(3) Without prejudice to Articles 5, 15 and 16 of Regulation (EU) 2015/2283, the Commission should verify whether the notification falls within the scope of that Regulation and the validity of the notification or the application.

(4) Notifications referred to in Article 14 of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify the validity and enable Member States and the Authority to evaluate the history of safe use of the traditional food from a third country.

(5) Applications referred to in Article 16 of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify the validity and enable the Authority to conduct comprehensive risk assessments.

(6) Where the applicant submits a notification or an application to add, remove or change the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised traditional food from a third country, it may not be necessary for the applicant to provide all the data required for the safety assessment where the applicant provides adequate verifiable justification.

(7) The exchange of information between the Commission, the Member States and the Authority should allow that duly reasoned safety objections are submitted to the Commission where necessary.

(8) The opinion of the Authority should provide sufficient information to ascertain whether the proposed use of the traditional food from a third country is safe for consumers.

(9) Pursuant to Article 35(3) of Regulation (EU) 2015/2283 the Commission has to adopt implementing acts laying down the requirements referred to in Article 20 of that Regulation.

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

([1]) OJ L 327, 11.12.2015, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Scope and subject matter

This Regulation lays down rules for the implementation of Article 20 of Regulation (EU) 2015/2283 as regards the administrative and scientific requirements concerning traditional foods from third countries and transitional measures referred to in Article 35(3) of that Regulation.

It applies to notifications and applications as referred to in Articles 14 and 16 of Regulation (EU) 2015/2283.

Article 2

Definitions

In addition to the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([1]) and Regulation (EU) 2015/2283, the following definitions shall apply:

(a) 'notification' means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 14 of Regulation (EU) 2015/2283.

(b) 'application' means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 16 of Regulation (EU) 2015/2283.

Article 3

Structure, content and presentation of a notification

1. A notification shall be submitted electronically to the Commission and shall consist of the following:

(a) a cover letter;

(b) a technical dossier;

(c) a summary of the dossier.

2. The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex I.

3. The technical dossier referred to in paragraph 1(b) shall contain:

(a) the administrative data as provided for in Article 5;

(b) the scientific data as provided for in Article 6.

4. Where the applicant submits a notification to modify the conditions of use, the specifications, specific labelling requirements or post-market monitoring requirements of an authorised traditional food from a third country, it may not be necessary for the applicant to provide all the data required under Article 6 where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the existing safety assessment.

5. The summary of the dossier referred to in paragraph 1(c) shall provide evidence that the use of a traditional food from a third country complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283.

Article 4

Structure, content and presentation of an application

1. An application shall be submitted electronically to the Commission and shall consist of the following:

(a) a cover letter;

(b) a technical dossier;

(c) a summary of the dossier;

(d) duly reasoned safety objections referred to in Article 15(2) of Regulation (EU) 2015/2283;

(e) the applicant's response to duly reasoned safety objections.

([1]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

2. The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex II.

3. The technical dossier referred to in paragraph 1(b) shall contain:

(a) the administrative data as provided for in Article 5;

(b) the scientific data as provided for in Article 6.

4. Where the applicant submits an application to modify the conditions of use, the specifications, specific labelling requirements or post-market monitoring requirements of an authorised traditional food from a third country, it may not be necessary for the applicant to provide all the data required under Article 6 where the applicant provides verifiable justification explaining that the proposed changes not affect the results of the existing safety assessment.

5. The summary of the dossier referred to in paragraph 1(c) shall provide evidence that the use of a traditional food from a third country complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283.

Article 5

Administrative data to be provided in a notification or an application

In addition to the information set out in Article 14 of Regulation (EU) 2015/2283, the notifications and the applications shall include the following administrative data:

(a) the name, address and contact details of the person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission;

(b) the date of submission of the dossier;

(c) a table of contents of the dossier;

(d) a detailed list of documents annexed to the dossier, including references to titles, volumes and pages;

(e) a list of the parts of the dossier to be treated as confidential in accordance with Article 23 of Regulation (EU) 2015/2283 and the rules set out in Annex III to this Regulation.

Article 6

Scientific data to be provided in a notification or an application

1. The dossier submitted in support of a notification or an application for the authorisation of a traditional food from a third country shall enable a history of safe use of the traditional food from a third country to be assessed.

2. The applicant shall provide a copy of the documentation on the procedure followed when gathering the data.

3. The applicant shall provide a description of the safety evaluation strategy and shall justify the inclusion and exclusion of specific studies or information.

4. The applicant shall propose an overall conclusion on the safety of the proposed uses of the traditional food from a third country. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Article 7

Verification of the validity of a notification

1. On receipt of a notification of a traditional food from a third country, the Commission shall without delay verify whether the food concerned falls within the scope of Regulation (EU) 2015/2283 and whether the notification fulfils the requirements set out in Articles 3, 5 and 6 of this Regulation.

2. The Commission may request additional information from the applicant as regards the validity of the notification and inform the applicant of the period within which that information shall be provided.

3. By way of derogation from paragraph 1 of this Article and without prejudice to Article 14 of Regulation (EU) 2015/2283, a notification may be considered valid even if it does not contain all the elements required under Articles 3, 5 and 6 of this Regulation, provided that the applicant has submitted verifiable justification for each missing element.

4. The Commission shall inform the applicant, the Member States and the Authority of the reasons why the notification is considered not valid.

Article 8

Verification of the validity of an application

1. On receipt of an application for the authorisation of a traditional food from a third country the Commission shall without delay verify whether the application fulfils the requirements of Articles 4 to 6.

2. The Commission may request additional information from the applicant on matters regarding the validity of the application and inform the applicant of the period within which that information shall be provided.

3. By way of derogation from paragraph 1 of this Article and without prejudice to Article 16 of Regulation (EU) 2015/2283, an application may be considered valid even if it does not contain all the elements required under Articles 4 to 6 of this Regulation, provided that the applicant has submitted verifiable justification for each missing element.

4. The Commission shall inform the applicant, the Member States and the Authority whether the application is considered valid or not. If the application is not considered valid, the Commission shall indicate the reasons why it is not valid.

Article 9

Duly reasoned safety objections

1. On receipt of a valid notification, consultation between the Commission, the Member States and the Authority may be carried out in the first three months of the period established in Article 15(2) of Regulation (EU) 2015/2283.

2. The duly reasoned safety objections submitted by a Member State or the Authority to the Commission in accordance with Article 15(2) of Regulation (EU) 2015/2283 shall include the following information:

(a) the name and description of the traditional food from a third country;

(b) a scientific statement indicating why the traditional food from a third country may pose a safety risk to human health.

Article 10

Information to be included in the opinion of the Authority

1. The opinion of the Authority shall include the following information:

(a) the identity and characterisation of the traditional food from a third country;

(b) the assessment of the history of safe use in a third country;

(c) an overall risk assessment establishing if possible the safety of the traditional food from a third country and highlighting uncertainties and limitations where relevant;

(d) conclusions.

2. The Commission may ask for additional information in its request for an opinion of the Authority.

Article 11

Transitional measures

The notifications as referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be submitted to the Commission not later than 1 January 2019.

Article 12

Entry into force and application

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.

Done at Brussels, 20 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Template cover letter accompanying a notification for traditional food from a third country following the requirements of Article 14 of Regulation (EU) 2015/2283

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date: .....

Subject: Notification for authorisation of a traditional food from a third country in accordance with Regulation (EU) 2015/2283.

(Please indicate clearly by ticking one of the boxes)

☐ Notification for an authorisation of a new traditional food.

☐ Notification for adding, removing or changing the conditions of use of an already authorised traditional food. Please provide a reference to that notification.

☐ Notification for adding, removing or changing the specifications of an already authorised traditional food. Please provide a reference to that notification.

☐ Notification for adding, removing or changing additional specific labelling requirements of an already authorised traditional food. Please provide a reference to that notification.

☐ Notification for adding, removing or changing the post-market monitoring requirements of an already authorised traditional food. Please provide a reference to that notification.

The Applicant(s) or their Representative(s) in the Union

(name(s), address(es)…)

.....

.....

.....

submit(s) this notification in order to update the Union list on novel foods.

Identity of the traditional food:

.....

.....

Confidentiality ([1]). Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

☐ Yes

☐ No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement
—		

Yours sincerely,

Signature .....

([1]) Applicants should use the format established in Annex III to indicate which information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.

Enclosures:

☐ Complete technical dossier

☐ Summary of the dossier

☐ List of the parts of the dossier requested to be treated as confidential and verifiable justification for such claims

☐ Copy of administrative data of applicant(s)

ANNEX II

Template cover letter accompanying an application for traditional food from a third country following the requirements of Article 16 of Regulation (EU) 2015/2283

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date: .....

Subject: Application for authorisation of a traditional food from a third country following the requirements of Article 16 of Regulation (EU) 2015/2283

The Applicant(s) or their Representative(s) within the European Union

(name(s), address(es)…)

.....

.....

.....

submit(s) this application in order to update the Union list on novel foods.

Identity of the traditional food:

.....

.....

Confidentiality ([1]). Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

☐ Yes

☐ No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement

Yours sincerely,

Signature .....

Enclosures:

☐ Complete application

☐ Summary of the application

☐ List of the parts of the application requested to be treated as confidential and verifiable justification for such claims

☐ Documented data relating to the duly reasoned safety objections

☐ Copy of administrative data of applicant(s)

([1]) Applicants should use the format established in Annex III to indicate the information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.

ANNEX III

Justification for confidential information

This Annex shall be updated during the notification or application procedure each time an applicant submits a request for information to be treated as confidential.

Where the production process contains confidential data, a non-confidential summary of the production process shall be provided.

Information requested to be considered as confidential	**Justification**
Section x.y (submitted on YYYY/MM/DD)	
Annex X (submitted on YYYY/MM/DD)	
Section x.y. (submitted on YYYY/MM/DD)	
Annex X (submitted on YYYY/MM/DD)	

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469

of 20 December 2017

laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 13 and Article 35(3) thereof,

Whereas:

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

(2) Pursuant to Article 13 of Regulation (EU) 2015/2283, the Commission has to adopt implementing acts laying down administrative and scientific data requirements for applications referred to in Article 10(1) of that Regulation.

(3) Without prejudice to Articles 5 and 10 of Regulation (EU) 2015/2283, the Commission should verify whether the application falls within the scope of that Regulation and its validity.

(4) Applications referred to in Article 10(1) of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify their validity and enable the European Food Safety Authority (the Authority) to conduct comprehensive risk assessments of the novel foods.

(5) The applications should include detailed descriptions of the safety evaluation strategy, the raw data, information on the relevance of the test material used in the toxicological studies, and detection and characterisation test methods for the engineered nanomaterials.

(6) Experience has shown that in certain cases a novel food intended for a particular group of the population may also reasonably be expected to be consumed by other groups of the population and that risk management measures may be necessary to mitigate potential health risks to those other population groups. Therefore, sufficient information should be provided in the application to enable the risks to those population groups to be assessed.

(7) Where the applicant submits an application to add, remove or change the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food, it may not be necessary for the applicant to provide all the data required for the risk assessment, where the applicant provides verifiable justification.

(8) In order to ensure that toxicological tests are performed to a certain standard, they should be carried out in accordance with the rules set out in Directive 2004/10/EC of the European Parliament and of the Council ([2]). Where those tests are carried out outside the territory of the Union, they should follow the OECD Principles of Good Laboratory Practice ([3]).

(9) The opinion of the Authority should provide sufficient information to ascertain whether the proposed use of the novel food is safe for consumers.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

([3]) OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17.

(10) In order to benefit from data protection, as laid down in Article 26 of Regulation (EU) 2015/2283, requests for protection of proprietary data should be justified and all data concerned should be kept in a separate part of the application.

(11) Pursuant to Article 35 of Regulation (EU) 2015/2283, it is necessary to lay down transitional measures for the entry into force of that Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Scope and subject matter

This Regulation lays down rules for the implementation of Article 13 of Regulation (EU) 2015/2283 as regards the administrative and scientific requirements for applications referred to in Article 10(1) and the transitional measures referred to in Article 35(3) of that Regulation.

Article 2

Definitions

In addition to the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council [1] and Regulation (EU) 2015/2283, the following definition shall apply:

'application' means a stand-alone dossier containing the information and the scientific data submitted for the authorisation of a novel food pursuant to Article 10(1) of Regulation (EU) 2015/2283.

Article 3

Structure, content and presentation of an application

1. An application shall be submitted electronically to the Commission and shall consist of the following:

(a) a cover letter;

(b) a technical dossier;

(c) a summary of the dossier.

2. The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex I.

3. The technical dossier referred to in paragraph 1(b) shall contain:

(a) the administrative data as provided for in Article 4;

(b) the scientific data as provided for in Article 5.

4. Where the applicant submits an application to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food, it may not be necessary for the applicant to provide all the data required under Article 5 of this Regulation where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the existing risk assessment.

5. In addition to the information referred to in points (a), (b) and (e) of Article 10(2) of Regulation (EU) 2015/2283, the summary of the dossier referred to in paragraph 1(c) of this Article shall set out the reasons why the use of the novel food complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283.

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Article 4

Administrative data requirements

In addition to the information set out in Article 10(2) of Regulation (EU) 2015/2283, the application shall include the following administrative data:

(a) the name(s) of the manufacturer(s) of the novel food, if different than the applicant's, address and contact details;

(b) the name, address and contact details of the person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission;

(c) the date of submission of the dossier;

(d) a table of contents of the dossier;

(e) a detailed list of documents annexed to the dossier, including references to titles, volumes and pages;

(f) a list of the parts of the dossier to be treated as confidential and verifiable justification in accordance with Article 23 of Regulation (EU) 2015/2283 and the rules set out in Annex II to this Regulation. Where the production process contains confidential data, a non-confidential summary of the production process shall be provided;

(g) information and explanations substantiating the existence of the applicant's right of reference to the proprietary scientific evidence or scientific data in accordance with Article 26 of Regulation (EU) 2015/2283. That information shall be included in a separate folder.

Article 5

Scientific data requirements

1. The dossier submitted in support of an application for the authorisation of a novel food shall enable a comprehensive risk assessment of the novel food.

2. Where the application for the authorisation of a novel food involves the use of engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283, the applicant shall provide detection and characterisation test methods in compliance with the requirements of Article 10(4) of that Regulation.

3. The applicant shall provide a copy of the documentation on the procedure and strategy followed when gathering the data.

4. The applicant shall provide a description of the safety evaluation strategy and the corresponding toxicological testing strategy and shall justify the inclusion or exclusion of specific studies or information.

5. The applicant shall provide on request the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application. This information includes data used to generate the conclusions of the individual studies and results of examinations.

6. Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.

7. For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration.

Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.

8. The applicant shall propose an overall conclusion on the safety of the proposed uses of the novel food. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Article 6

Verification of the validity of an application

1. On receipt of an application the Commission shall without delay verify whether the application falls within the scope of Regulation (EU) 2015/2283 and whether the application fulfils the requirements set out in Article 10(2) of that Regulation.

2. The Commission may consult the Authority. The Authority shall provide the Commission with its views on whether the application fulfils the relevant requirements set out in Article 10(2) of Regulation (EU) 2015/2283 within a period of 30 working days.

3. The Commission may request additional information from the applicant as regards the validity of the application and agree with the applicant of the period within which that information shall be provided.

4. By way of derogation from paragraph 1 of this Article, and without prejudice to Article 10(2) of Regulation (EU) 2015/2283, an application may be considered as valid even if it does not contain all the elements required under Articles 3 to 5 of this Regulation, provided that the applicant has submitted appropriate justification for each missing element.

5. The Commission shall inform the applicant, the Member States and the Authority whether the application is considered valid or not. If the application is not considered valid, the Commission shall indicate the reasons why it is not valid.

Article 7

Information to be included in the opinion of the Authority

1. The opinion of the Authority shall include the following information:

(a) the identity of the novel food;

(b) the assessment of the production process;

(c) compositional data;

(d) specifications;

(e) the history of use of the novel food and/or its source;

(f) the proposed uses and use levels and anticipated intake;

(g) absorption, distribution, metabolism and excretion (ADME);

(h) nutritional information;

(i) toxicological information;

(j) allergenicity;

(k) an overall risk assessment for the novel food under the proposed uses and use levels and highlighting uncertainties and limitations where relevant;

(l) when the dietary exposure exceeds the health-based guidance value identified in the overall risk assessment, the dietary exposure assessment of the novel food shall be detailed, providing the contribution to the total exposure of each food category or foodstuff for which the use is authorised or has been requested;

(m) conclusions.

2. The Commission may ask for additional information in its request for an opinion of the Authority.

Article 8

Transitional measures

1. By 1 January 2018 the Member States shall notify to the Commission the lists of requests referred to in Article 35(1) of Regulation (EU) 2015/2283.

2. The Members States shall make available all the information they have received on each request referred to in paragraph 1 to the Commission.

3. Any request referred to in paragraph 1 of this Article shall be updated by the applicant in order to comply with the requirements set out in Article 10(2) of Regulation (EU) 2015/2283 and in this Regulation.

4. By way of derogation, paragraphs 1 and 2 shall not apply to requests referred to in paragraph 1 of this Article for which an initial assessment report has been forwarded to the Commission pursuant to Article 6(4) of Regulation (EC) No 258/97 of the European Parliament and of the Council [1] by 1 January 2018, and for which no reasoned objections have been made to the marketing of the novel food concerned within the period established in Article 6(4) of that Regulation.

5. The deadline for the submission of the applications referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be 1 January 2019.

Article 9

Entry into force and application

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.

Done at Brussels, 20 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

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

ANNEX I

Template cover letter accompanying an application for novel food

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date: .....

Subject: Application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283.

(Please indicate clearly by ticking one of the boxes)

☐ Application for an authorisation of a new novel food.

☐ Application for adding, removing or changing the conditions of use of an already authorised novel food. Please provide a reference to that authorisation.

☐ Application for adding, removing or changing the specifications of an already authorised novel food. Please provide a reference to that authorisation.

☐ Application for adding, removing or changing additional specific labelling requirements of an already authorised novel food. Please provide a reference to that authorisation.

☐ Application for adding, removing or changing post market monitoring requirements of an already authorised novel food. Please provide a reference to that authorisation.

The Applicant(s) or their Representative(s) in the Union

(name(s), address(es)…)

.....

.....

.....

submit(s) this application in order to update the Union list on novel foods.

Identity of the novel food (information on the identity of the novel food should be provided, depending on the category(ies) under which the novel food falls):

.....

.....

Confidentiality ([1]). Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

☐ Yes

☐ No

Data Protection ([2]). Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283:

☐ Yes

☐ No

([1]) Applicants should use the format established in Annex II to indicate which information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.

([2]) Applicant should specify the part(s) of the application which include(s) proprietary data for which protection is requested, clearly stating section(s) and page number(s). Applicant should provide verifiable justification /declaration for the proprietary claim.

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement

Yours sincerely,

Signature .....

Enclosures:

☐ Complete dossier

☐ Summary of the dossier

☐ List of the parts of the dossier requested to be treated as confidential and verifiable justification for such claims

☐ Information supporting the protection of proprietary data relating to the novel food application

☐ Copy of administrative data of applicant(s)

ANNEX II

Justification for confidential information

This Annex shall be updated during the application procedure each time an applicant submits a request for information to be treated as confidential.

Where the production process contains confidential data, a non-confidential summary of the production process shall be provided.

Information requested to be considered as confidential	**Justification**
Section x.y (submitted on YYYY/MM/DD)	
Annex X (submitted on YYYY/MM/DD)	
Section x.y (submitted on YYYY/MM/DD)	
Annex X (submitted on YYYY/MM/DD)	

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

of 20 December 2017

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

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

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

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

HAS ADOPTED THIS REGULATION:

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.

Done at Brussels, 20 December 2017.

For the Commission

The President

Jean-Claude JUNCKER

([1]) OJ L 327, 11.12.2015, p. 1.

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

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

Table 1: Authorised novel foods

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
	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)		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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		
***Adansonia digitata* (Baobab) dried fruit pulp**	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Baobab fruit pulp'	
***Ajuga reptans* extract from cell cultures**	*Specified food category*	*Maximum levels*		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract of the flowering aerial parts of *Ajuga reptans*		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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			
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		
***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	20 g/100 g		
***Aloe macroclada* Baker leaf extract**	*Specified food category*	*Maximum levels*		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of the similar gel derived from *Aloe vera* (L.) Burm.		
Antarctic Krill oil from *Euphausia superba*	*Specified food category*	*Maximum levels of combined DHA and EPA*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)'	
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g		
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of combined DHA and EPA*		
	Non-alcoholic beverages Milk-based drinks Dairy analogue drinks	80 mg/100 ml		
	Spreadable fat and dressings	600 mg/100 g		
	Cooking fats	360 mg/100 ml		
	Breakfast cereals	500 mg/100 g		
	Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g		
	Nutrition bars/cereal bars	500 mg/100 g		
	Food Supplements as defined in Directive 2002/46/EC	3 000 mg/day for the general population 450 mg/day for pregnant and lactating women		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
	Processed cereal-based food and baby food 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			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of combined DHA and EPA*		
	Processed cereal-based food and baby food intended for infants and young children covered by Regulation (EU) No 609/2013	200 mg/100 ml		
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
Arachidonic acid-rich oil from the fungus *Mortierella alpina*	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from *Mortierella alpina*' or '*Mortierella alpina* oil'	
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
	Foods for special medical purposes for premature infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
Argan oil from *Argania spinosa*	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Argan oil' and if used as seasoning 'Vegetable oil only for seasoning' shall be mentioned on the label	
	As seasonings	Not specified		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of vegetable oils		
Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Astaxanthin'	
	Food Supplements as defined in Directive 2002/46/EC	40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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*)		
Fermented black bean extract	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fermented black bean (Soya) extract' or 'Fermented Soya extract'	
	Food Supplements as defined in Directive 2002/46/EC	4,5 g/day		
Bovine lactoferrin	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lactoferrin from cows' milk'	
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 (ready to drink)	100 mg/100 ml		
	Foods on dairy basis intended for young children (ready to eat/drink)	200 mg/100 g		
	Processed cereal food (solid)	670 mg/100 g		
	Foods for special medical 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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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		
***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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
***Calanus finmarchicus* oil**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from *Calanus finmarchicus* (crustacean)'	
	Food supplements as defined in Directive 2002/46/EC	2,3 g/day		
Chewing gum base (monomethoxypolyethylene glycol)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Gum base (including 1,3-butadiene, 2-methyl-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		
Chia seeds (*Salvia hispanica*)	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia seeds (*Salvia hispanica*)' 2. Pre-packaged Chia (*Salvia hispanica*) seeds shall carry additional labelling to inform the consumer that the daily intake is no more than 15 g.	
	Bread products	5 % (whole or ground chia seeds)		
	Baked products	10 % whole chia seeds		
	Breakfast cereals	10 % whole chia seeds		
	Fruit, nut and seed mixes	10 % whole chia seeds		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Fruit juice and fruit/vegetable blend beverages	15 g/day for addition of whole, mashed or ground chia seeds		
	Pre-packaged Chia seed as such	15 g/day whole chia seeds		
	Fruit spreads	1 % whole chia seeds		
	Yoghurt	1,3 g whole chia seeds per 100 g of yoghurt or 4,3 g whole chia seeds per 330 g of yoghurt (portion)		
	Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses	5 % whole chia seeds		
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 on the labelling of the foodstuff 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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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]			
***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		
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			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
***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'	
Dextran preparation produced by *Leuconostoc mesenteroides*	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Dextran'	
	Bakery products	5 %		
Diacylglycerol oil of plant origin	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Diacylglycerol oil of plant origin (at least 80 % diacylglycerols)'	
	Cooking oils			
	Fat spreads			
	Salad dressings			
	Mayonnaise			
	Meal replacement for weight control (as drinks)			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Bakery products			
	Yoghurt type products			
Dihydrocapsiate (DHC)	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Dihydrocapsiate' 2. Food supplements containing synthetic dihydrocapsiate will be labelled as 'not intended for children up to 4,5 years'	
	Cereal bars	9 mg/100 g		
	Biscuits, cookies and crackers	9 mg/100 g		
	Rice based snacks	12 mg/100 g		
	Carbonated drinks, dilutable drinks, fruit juice based beverages	1,5 mg/100 ml		
	Vegetable drinks	2 mg/100 ml		
	Coffee based drinks, tea based drinks	1,5 mg/100 ml		
	Flavoured water - still	1 mg/100 ml		
	Precooked oatmeal cereal	2,5 mg/100 g		
	Other cereals	4,5 mg/100 g		
	Ice cream, dairy desserts	4 mg/100 g		
	Pudding mixes (ready to eat)	2 mg/100 g		
	Products based on yoghurt	2 mg/100 g		
	Chocolate confectionery	7,5 mg/100 g		
	Hard candy	27 mg/100 g		
	Sugar-free gum	115 mg/100 g		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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		
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*		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
***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		
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	
	Food Supplements as defined in Directive 2002/46/EC	150 mg of extract in one portion of food or food supplement		
	Foods fortified in accordance with Regulation (EC) No 1925/2006			
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'	
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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			
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)		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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. 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.	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l		
	Unflavoured fermented milk-based products	1,2 g/l beverages		
		19,2 g/kg products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	1,2 g/l beverages		
		19,2 g/kg products other than beverages		
	Dairy analogues, including beverage whiteners	1,2 g/l beverages		
		12 g/kg for products other than beverages		
		400 g/kg for whitener		
	Cereal bars	12 g/kg		
	Table-top sweeteners	200 g/kg		
	Infant formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto-*N*-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Follow-on formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto-*N*-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	12 g/kg for products other than beverages		
		1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Milk-based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products added alone or in combination with up to 0,6 g/l lacto-N-neotetraose, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as 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 Commission Implementing Regulation (EU) No 828/2014	60 g/kg		
	Flavoured drinks	1,2 g/l		
	Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9,6 g/l - the maximum level refers to the products ready to use		
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	3,0 g/day for general population		
		1,2 g/day for young children		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Galacto-oligosaccharide	*Specified food category*	*Maximum levels (expressed as ratio kg galacto-oligosaccharide/kg final food)*		
	Food Supplements as defined in Directive 2002/46/EC	0,333		
	Milk	0,020		
	Milk drinks	0,030		
	Meal replacement for weight control (as drinks)	0,020		
	Dairy analogue drinks	0,020		
	Yoghurt	0,033		
	Dairy based deserts	0,043		
	Frozen dairy deserts	0,043		
	Fruit drinks and energy drinks	0,021		
	Infant meal replacement drinks	0,012		
	Baby juice	0,025		
	Baby yogurt drink	0,024		
	Baby desert	0,027		
	Baby snack	0,143		
	Baby cereals	0,027		
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	0,013		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels (expressed as ratio kg galacto-oligosaccharide/kg final food)*		
	Juice	0,021		
	Fruit pie fillings	0,059		
	Fruit preparations	0,125		
	Bars	0,125		
	Cereals	0,125		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	0,008		
Glucosamine HCl	*Specified food category*	*Maximum levels*		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish		
	Foods covered by Regulation (EU) No 609/2013			
	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			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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 before consumption, in order to take into account the potential risk of gastro-intestinal obstruction.	
	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		
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)			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Hydroxytyrosol	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the food products containing 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			
Isomalto-oligosaccharide	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Isomaltooligosaccharide'. 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 %		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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 %		
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'.	
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 (capsules or tablets) intended for the adult population	20 g/day		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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 in Regulation (EU) No 609/2013	0,6 g/l in combination with up to 1,2 g/l of 2′-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Follow-on formula as defined in Regulation (EU) No 609/2013	0,6 g/l in combination with up to 1,2 g/l of 2′-fucosyllactose at a ratio of 1: 2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	6 g/kg for products other than beverages 0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Milk-based drinks and similar products intended for young children	0,6 g/l for milk-based drinks and similar products added alone or in combination with 2′-O-fucosyllactose, at concentrations up to 1,2 g/l, at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Foods for special medical purposes as defined in Regulation (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		
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	1,5 g/day for general population 0,6 g/day for young children		
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		
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Lycopene from *Blakeslea trispora*	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lycopene'	
	Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g		
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal		
	Breakfast cereals	5 mg/100 g		
	Fats and dressings	10 mg/100 g		
	Soups other than tomato soups	1 mg/100 g		
	Bread (including crispy breads)	3 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Food supplements as defined in Directive 2002/46/EC	15 mg/day		
Lycopene from tomatoes	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lycopene'	
	Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g		
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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		
Lycopene oleoresin from tomatoes	*Specified food category*	*Maximum levels of lycopene*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lycopene oleoresin from tomatoes'	
	Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g		
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g		
	Total diet replacement for weight control covered by Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal		
	Breakfast cereals	5 mg/100 g		
	Fats and dressings	10 mg/100 g		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of lycopene*		
	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		
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 %		
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			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Flavoured or unflavoured fermented milk products			
	Cold desserts (dairy, fat, fruit, cereal, egg-based products)			
	Fruit preparations (pulps, purees or compotes)			
	Soups and broths			
(6S)-5-methyltetrahydrofolic acid, glucosamine salt	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '(6S)-5-methyltetrahydrofolic acid, glucosamine salt' or '5MTHF-glucosamine'	
	Food Supplements as defined in Directive 2002/46/EC as a source of folate			
Monomethylsilanetriol (Organic Silicon)	*Specified food category*	*Maximum levels of silicon*	The designation of the novel food on the labelling of the food supplements containing it shall be 'Organic silicon (monomethylsilanetriol)'	
	Food Supplements as defined in Directive 2002/46/EC for adult population (in liquid form)	10,40 mg/day		
Mycelial extract from Shiitake mushroom (*Lentinula edodes*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'extract from the mushroom *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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Noni fruit juice (*Morinda citrifolia*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of *Morinda citrifolia*'	
	Pasteurised fruit and fruit nectar based drinks	30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per day		
Noni fruit juice powder (*Morinda citrifolia*)	Food supplements as defined in Directive 2002/46/EC	6,6 g/day (equivalent to 30 ml of noni juice)	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice powder' or 'Juice powder of *Morinda citrifolia*'	
Noni fruit puree and concentrate (*Morinda citrifolia*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of 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		
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	Sweet spreads, fillings and icings	7 g/100 g		
	Savoury sauces, pickles, gravies and condiments	20 g/100 g		
	Food Supplements as defined in Directive 2002/46/EC	6 g/day		
Noni leaves (*Morinda citrifolia*)	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs 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 %		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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, 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			
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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of DHA and EPA combined*		
	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		
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			
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			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Phosphatidylserine from fish phospholipids	*Specified food category*	*Maximum levels of phosphatidylserine*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fish phosphatidylserine'	
	Beverages based on yoghurt	50 mg/100 ml		
	Powders based on milk powders	3 500 mg/100 g (equivalent to 40 mg/100 ml ready to drink)		
	Foods based on yoghurt	80 mg/100 g		
	Cereal bars	350 mg/100 g		
	Chocolate based confectionary	200 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
	Food supplements as defined in Directive 2002/46/EC	300 mg/day		
Phosphatidylserine from soya phospholipids	*Specified food category*	*Maximum levels of phosphatidylserine*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Soya phosphatidylserine'	
	Beverages based on yoghurt	50 mg/100 ml		
	Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready to drink)		
	Foods based on yoghurt	80 mg/100 g		
	Cereal bars	350 mg/100 g		
	Chocolate based confectionary	200 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
Phospholipid product containing equal amounts of 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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of phosphatidylserine*		
	Foods based on yogurt	80 mg/100 g		
	Soy-based yogurt-like products	80 mg/100 g		
	Yogurt based-drinks	50 mg/100 g		
	Soy-based yogurt-like drinks	50 mg/100 g		
	Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready-to drink)		
	Food Supplements as defined in Directive 2002/46/EC	800 mg/day		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
Phospholipides from egg yolk	*Specified food category*	*Maximum levels*		
	Not specified			
Phytoglycogen	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Phytoglycogen'	
	Processed foods	25 %		
Phytosterols/phytostanols	*Specified food category*	*Maximum levels*	In accordance with Annex III.5 of Regulation (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.			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
	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, Appendix II points B and C, of Regulation (EU) No 1308/2007, and excluding cooking and frying fats and spreads based on butter or other animal fat.			
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'	

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
Protein extract from pig kidneys	*Specified food category*	*Maximum levels*		
	Food Supplements as defined in Directive 2002/46/EC	3 capsules/day; equalizing 12,6 mg pig kidney extract a day Diamine oxidase (DAO) content: 0,9 mg/day (3 capsules with a content of DAO of 0,3 mg/capsule)		
	Food for special medical purposes as defined in Regulation (EU) No 609/2013			
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.	

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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 adult population (capsule or tablet form)	150 mg/day		
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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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 gastrointestinal disturbance. 3. There shall be a statement that the products are not intended for use by children.	
	Bakery products and confectionary			
***Schizochytrium* sp. oil rich in DHA and EPA**	*Specified food category*	*Maximum levels of DHA and EPA combined*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the microalgae *Schizochytrium* sp.'	
	Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	3 000 mg/day		
	Food Supplements as defined in Directive 2002/46/EC for pregnant and lactating women	450 mg/day		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
	Milk-based drinks and similar products intended for young children	200 mg/100 g		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of DHA and EPA combined*		
	Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013			
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
	Bakery Products (Breads, Rolls and Sweet Biscuits)	200 mg/100 g		
	Breakfast Cereals	500 mg/100 g		
	Cooking Fats	360 mg/100 g		
	Dairy Analogues except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)		
	Dairy Products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)		
	Non-alcoholic Beverages (including dairy analogue and milk-based drinks)	80 mg/100 g		
	Cereal/Nutrition Bars	500 mg/100 g		
	Spreadable Fats and Dressings	600 mg/100 g		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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. (ATCC PTA-9695)'	
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g		
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g		
	Spreadable fats and dressings	600 mg/100 g		
	Breakfast cereals	500 mg/100 g		
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population		
		450 mg DHA/day for pregnant and lactating women		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
	Milk-based drinks and similar products intended for young children	200 mg/100 g		
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of DHA*		
	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		
***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 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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of DHA*		
	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			
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
***Schizochytrium* sp. (T18) oil**	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* sp.'	
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g		
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g		
	Spreadable fats and dressings	600 mg/100 g		
	Breakfast cereals	500 mg/100 g		
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population		
		450 mg DHA/day for pregnant and lactating women		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
	Milk-based drinks and similar products intended for young children	200 mg/100 g		
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of DHA*		
	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		
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		
Spermidine-rich wheat germ extract (*Triticum aestevium*)	*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	Equivalent of max. 6 mg/day spermidine		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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 %		
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		
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 250 mg/day		
	Special salts	1 %		
	Condiment	250 mg/day		
	Food Supplements as defined in Directive 2002/46/EC	250 mg/day		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
***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			
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'.	
	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		
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			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
UV-treated mushrooms (*Agaricus bisporus*)	*Specified food category*	*Maximum levels of vitamin D_2*		
	Mushrooms (*Agaricus bisporus*)	10 µg of vitamin D_2/100 g fresh weight	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'.	
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 of vitamin D_2/100 g		
	Yeast-leavened fine bakery wares	5 µg of vitamin D_2/100 g		
	Food Supplements as defined in Directive 2002/46/EC	5 µg of vitamin D_2/day		
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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
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		
	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		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels of pure beta-glucans from yeast (Saccharomyces cervisiae)*		
	Wholegrain and high fibre instant hot breakfast cereals	1,5 g/kg		
	Cookie-type biscuits	6,7 g/kg		
	Cracker-type biscuits	6,7 g/kg		
	Milk based beverages	3,8 g/kg		
	Fermented milk products	3,8 g/kg		
	Milk product analogues	3,8 g/kg		
	Dried milk/milk powder	25,5 g/kg		
	Soups and soup mixes	0,9 g/kg (ready to eat)		
		1,8 g/kg (condensed)		
		6,3 g/kg (powder)		
	Chocolate and confectionery	4 g/kg		
	Protein bars and powders	19,1 g/kg		
	Jam, marmalade and other fruit spreads	11,3 g/kg		
Zeaxanthin	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'synthetic zeaxanthin'	
	Food Supplements as defined in Directive 2002/46/EC	2 mg/day		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Zinc L-pidolate	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Zinc L-pidolate'	
	Foods covered by Regulation (EU) No 609/2013	3 g/day		
	Milk based drinks and similar products intended for young children			
	Meal replacement for weight control			
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Food bearing statement on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
	Food Supplements as defined in Directive 2002/46/EC			

(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).

Table 2: Specifications

Authorised Novel Food	Specification
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)

Authorised Novel Food	Specification
	Residual solvents: 2-Propanol: < 0,1 % (w/w) Acetone: < 0,1 % (w/w) Ethyl acetate: < 0,1 % (w/w) **Microbiological criteria:** *Salmonella*: Absence in 25 g Aerobic mesophilic total count: < 500 CFU/g Enterobacteriaceae: Absence in 10 g *Cronobacter (Enterobacter) sakazakii*: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g *Bacillus cereus*: < 50 CFU/g Yeasts: < 10 CFU/g Moulds: < 10 CFU/g Residual endotoxins: < 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.
***Adansonia digitata* (Baobab) dried fruit pulp**	**Description/Definition:** The Baobab (*Adansonia digitata*) fruits are harvested from trees. The hard shells are cracked open and the pulp is separated from the seeds and the shell. This is milled, separated into coarse and fine lots (particle size 3 to 600 µ) and then packaged. **Typical nutritional components:** Moisture (loss on drying) (g/100 g): 4,5-13,7 Protein (g/100 g): 1,8-9,3 Fat (g/100 g): 0-1,6 Total carbohydrate (g/100 g): 76,3-89,5 Total sugars (as glucose): 15,2-36,5 Sodium (mg/100 g): 0,1-25,2 **Analytical specifications:** Foreign matter: Not more than 0,2 % Moisture (loss on drying) (g/100 g): 4,5-13,7 Ash (g/100 g): 3,8-6,6

Authorised Novel Food	Specification
***Ajuga reptans* extract from cell cultures**	**Description/Definition:** Hydroalcoholic extract from *Ajuga reptans* L. tissue cultures which is substantially equivalent to extracts from flowering aerial parts of *Ajuga reptans* obtained by traditional cultures.
L-Alanyl-L-Glutamine	**Description/Definition:** L-Alanyl-L-Glutamine is produced by fermentation with a genetically modified strain of *Escherichia coli*. During the fermentation process, the ingredient is secreted into the growth medium from which it is subsequently separated and purified to a concentration of > 98 %. Appearance: White crystalline powder Purity: > 98 % Infrared spectroscopy: Conformity with ref. standard Appearance of solution: Colourless and clear Assay (dry basis): 98-102 % Related substances (each): ≤ 0,2 % Residue on ignition: ≤ 0,1 % Loss on drying: ≤ 0,5 % Optical rotation: + 9,0 - + 11,0° pH (1 %; H_2O): 5,0-6,0 Ammonium (NH_4): ≤ 0,020 % Chloride (Cl): ≤ 0,020 % Sulphate (SO_4): ≤ 0,020 % **Microbiological criteria:** *Escherichia coli*: Absence/g
Algal oil from the microalgae *Ulkenia* sp.	**Description/Definition:** Oil from the micro-algae *Ulkenia* sp. Acid value: ≤ 0,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % DHA content: ≥ 32 %

Authorised Novel Food	Specification
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:** Lauric acid (C12:0): < 1,0 % Myristic acid (C14:0): < 1,0 % Palmitic acid (C16:0): < 2,0 % Palmitoleic acid (C16:1): < 1,0 % Stearic acid (C18:0): 45-58 % Oleic acid (C18:1): 40-51 % Linoleic acid (C18:2): < 1,0 % γ-Linolenic acid (C18:3): < 1,0 % Arachidic acid (C20:0): < 1,0 % Free fatty acids: max 0,1 % **Characteristics:** Trans fatty acids: max 0,5 % Peroxide value: max 0,8 meq/kg Iodine value: < 46 g/100 g Unsaponifiable matter: max 1,0 % Saponification value: 185-198 mg KOH/g
***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. leaves. Ash: 25 % Dietary fibres: 28,6 % Fat: 2,7 % Moisture: 4,7 % Polysaccharides: 9,5 % Protein: 1,63 % Glucose: 8,9 %

Authorised Novel Food	Specification
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 Moisture and volatiles: ≤ 3 % or 0,6 expressed as water activity at 25 °C Phospholipids: 35-50 % Trans-fatty acids: ≤ 1 % EPA (eicosapentaenoic acid): ≥ 9 % DHA (docosahexaenoic acid): ≥ 5 %
Antarctic Krill oil rich in phospholipids from *Euphausia superba*	**Description/Definition:** Oil rich in phospholipids is produced from Antarctic krill (*Euphausia superba*) by repeated solvent washings with an approved solvent (under Directive 2009/32/EC) to increase phospholipid content of the oil. Solvents are removed from the final product by evaporation. Saponification value: ≤ 230 mg KOH/g Peroxide value (PV): ≤ 3 meq O_2/kg oil Oxidative stability: All food products containing Antarctic Krill oil rich in phospholipids 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: ≥ 60 % Trans-fatty acids: ≤ 1 % EPA (eicosapentaenoic acid): ≥ 9 % DHA (docosahexaenoic acid): ≥ 5 %
Arachidonic acid-rich oil from the fungus *Mortierella alpina*	**Description/Definition:** The clear yellow arachidonic acid-rich oil is obtained by fermentation of the non-genetically modified strains IS-4, I49-N18 and FJRK-MA01 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 %

Authorised Novel Food	Specification
	Peroxide value: ≤ 5 meq/kg Anisidin value: ≤ 20 Acid value: ≤ 1,0 KOH/g Moisture: ≤ 0,5 %
Argan oil from *Argania spinosa*	**Description/Definition:** Argan oil is the oil obtained by cold pressing of the almond like kernels of the fruits of *Argania spinosa* (L.) Skeels. Kernels may be roasted prior to pressing, but with no direct contact with a flame. **Composition:** Palmitic acid (C16:0): 12-15 % Stearic acid (C18:0): 5-7 % Oleic acid (C18:1): 43-50 % Linoleic acid (C18:2): 29-36 % Unsaponifiable matter: 0,3-2 % Total sterols: 100-500 mg/100 g Total tocopherols: 16-90 mg/100 g Oleic acidity: 0,2-1,5 % Peroxide value: < 10 meq O_2/kg
Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	**Description/Definition:** Astaxanthin is a carotenoid produced by *Haematococcus pluvialis* algae. Production methods for the growth of the algae are variable; using closed systems exposed to sunlight or strictly controlled illuminated light alternatively open ponds may be used. The algal cells are harvested and dried; the oleoresin is extracted using either super critical CO_2 or a solvent (ethyl acetate). The Astaxanthin is diluted and standardized to 2,5 %, 5,0 %, 7,0 %, 10 %, 15 % or 20 % using olive oil, safflower oil, Sunflower oil or MCT (Medium Chain Triglycerides). **Composition of the Oleoresin:** Fat: 42,2- 99 % Protein: 0,3-4,4 % Carbohydrate: 0-52,8 % Fibre: < 1,0 % Ash: 0,0-4,2 % Specification of Carotenoids w/w% Total Astaxanthins: 2,9-11,1 %

Authorised Novel Food	Specification
	9-cis-astaxanthin: 0,3-17,3 % 13-cis-astaxanthin: 0,2-7,0 % Astaxanthin monoesters: 79,8-91,5 % Astaxanthin diesters: 0,16-19,0 % B-Carotene: 0,01-0,3 % Lutein: 0-1,8 % Canthaxanthin: 0-1,30 % **Microbiological criteria:** Total aerobic bacteria: < 3 000 CFU/g Yeast and Moulds: < 100 CFU/g Coliforms: < 10 CFU/g *E. coli*: Negative *Salmonella*: Negative *Staphylococcus*: Negative
Basil seeds (*Ocimum basilicum*)	**Description/Definition:** Basil (*Ocimum basilicum* L.) belongs to the family '*Lamiaceae*' within the order 'Lamiales'. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed. Highest level of purity of Basil seeds has to be ensured by filtering (optical, mechanical). Production process of fruit juice and fruit/vegetable blend beverages containing Basil seeds (*Ocimum basilicum* L.) includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place. Dry Matter: 94,1 % Protein: 20,7 % Fat: 24,4 % Carbohydrate: 1,7 % Dietary Fibre 40,5 % (Method: AOAC 958.29) Ash: 6,78 %
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 %

Authorised Novel Food	Specification
	Water: ≤ 7,0 % Ash: ≤ 10 % Carbohydrate: ≥ 20 % a-glucosidase inhibitory activity: IC50 min 0,025 mg/ml Soy isoflavone: ≤ 0,3 g/100 g
Bovine lactoferrin	**Description/Definition:** Bovine lactoferrin is a protein that occurs naturally in cows' milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids. Production process: Bovine lactoferrin is isolated from skimmed milk or cheese whey via ion exchange and subsequent ultra-filtration steps. Finally it is dried by freeze drying or spraying and the large particles are sieved out. It is a virtually odourless, light pinkish powder. **Physical-Chemical properties of Bovine lactoferrin:** Moisture: < 4,5 % Ash: < 1,5 % Arsenic: < 2,0 mg/kg Iron: < 350 mg/kg Protein: > 93 % of which bovine lactoferrin: > 95 % of which other proteins: < 5,0 % pH (2 % solution, 20 °C): 5,2-7,2 Solubility (2 % solution, 20 °C): complete
***Buglossoides arvensis* seed oil**	**Description/Definition:** Refined Buglossoides oil is extracted from the seeds of *Buglossoides arvensis* (L.) I.M.Johnst Alpha-linolenic acid: ≥ 35 % w/w of total fatty acids Stearidonic acid: ≥ 15 % w/w of total fatty acids Linoleic acid: ≥ 8,0 % w/w of total fatty acids Trans fatty acids: ≤ 2,0 % w/w of total fatty acids Acid value: ≤ 0,6 mg KOH/g Peroxide value: ≤ 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

Authorised Novel Food	Specification
***Calanus finmarchicus* oil**	**Description/Definition:** The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton) *Calanus finmarchicus*. The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids. **Specifications:** Water: < 1,0 % Wax esters: > 85 % Total fatty acids: > 46 % Eicosapentaenoic acid (EPA): > 3,0 % Docosahexaenoic acid (DHA): > 4,0 % Total fatty alcohols: > 28 % C20:1 n-9 fatty alcohol: > 9,0 % C22:1 n-11 fatty alcohol: > 12 % Trans fatty acids: < 1,0 % Astaxanthinesters: < 0,1 % Peroxide value: < 3,0 meq. O_2/kg
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 **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 %

Authorised Novel Food	Specification
	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 **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

Authorised Novel Food	Specification
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: ≤ 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 (EU: carbohydrates are available = sugar + starch) (**) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin **Production process:** Production process of fruit juices and fruit juice blends beverages, containing Chia seeds, includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.
Chitin-glucan from *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).

Authorised Novel Food	Specification
	Loss on drying: ≤ 10 % Chitin-glucan: ≥ 90 % Ratio of chitin to glucan: 30:70 to 60:40 Ash: ≤ 3,0 % Lipids: ≤ 1,0 % Proteins: ≤ 6,0 %
Chitin-glucan complex from *Fomes fomentarius*	**Description/Definition:** Chitin-glucan complex is obtained from the cell walls of the fruit bodies of the fungus *Fomes fomentarius*. It consists primarily of two polysaccharides: — Chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4); — Beta-(1,3)(1,6)-D-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9). The production process consists of several steps, including: cleaning, reduction in size and grinding, softening in water and heating in an alkaline solution, washing, drying. No hydrolysis is applied during the production process. Appearance: Powder, odourless, flavourless, brown **Purity:** Moisture: ≤ 15 % Ash: ≤ 3,0 % Chitin-glucan: ≥ 90 % Ratio of chitin to glucan: 70:20 Total carbohydrates, excluding glucans: ≤ 0,1 % Proteins: ≤ 2,0 % Lipids: ≤ 1,0 % Melanins: ≤ 8,3 % Additives: None pH: 6,7-7,5 **Heavy metals:** Lead (ppm): ≤ 1,00 Cadmium (ppm): ≤ 1,00 Mercury (ppm): ≤ 0,03 Arsenic (ppm): ≤ 0,20

Authorised Novel Food	Specification
	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 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/dry weight): ≤ 3,0 Proteins (% w/dry weight): ≤ 2,0 Particle size: > 100 nm Taped density (g/cm^3): 0,7-1,0 Fat binding capacity 800 × 9 w/wet weight): pass

Authorised Novel Food	Specification
	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/25 g *Listeria monocytogenes*: Absence/25 g
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 24502). Chondroitin sulphate (sodium salt) (% dry basis): 95-105 MWw (weight avg.) (kDa): 5-12 MWn (number avg.) (kDa): 4-11 Dispersity ($w_h/w_{0,05}$): ≤ 0,7 Sulphation pattern (ΔDi-6S) (%): ≤ 85 Loss on drying (%) (105 °C to constant weight): ≤ 10,0 Residue on ignition (% dry basis): 20-30 Protein (% dry basis): ≤ 0,5 Endotoxins (EU/mg): ≤ 100 Total organic impurities (mg/kg): ≤ 50
Chromium Picolinate	**Description/Definition:** Chromium picolinate is a reddish free-flowing powder, slightly soluble in water at pH 7. The salt is also soluble in polar organic solvents. Chemical name: tris(2pyridinecarboxylato-N,O)chromium(III) or 2-pyridinecarboxylic acid chromium(III) salt CAS No.: 14639-25-9

Authorised Novel Food	Specification
	Chemical formula: $Cr(C_6H_4NO_2)_3$ Chemical characteristics: Chromium Picolinate: ≥ 95 % Chromium (III): 12-13 % Chromium (VI): not detected Water: ≤ 4,0 %
***Cistus incanus* L. Pandalis herb**	**Description:** *Cistus incanus* L. Pandalis herb; species belonging to the *Cistaceae* family and native to the Mediterranean region, Chalkidiki Peninsula. **Composition:** Moisture: 9–10 g/100 g herbs Protein: 6,1 g/100 g herbs Fat: 1,6 g/100 g herbs Carbohydrates: 50,1 g/100 g herbs Fiber: 27,1 g/100 g herbs Minerals: 4,4 g/100 g herbs Sodium: 0,18 g Potassium: 0,75 g Magnesium: 0,24 g Calcium: 1,0 g Iron: 65 mg Vitamin B1: 3,0 µg Vitamin B2: 30 µg Vitamin B6: 54 µg Vitamin C: 28 mg Vitamin A: less than 0,1 mg Vitamin E: 40–50 mg Alpha-Tocopherol: 20–50 mg Beta and Gamma-Tocopherols: 2–15 mg Delta-Tocopherol: 0,1–2 mg

Authorised Novel Food	Specification
Citicoline	***Citicoline (synthetic)*** **Description/Definition:** 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 ***Citicoline (microbial source)*** **Description/Definition:** It is produced by fermentation using a genetically modified strain of *E. coli* (BCT19/p40k) The specification on citicoline from the microbial source is identical to the authorised synthetic citicoline.
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

Authorised Novel Food	Specification
	Staphylococcus aureus: Not detected in 1 g *Pseudomonas aeruginosa*: Not detected in 1 g Yeast and moulds: ≤ 10^2 CFU/g
Extract of defatted cocoa powder	Cocoa (*Theobroma cacao* L.) Extract Appearance: Dark brown powder free of visible impurities Physical and chemical properties: Polyphenol content: Min 55,0 % GAE Theobromine content: Max 10,0 % Ash content: Max 5,0 % Moisture content: Max 8,0 % Bulk density: 0,40-0,55 g/cm^3 pH: 5,0-6,5 Residual solvent: Max 500 ppm
Low fat cocoa extract	Low fat Cocoa (*Theobroma cacao* L.) extract Appearance: Dark red to purple powder Cocoa extract, concentrate: Min 99 % Silicon dioxide (technological aid): Max 1,0 % Cocoa flavanols: Min. 300 mg/g (-) Epicatechin: Min. 45 mg/g Loss on drying: Max. 5,0 %
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. Slight yellow colour, bland taste CAS No.: 8008-52-4 Composition of fatty acids: Palmitic acid (C16:0): 2-5 % Stearic acid (C18:0): < 1,5 % Petroselinic acid (cis-C18:1(n-12)): 60-75 % Oleic acid (cis-C18:1 (n-9)): 8-15 %

Authorised Novel Food	Specification
	Linoleic acid (C18:2): 12-19 % α-Linolenic acid (C18:3): < 1,0 % Trans fatty acids: ≤ 1,0 % **Purity:** Refractive index (20°C): 1,466-1,474 Acid value: ≤ 2,5 mg KOH/g Peroxide value: ≤ 5,0 meq/kg Iodine value: 88-110 units Saponification value: 186-200 mg KOH/g Unsaponifiable matter: ≤ 15 g/kg
***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 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

Authorised Novel Food	Specification
	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: [α]D 25: Between + 145° and +151° (1 % solution) Chromatography: The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for α-cyclodextrin in a chromatogram of reference α-cyclodextrin (available from *Consortium für Elektrochemische Industrie GmbH, München, Germany or Wacker Biochem Group, Adrian, MI, USA*) using the conditions described in the METHOD OF ASSAY **Purity:** Water: ≤ 11 % (Karl Fischer Method) Residual complexant: ≤ 20 mg/kg (1-decanol) Reducing substances: ≤ 0,5 % (as glucose) Sulphated ash: ≤ 0,1 % Lead: ≤ 0,5 mg/kg **Method of assay:** Determine by liquid chromatography using the following conditions: Sample solution: Weigh accurately about 100 mg of test sample into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath (10-15 min) and dilute to the mark with purified deionised water. Filter through a 0,45-micrometer filter Reference solution: Weigh accurately about 100 mg of α-cyclodextrin into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath and dilute to the mark with purified deionised water. Chromatography: Liquid chromatograph equipped with a refractive index detector and an integrating recorder. Column and packing: Nucleosil-100-NH_2 (10 µm) (*Macherey & Nagel Co. Düren*, Germany) or similar Length: 250 mm Diameter: 4 mm Temperature: 40 °C Mobile phase: acetonitrile/water (67/33, v/v) Flow rate: 2,0 ml/min Injection volume: 10 µl

Authorised Novel Food	Specification
	Procedure: 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 × (AS/AR) (WR/WS) where As and AR are the areas of the peaks due to α-cyclodextrin for the sample solution and reference solution, respectively. Ws and WR are the weights (mg) of the test sample and reference α-cyclodextrin, respectively, after correcting for water content.
γ-cyclodextrin	**Description/Definition:** A non-reducing cyclic saccharide consisting of eight α-1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolysed starch. Recovery and purification of γ-cyclodextrin may be carried out by precipitation of a complex of γ-cyclodextrin with 8-cyclohexadecen-1-one, dissolution of the complex with water and n-decane, steam-stripping of the aqueous phase and recovery of gamma-CD from the solution by crystallisation. Virtually odourless, white or almost white crystalline solid Synonyms: γ-cyclodextrin, γ-dextrin, cyclooctaamylose, cyclomaltooctaose, γ-cycloamylase Chemical name: Cyclooctaamylose CAS number: 17465-86-0 Chemical formula: $(C_6H_{10}O_5)_8$ Assay: ≥ 98 % (dry basis) **Identification:** Melting range: Decomposes above 285 °C Solubility: Freely soluble in water; very slightly soluble in ethanol Specific rotation: [α]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): ≤ 6 mg/kg Reducing substances: ≤ 0,5 % (as glucose) Sulphated ash: ≤ 0,1 %
Dextran preparation produced by *Leuconostoc mesenteroides*	1. **Powdered form:** Carbohydrates: 60 % with: (Dextran: 50 %, Mannitol: 0,5 %, Fructose: 0,3 %, Leucrose: 9,2 %) Protein: 6,5 % Lipid: 0,5 %

Authorised Novel Food	Specification
	Lactic acid: 10 % Ethanol: traces Ash: 13 % Moisture: 10 % 2. **Liquid form:** Carbohydrates: 12 % with: (Dextran: 6,9 %, Mannitol: 1,1 %, Fructose: 1,9 %, Leucrose: 2,2 %) Protein: 2,0 % Lipid: 0,1 % Lactic acid: 2,0 % Ethanol: 0,5 % Ash: 3,4 % Moisture: 80 %
Diacylglycerol oil of plant origin	**Description/Definition:** Manufactured from glycerol and fatty acids derived from edible vegetable oils, in particular from soybean oil (*Glycine max*) or rapeseed oil (*Brassica campestris*, *Brassica napus*) using a specific enzyme. **Acylglycerol Distribution:** Diacylglycerols (DAG): ≥ 80 % 1,3-Diacylglycerols (1,3-DAG): ≥ 50 % Triacylglycerols (TAG): ≤ 20 % Monoacylglycerols (MAG): ≤ 5,0 % **Fatty Acid Composition (MAG, DAG, TAG):** Oleic acid (C18:1): 20-65 % Linoleic acid (C18:2): 15-65 % Linolenic acid (C18:3): ≤ 15 % Saturated fatty acids: ≤ 10 % **Others:** Acid value: ≤ 0,5 mg KOH/g Moisture and volatile: ≤ 0,1 % Peroxide value: ≤ 1,0 meq/kg Unsaponifiables: ≤ 2,0 % Trans fatty acids≤ 1,0 % MAG = monoacylglycerols, DAG = diacylglycerols, TAG = triacylglycerols

Authorised Novel Food	Specification
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 %
Dried extract of *Lippia citriodora* from cell cultures	**Description/Definition: Dried extract of cell cultures HTN®Vb of *Lippia citriodora* (Palau) Kunth**.
***Echinacea angustifolia* extract from cell cultures**	Extract of the roots of *Echinacea angustifolia* obtained from tissue culture plant which is substantially equivalent to a root extract from *Echinacea angustifolia* obtained in ethanol-water titrated to 4 % echinacoside.
***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: ≤ 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
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

<table>
<tr><th>Authorised Novel Food</th><th>Specification</th></tr>
<tr><td></td><td>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</td></tr>
<tr><td>L-ergothioneine</td><td>Definition
Chemical name (IUPAC): (2S)-3-(2-thioxo-2,3-dihydro-1H-imidazol-4-yl)-2-(trimethylammonio)-Propanoate
Chemical formula: $C_9H_{15}N_3O_2S$
Molecular mass: 229,3 Da
CAS No.: 497-30-3
<table>
<tr><th>Parameter</th><th>Specification</th><th>Method</th></tr>
<tr><td>Appearance</td><td>White powder</td><td>Visual</td></tr>
<tr><td>Optical rotation</td><td>$[\alpha]_D \geq (+)\ 122°$ (c = 1, H_2O)[a)]</td><td>Polarimetry</td></tr>
<tr><td>Chemical purity</td><td>≥ 99,5 %
≥ 99,0 %</td><td>HPLC [Eur. Ph. 2.2.29]
1H-NMR</td></tr>
<tr><td>Identification</td><td>Compliant with the structure</td><td>1H-NMR</td></tr>
<tr><td></td><td>C: 47,14 ± 0,4 %
H: 6,59 ± 0,4 %
N: 18,32 ± 0,4 %</td><td>Elemental analysis</td></tr>
<tr><td>Total residual solvents
(methanol, ethyl acetate, isopropanol, ethanol)</td><td>[Eur. Ph. 01/2008:50400]
< 1 000 ppm</td><td>Gas chromatography
[Eur. Ph. 01/2008:20424]</td></tr>
<tr><td>Loss on drying</td><td>Internal standard < 0,5 %</td><td>[Eur. Ph. 01/2008:20232]</td></tr>
<tr><td>Impurities</td><td>< 0,8 %</td><td>HPLC/GPC or 1H-NMR</td></tr>
</table></td></tr>
</table>

Authorised Novel Food	Specification		
	Parameter	**Specification**	**Method**
	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)	≤ 1×10^3 CFU/g	[Eur. Ph. 01/2011:50104]
	Total yeast and mould count (TYMC)	≤ 1×10^2 CFU/g	
	Escherichia coli	Absence in 1 g	
	Eur. Ph.: European Pharmacopoeia; 1H-NMR: proton nuclear magnetic resonance; HPLC: high-performance liquid chromatography; GPC: gel permeation chromatography; ICP/AES: Inductively coupled plasma atomic emission spectroscopy; CFU: colony-forming units.		
	a) Lit. $[\alpha]_D$ = (+) 126,6° (c = 1, H_2O)		
	b) Analyses conducted on each batch		
	c) Maximum levels in accordance with Regulation (EC) No 1881/2006		
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: $C_{10}H_{12}FeN_2NaO_8 \cdot 3H_2O$		
	Chemical characteristics:		
	pH of 1 % solution: 3,5-5,5		
	Iron: 12,5-13,5 %		
	Sodium: 5,5 %		
	Water: 12,8 %		
	Organic matter (CHNO): 68,4 %		
	EDTA: 65,5-70,5 %		
	Water insoluble matter: ≤ 0,1 %		
	Nitrilo-triacetic acid: ≤ 0,1 %		
Ferrous ammonium phosphate	**Description/Definition:**		
	Ferrous ammonium phosphate is a grey/green fine powder, practically insoluble in water and soluble in dilute mineral acids.		
	CAS No.: 10101-60-7		

Authorised Novel Food	Specification
	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 powder Peptides (*) (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 (*) Kjeldahl method
Flavonoids from *Glycyrrhiza glabra*	**Description/Definition:** Flavonoids derived from the roots or rootstock of *Glycyrrhiza glabra* L. are extracted with ethanol followed by further extraction of this ethanolic extract with medium-chain triglycerides. It is a dark-brown coloured liquid, containing 2,5 % to 3,5 % of glabridin. Moisture: < 0,5 % Ash: < 0,1 % Peroxide value: < 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

Authorised Novel Food	Specification
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 %

Authorised Novel Food	Specification
	Polyphloroglucinol: 20-30 % Mannitol: < 1,0 % Natural salts/Free Minerals: 0,5-2,0 % Other carbohydrates: 0,5-2,0 % Protein: 2,0-2,5 %
Fucoidan extract from the seaweed *Undaria pinnatifida*	**Description/Definition:** Fucoidan from seaweed *Undaria pinnatifida* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications: Off-white to brown powder Odour and Taste: Bland odour and 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 **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 %

Authorised Novel Food	Specification
	Natural salts/Free Minerals: 0,5-1,0 % Other carbohydrates: 0,5-2,0 % Protein: 2,0-2,5 % Extract 2: Fucoidan: 50-55 % Alginate: 2,0-4,0 % Polyphloroglucinol: 1,0-3,0 % Mannitol: 25-35 % Natural salts/Free Minerals: 8-10 % Other carbohydrates: 0,5-2,0 % Protein: 1,0-1,5 %
2′-Fucosyllactose (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 and is isolated by crystallisation. **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 %

<table>
<tr><th>Authorised Novel Food</th><th colspan="2">Specification</th></tr>
<tr><td></td><td colspan="2">Heavy Metals:
Palladium: ≤ 0,1 mg/kg
Nickel: ≤ 3,0 mg/kg
Microbiological criteria:
Aerobic mesophilic bacteria total count: ≤ 500 CFU/g
Yeasts and Moulds: ≤ 10 CFU/g
Residual endotoxins: ≤ 10 EU/mg</td></tr>
<tr><td rowspan="3">2′-Fucosyllactose (microbial source)</td><td colspan="2">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</td></tr>
<tr><td>Source:
Genetically modified strain of Escherichia coli K-12</td><td>Source:
Genetically modified strain of Escherichia coli BL21</td></tr>
<tr><td>Description:
2′-Fucosyllactose is a white to off-white crystalline powder that is produced by a microbial process. 2′-Fucosyllactose is isolated by crystallisation.
Purity:
2′-Fucosyllactose: ≥ 94 %
D-Lactose: ≤ 3,0 %
L-Fucose: ≤ 1,0
Difucosyl-D-lactose: ≤ 1,0 %
2′-Fucosyl-D-lactulose: ≤ 1,0 %
pH (20 °C, 5 % solution): 3,2-5,0
Water: ≤ 5,0 %
Ash, sulphated: ≤ 1,5 %
Acetic acid: ≤ 1,0 %
Residual proteins: ≤ 0,01 %</td><td>Description:
2′-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % ± 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2′-Fucosyllactose is produced by a microbiological process. 2′-Fucosyllactose is isolated by spray drying.
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)</td></tr>
</table>

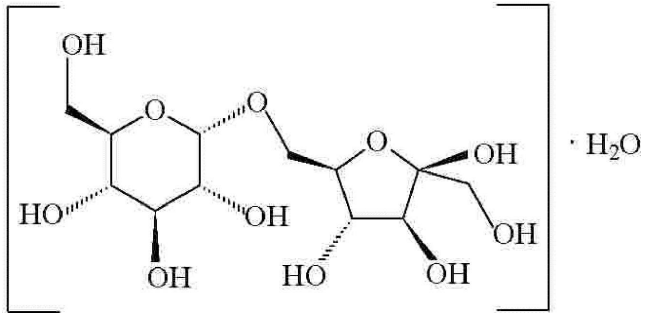
Authorised Novel Food	Specification	
	Microbiological criteria: Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts: ≤ 10 CFU/g Moulds: ≤ 100 CFU/g Endotoxins: ≤ 10 EU/mg	**Heavy Metals:** Lead: ≤ 0,02 mg/kg (powder and liquid); Arsenic: ≤ 0,2 mg/kg (powder and liquid) Cadmium: ≤ 0,1 mg/kg (powder and liquid) Mercury: ≤ 0,5 mg/kg (powder and liquid) **Microbiological criteria:** Total plate count: ≤ 10^4 CFU/g (powder), ≤ 5 000 CFU/g (liquid) Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid) Enterobacteriaceae/Coliforms: absence in 11 g (powder and liquid) *Salmonella*: negative/100 g (powder), negative/200 ml (liquid) *Cronobacter*: negative/100 g (powder), negative/200 ml (liquid) Endotoxins: ≤ 100 EU/g (powder), ≤ 100 EU/ml (liquid) Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid)
Galacto-oligosaccharide	**Description/Definition:** **Galacto-oligosaccharide is produced from milk lactose by an enzymatic process using β-galactosidases from *Aspergillus oryzae, Bifidobacterium bifidum* and *Bacillus circulans*.** GOS: min 46 % Dry Matter (DM) Lactose: max 40 % DM Glucose: max 22 % DM Galactose: min 0,8 % DM Ash: max 4,0 % DM Protein: max 4,5 % DM Nitrite: max. 2 mg/kg	
Glucosamine HCl from *Aspergillus niger* and genetically modified strain of *E. Coli* K12	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°	

Authorised Novel Food	Specification
Glucosamine sulphate KCl from *Aspergillus niger* and genetically modified strain of *E. Coli* K12	White crystalline odourless powder Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$ Relative molecular mass: 605,52 g/mol D-Glucosamine Sulphate 2KCl 98,0-102,0 % of reference standard (HPLC) Specific Rotation + 50,0° to + 52,0°
Glucosamine sulphate NaCl from *Aspergillus niger* and genetically modified strain of *E. Coli* K12	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° - + 54°
Guar Gum	**Description/Definition:** Native guar gum is the ground endosperm of seeds from natural strains of guar *Cyamopsis tetragonolobus* L. Taub. (*Leguminosae* family). It consists of a high molecular weight polysaccharide, primarily composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as a galactomannan (galactomannan content not less than 75 %). Appearance: White to yellowish powder Molecular weight: Between 50 000 – 8 000 000 Daltons CAS number: 9000-30-0 EINECS Number: 232-536-8 Purity: As specified by Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council [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]. **Physico-chemical properties:** **Powder** Shelf-life: 2 years Colour: White Odour: Light Average diameter of particles: 60-70 µm Moisture: Max 15 % Viscosity (*) at 1 hour —

Authorised Novel Food	Specification
	Viscosity (*) at 2 hours: Min 3 600 mPa.s Viscosity (*) at 24 hours: Min 4 000 mPa.s Solubility: Soluble in hot and cold water pH for 10g/L, at 25 °C - 6-7,5 **Flakes** Useful life: 1 year Colour: White/off white with absence or minimal presence of black spots Odour: Light Average diameter of particles: 1-10 mm Moisture: Max 15 % Viscosity (*) at 1 hour: Min 3 000 mPa.s Viscosity (*) at 2 hours — Viscosity(*) at 24 hours — Solubility - Soluble in hot and cold water pH for 10g/L, at 25 °C - 5-7,5 (*) The measurements of viscosity are carried out under the following conditions: 1 %, 25 °C, 20 rpm
Heat-treated milk products fermented with *Bacteroides xylanisolvens*	**Description/Definition:** Heat-treated fermented milk products are produced with *Bacteroides xylanisolvens* (DSM 23964) as starter culture. Semi-skimmed milk (between 1,5 % and 1,8 % fat) or skimmed milk (0,5 % fat or less) is pasteurised or ultra-heat-treated before starting the fermentation with *Bacteroides xylanisolvens* (DSM 23964). The resulting fermented milk product is homogenised and then heat-treated to inactivate *Bacteroides xylanisolvens* (DSM 23964). The final product does not contain viable cells of *Bacteroides xylanisolvens* (DSM 23964) (*). (*) 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: Characteristic

Authorised Novel Food	Specification
	Taste: Slightly bitter Solubility (water): Miscible with water pH: 3,5-4,5 Refractive Index: 1,571-1,575 **Purity:** Hydroxytyrosol: ≥ 99 % Acetic acid: ≤ 0,4 % Hydroxytyrosol acetate: ≤ 0,3 % Sum of homovanillic acid, iso-homovanilic acid, and 3-methoxy-4hydroxyphenylglycol: ≤ 0,3 % **Heavy Metals** Lead: ≤ 0,03 mg/kg Cadmium: ≤ 0,01 mg/kg Mercury: ≤ 0,01 mg/kg **Residual Solvents** Ethyl acetate: ≤ 25,0 mg/kg Isopropanol: ≤ 2,50 mg/kg Methanol: ≤ 2,00 mg/kg Tetrahydrofuran: ≤ 0,01 mg/kg
Ice Structuring Protein type III HPLC 12	**Description/Definition:** The Ice Structuring Protein (ISP) preparation is a light-brown liquid produced by submerged fermentation of a genetically-modified strain of food-grade baker's yeast (*Saccharomyces cerevisiae*) in which a synthetic gene for the ISP has been inserted into the yeast's genome. The protein is expressed and secreted into the growth medium where it is separated from the yeast cells by micro-filtration and concentrated by ultra-filtration. As a result, the yeast cells are not transferred into the ISP preparation as such or under an altered form. The ISP preparation consists of native ISP, glycosylated ISP and proteins and peptides from the yeast and sugars as well as acids and salts commonly found in food. The concentrate is stabilised with 10 mM citric acid buffer. Assay: ≥ 5 g/l active ISP pH: 2,5-3,5 Ash: ≤ 2,0 % DNA: Not detectable
Aqueous extract of dried leaves of *Ilex guayusa*	**Description/Definition:** Dark brown liquid. Aqueous extracts of dried leaves of *Ilex guayusa*.

Authorised Novel Food	Specification
	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/100 ml
Isomalto-oligosaccharide	**Powder:** Solubility (water) (%): > 99 Glucose (% dry basis): ≤ 5,0 Isomaltose + DP3 to DP9 (% dry basis): ≥ 90 Moisture (%): ≤ 4,0 Sulphated ash (g/100 g): ≤ 0,3 **Heavy metals:** Lead (mg/kg): ≤ 0,5 Arsenic (mg/kg): ≤ 0,5 **Syrup:** Dried solids (g/100 g): > 75 Glucose (% dry basis): ≤ 5,0 Isomaltose + DP3 to DP9 (% dry basis): ≥ 90 pH: 4 - 6 Sulphated ash (g/100 g): ≤ 0,3 **Heavy metals:** Lead (mg/kg): ≤ 0,5 Arsenic (mg/kg): ≤ 0,5
Isomaltulose	**Description/Definition:** A reducing disaccharide that consists of one glucose and one fructose moiety linked by an alpha-1,6-glycosidic bond. It is obtained from sucrose by an enzymatic process. The commercial product is the monohydrate. Appearance: Virtually odourless, white or almost white crystals with a sweet taste

Authorised Novel Food	Specification
	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) **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 (*), 'Instrumental methods' (*) Food and Nutrition Paper 5 Rev. 2 — Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA), 1991, 322 pp., English, ISBN 92-5-102991-1.
Lactitol	**Description/Definition:** Crystalline powder or colourless solution manufactured via catalytic hydrogenation of lactose. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst. Chemical name: 4-O-β-D-Galactopyranosyl-D-glucitol Chemical formula: $C_{12}H_{24}O_{11}$ Molecular weight: 344,31 g/mol CAS No: 585-86-4

Authorised Novel Food	Specification
	Purity: Solubility (in water): Very soluble in water Specific rotation [α] D20 = + 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 Sulphated ash: ≤ 0,1 % d.b Nickel: ≤ 2,0 mg/kg d.b Arsenic: ≤ 3,0 mg/kg d.b Lead: ≤ 1,0 mg/kg d.b
Lacto-N-neotetraose (synthetic)	**Definition:** Chemical name: β-d-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-d-glucopyranosyl-(1→3)-β-d-galactopyranosyl-(1→4)-d-glucopyranose Chemical formula: $C_{26}H_{45}NO_{21}$ CAS No: 13007-32-4 Molecular weight: 707,63 g/mol **Description:** Lacto-N-neotetraose is a white to off-white powder. Produced by a chemical synthesis process and is isolated by crystallisation. **Purity:** Assay (water free): ≥ 96 % D-Lactose: ≤ 1,0 % Lacto-N-triose II: ≤ 0,3 % Lacto-N-neotetraose fructose isomer: ≤ 0,6 % pH (20 °C, 5 % solution): 5,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 0,4 % Acetic acid: ≤ 0,3 %

Authorised Novel Food	Specification
	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
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 **Source:** Genetically modified strain of *Escherichia coli* K-12 **Description:** Lacto-N-neotetraose is a white to off-white crystalline powder that is produced by a microbiological process. Lacto-N-neotetraose is isolated by crystallisation. **Purity:** Assay (water free): ≥ 92 % D-Lactose: ≤ 3,0 % Lacto-N-triose II: ≤ 3,0 % *para*-Lacto-N-neohexaose: ≤ 3,0 % Lacto-N-neotetraose fructose isomer: ≤ 1,0 % pH (20 °C, 5 % solution): 4,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 0,4 % Residual solvents (methanol): ≤ 100 mg/kg Residual proteins: ≤ 0,01 %

Authorised Novel Food	Specification
	Microbiological criteria: Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts: ≤ 10 CFU/g Moulds: ≤ 10 CFU/g Residual endotoxins: ≤ 10 EU/mg
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

Authorised Novel Food	Specification
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 %
Magnesium citrate malate	**Description/Definition:** Magnesium citrate malate is a white to yellowish-white, amorphous powder.

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	Chemical formula: $Mg_5(C_6H_5O_7)_2(C_4H_4O_5)_2$ Chemical name: Pentamagnesium di-(2-hydroxybutanedioate)-di-(2-hydroxypropane-1,2,3-tricarboxylate) CAS No.: 1259381-40-2 Molecular weight: 763,99 Daltons (anhydrous) Solubility: Freely soluble in water (about 20 g in 100 ml) Description of the physical state: Amorphous powder Assay magnesium: 12,0-15,0 % Loss on drying (120 °C/4 hours): ≤ 15 % Colour (solid): White to yellowish-white Colour (20 % aqueous solution): Colourless to yellowish Appearance (20 % aqueous solution): Clear solution pH (20 % aqueous solution): Approx. 6,0 **Impurities:** Chloride: ≤ 0,05 % Sulphate: ≤ 0,05 % Arsenic: ≤ 3,0 ppm Lead: ≤ 2,0 ppm Cadmium: ≤ 1 ppm Mercury: ≤ 0,1 ppm
Magnolia Bark Extract	**Description/Definition:** Magnolia bark extract is obtained from the bark of the plant *Magnolia officinalis* L. and produced with supercritical carbon dioxide. The bark is washed and oven dried to reduce moisture content before being crushed and extracted with supercritical carbon dioxide. The extract is dissolved in medical-grade ethanol and re-crystallised to yield magnolia bark extract. Magnolia bark extract is mainly composed of two phenolic compounds, magnolol and honokiol. Appearance: Light brownish powder **Purity:** Magnolol: ≥ 85,2 % Honokiol: ≥ 0,5 % Magnolol & Honokiol: ≥ 94 % Total Eudesmol: ≤ 2 % Moisture: 0,50 %

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	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: ≤ 10 mEq O_2/kg **Heavy metals:** Iron (Fe): < 1 500 µg/kg Copper (Cu): < 100 µg/kg **Impurities:** Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 µg/kg Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'maize-germ oil high in unsaponifiable matter'

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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: $C_6H_7O_2(OR1)(OR2)(OR3)$ 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
(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

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	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 10 g
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 **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)

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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 (*): < 0,1 mg/ml N-containing constituents (**): < 10 mg/ml Lentinan: 0,8 – 1,2 mg/ml (*) Bradford method (**) Kjeldahl method
Noni fruit juice (*Morinda citrifolia*)	**Description/Definition:** Noni fruits (fruits of *Morinda citrifolia* L.) are pressed. The obtained juice is pasteurised. An optional fermentation step before or after the pressing may occur. Rubiadin: ≤ 10 µg/kg Lucidin: ≤ 10 µg/kg
Noni fruit juice powder (*Morinda citrifolia*)	**Description/Definition:** Seeds and skin of the sun-dried fruits of *Morinda citrifolia* are separated. The obtained pulp is filtered to separate juice from the flesh. Desiccation of the produced juice occurs in one or two ways: Either by atomisation using maize maltodextrins, this mixture is obtained by keeping the rates of inflow of the juice and maltodextrins constant Or by zeodratation or drying and then mixing with an excipient, this process allows the juice to be dried initially and then mixed with maltodextrins (same amount as used in atomisation).
Noni fruit puree and concentrate (*Morinda citrifolia*)	**Description/Definition:** The fruits of *Morinda citrifolia* are harvested by hand. Seeds and skin may be separated mechanically from the pureed fruits. After pasteurisation, the puree is packaged in aseptic containers and stored under cold conditions.

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	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 (*): ≤ 0,254 µg/ml Lucidin (*): Not detectable Alizarin (*): Not detectable Rubiadin (*): Not detectable **Concentrate:** Moisture: 48-53 % Protein: 3-3,5 g/100 g Fat: < 0,04 g/100 g Ash: 4,5-5,0 g/100 g Total carbohydrates: 37-45 g/100 g Fructose: 9-11 g/100 g Glucose: 9-11 g/100 g Dietary fibre: 1,5-5,0 g/100 g 5,15-dimethylmorindol (*): ≤ 0,254 µg/ml (*) 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).

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Noni leaves (*Morinda citrifolia*)	**Description/Definition:** After cutting, the leaves of *Morinda citrifolia* are subject to drying and roasting steps. The product has a particle size ranging from broken leaves to coarse powder with fines. It is of greenish brown to brown colour. **Purity/Composition:** Moisture: < 5,2 % Protein: 17- 20 % Carbohydrate: 55-65 % Ash: 10-13 % Fat: 4-9 % Oxalic acid: < 0,14 % Tannic acid: < 2,7 % 5,15-dimethylmorindol: < 47 mg/kg Rubiadin: non detectable, ≤ 10 µg/kg Lucidin: non detectable, ≤ 10 µg/kg
Noni fruit powder (*Morinda citrifolia*)	**Description/Definition:** Noni fruit powder is made from pulped noni (*Morinda citrifolia L.*) fruits by freeze-drying. Fruits are pulped and seeds are removed. After freeze-drying during which water is removed from noni fruits, the remaining noni pulp is milled to a powder and encapsulated. **Purity/Composition** Moisture: 5,3-9 % Protein: 3,8-4,8 g/100 g Fat: 1-2 g/100 g Ash: 4,6-5,7 g/100 g Total carbohydrates: 80-85 g/100 g Fructose: 20,4-22,5 g/100 g Glucose: 22-25 g/100 g Dietary fibre: 15,4-24,5 g/100 g 5,15-dimethylmorindol (*): ≤ 2,0 µg/ml (*) 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 dimethyl-morindol)

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***Odontella aurita* microalgae**	Silicon: 3,3 % Crystalline silica: max 0,1-0,3 % as impurity
Oil enriched with phytosterols/phytostanols	**Description/Definition:** Oil enriched with phytosterols/phytostanols is composed of an oil fraction and a phytosterol fraction. **Acylglycerol Distribution:** Free fatty acids (expressed as oleic acid): ≤ 2,0 % Monoacylglycerols (MAG): ≤ 10 % Diacylglycerols (DAG): ≤ 25 % Triacylglycerols (TAG): Making up the balance **Phytosterol fraction:** β-sitosterol: ≤ 80 % β-sitostanol: ≤ 15 % campesterol: ≤ 40 % campestanol: ≤ 5,0 % stigmasterol: ≤ 30 % brassicasterol ≤ 3,0 % other sterols/stanols: ≤ 3,0 % **Others:** Moisture and volatile: ≤ 0,5 % Peroxide value: < 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: ≤ 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 %

Authorised Novel Food	Specification		
	Trans fatty acids: ≤ 1,0 % Docosahexaeonic acid: ≥ 20 % Eicosapentaenoic acid: ≥ 10 %		
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	
	° 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
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		

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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: < 5,0 meq O_2/kg ([1]) Tocopherols may be added as antioxidants according to Commission Regulation (EU) No 1129/2011
Phosphatidylserine from soya phospholipids	**Description/Definition:** The novel food ingredient is off-white to light yellow powder. It is also available in liquid form with a clear brown to orange colour. The liquid form contains medium chain triacylglycerides (MCT) as a carrier. It contains lower levels of Phosphatidylserine due to the fact that it includes significant amounts of oil (MCT). Phosphatidylserine from soya phospholipids is obtained through enzymatic transphosphatidylation of high-phosphatidylcholine soybean lecithin with the amino acid L-serine. Phosphatidylserine consists of a glycerophosphate skeleton conjugated with two fatty acids and L-serine via a phosphodiester linkage. **Characteristics of Phosphatidylserine from soya phospholipids:** **Powder form:** Moisture: < 2,0 % Phospholipids: ≥ 85 % Phosphatidylserine: ≥ 61 % Glycerides: < 2,0 % free L-serine: < 1,0 % Tocopherols: < 0,3 % Phytosterols: < 0,2 % **Liquid form:** Moisture: < 2,0 % Phospholipids: ≥ 25 %

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	Phosphatidylserine: ≥ 20 % Glycerides: not applicable free L-serine: < 1,0 % Tocopherols: < 0,3 % Phytosterols: < 0,2 %
Phospholipid product containing equal amounts of phosphatidylserine and phosphatidic acid	**Description/Definition:** The product is manufactured through enzymatic conversion of soy lecithin. The phospholipid product is a highly concentrated, yellow-brown powder form of phosphatidylserine and phosphatidic acid at an equal level. **Specification of the product:** Moisture: ≤ 2,0 % Total phospholipids: ≥ 70 % Phosphatidylserine: ≥20 % Phosphatidic acid: ≥ 20 % Glycerides: ≤ 1,0 % Free L-serine: ≤ 1,0 % Tocopherols: ≤ 0,3 % Phytosterols: ≤ 2,0 % Silicon dioxide is used with a maximum content of 1,0 %
Phospholipides from egg yolk	85 % and 100 % pure Phospholipides from egg yolk
Phytoglycogen	**Description:** White to off-white powder which is an odourless, colourless, flavourless polysaccharide derived from non-GM sweet corn using conventional food processing techniques **Definition:** Glucose polymer $(C_6H_{12}O_6)$n with linear linkages of α(1 − 4) glycosidic bonds branched every 8 to 12 glucose units by α(1 − 6) glycosidic bonds **Specifications:** Carbohydrates: 97 % Sugars: 0,5 % Fibre: 0,8 % Fat: 0,2 % Protein: 0,6 %

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Phytosterols/phytostanols	**Description/Definition:** Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids. **Composition** (with GC-FID or equivalent method): β-sitosterol: < 81 % β-sitostanol: < 35 % campesterol: < 40 % campestanol: < 15 % stigmasterol: < 30 % brassicasterol: < 3,0 % other sterols/stanols: < 3,0 % **Contamination/Purity** (GC-FID or equivalent method): Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.
Plum kernel oil	**Description/Definition:** Plum kernel oil is a vegetable oil obtained by cold pressing of plum (*Prunus domestica*) kernels. **Composition:** Oleic acid (C18:1): 68 % Linoleic acid (C18:2): 23 % γ-Tocopherol:80 % of total tocopherols β-Sitosterol: 80-90 % of total sterols Triolein: 40-55 % of triglycerides Cyanhydric acid: maximum 5 mg/kg oil
Potato proteins (coagulated) and 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

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Prolyl oligopeptidase (enzyme preparation)	**Specification of the enzyme:** Systematic name: Prolyl oligopeptidase Synonyms: Prolyl endopeptidase, proline-specific endopeptidase, endoprolylpeptidase Molecular weight: 66 kDa Enzyme Commission number: EC 3.4.21.26 CAS number: 72162-84-6 Source: A genetically modified strain of *Aspergillus niger* (GEP-44) **Description:** Prolyl oligopeptidase is available as an enzyme preparation containing approximately 30 % maltodextrin. **Specifications of the enzyme preparation of prolyl oligopeptidase:** Activity: > 580 000 PPI (*)/g (> 34,8 PPU (**)/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

Authorised Novel Food	Specification
	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) (*) PPI – Protease Picomole International (**) PPU – Prolyl Peptidase Units or Proline Protease Units
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 pig kidney extract is formulated as encapsulated enteric coated pellets to reach the active sites of digestion. Basic Product: Specification: pig kidney protein excerpt with natural content of Diamin oxidase (DAO): Physical condition: liquid Colour: brownish Appearance: slightly turbid solution pH value: 6,4-6,8 Enzymatic activity: > 2 677 kHDU DAO/ml (DAO REA (DAO Radioextractionassay)) Microbiological criteria: *Brachyspira* spp.: negative (Real Time PCR) *Listeria monocytogenes*: negative (Real Time PCR) *Staphylococcus aureus*: < 100 CFU/g Influenza A: negative (Reverse Transcription Real Time PCR) *Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^5 CFU/g Yeasts/moulds count: < 10^5 CFU/g *Salmonella*: Absence/10g Bile salt resistant enterobacteriaceae: < 10^4 CFU/g **Final product:** Specification pig kidney protein excerpt with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation: Physical condition: solid Colour: yellow gray

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	Appearance: micropellets Enzymatic activity: 110-220 kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay)) Acid stability 15 min 0,1M HCl followed by 60 min Borat pH=9,0: > 68 kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay)) Humidity: < 10 % *Staphylococcus aureus*: < 100 CFU/g *Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^4 CFU/g Total combined yeasts/moulds count: < 10^3 CFU/g *Salmonella*: Absence/10g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g
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: ≤ 10 mEq O_2/kg

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	Heavy metals: Iron (Fe): < 1 000 µg/kg Copper (Cu): < 100 µg/kg **Impurities:** Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 µg/kg Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'rapeseed oil high in unsaponifiable matter'.
Rapeseed Protein	**Definition:** Rapeseed protein is an aqueous protein-rich extract from rapeseed press cake originating from non-genetically modified *Brassica napus* L. and *Brassica rapa* L. **Description:** White to off-white, spray dried powder Total protein: ≥ 90 % Soluble protein: ≥ 85 % Moisture: ≤ 7,0 % Carbohydrates: ≤ 7,0 % Fat: ≤ 2,0 % Ash: ≤ 4,0 % Fibre: ≤ 0,5 % Total glucosinolates: ≤ 1 mmol/kg **Purity:** Total phytate: ≤ 1,5 % Lead: ≤ 0,5 mg/kg **Microbiological criteria:** Yeast and mould count: ≤ 100 CFU/g Aerobic bacteria count: ≤ 10 000 CFU/g Total coliform count: ≤ 10 CFU/g *Escherichia coli*: Absence in 10 g *Salmonella*: Absence in 25 g

Authorised Novel Food	Specification
Trans-resveratrol	**Description/Definition:** **Synthetic** *Trans*-resveratrol is off-white to beige crystals. Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol Chemical formula: $C_{14}H_{12}O_3$ Molecular weight: 228,25 Da CAS No: 501-36-0 **Purity:** *Trans*-resveratrol: ≥ 98 %-99 % Total by-products (related substances): ≤ 0,5 % Any single related substance: ≤ 0,1 % Sulphated ash: ≤ 0,1 % Loss on drying: ≤ 0,5 % **Heavy metals:** Lead: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm Arsenic: ≤ 1,0 ppm **Impurities:** Diisopropylamine: ≤ 50 mg/kg ***Microbial source***: A genetically modified strain of *Saccharomyces cerevisiae* Appearance: Off-white to slight yellow powder Particle size: 100 % less than 62,23 µm Trans-resveratrol content: Min. 98 % w/w (dry weight basis) Ash: Max. 0,5 % w/w Moisture: Max. 3 % w/w
Rooster comb extract	**Description/Definition:** Rooster comb extract is obtained from *Gallus gallus* by enzymatic hydrolysis of rooster comb and by subsequent filtration, concentration and precipitation steps. The principal constituents of rooster comb extract are the glycosaminoglycans hyaluronic acid, chondroitin sulphate A and dermatan sulphate (chondroitin sulphate B). White or almost white hygroscopic powder. Hyaluronic acid: 60-80 % Chondroitin sulphate A: ≤ 5,0 %

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	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 1 g
Sacha Inchi oil from *Plukenetia volubilis*	**Description/Definition:** Sacha inchi oil is a 100 % cold pressed vegetable oil obtained from the seeds of *Plukenetia volubiis* L. It is a transparent, fluid (liquid) and shiny oil at room temperature. It has a fruity, light, green vegetable taste without undesirable flavours. Aspect, limpidity, shine, colour: Fluid at room temperature, clean, shiny yellow gold Odour and taste: Fruity, vegetable without non acceptable taste or odour **Purity:** Water and Volatiles: < 0,2 g/100 g Impurities insoluble in hexane: < 0,05 g/100 g Oleic acidity: < 2,0 g/100 g Peroxide value: < 15 meq O_2/kg Trans fatty acids: < 1,0 g/100 g Total unsaturated fatty acids: > 90 %

Authorised Novel Food	Specification
	Omega 3 alpha linolenic acid (ALA): > 45 % Saturated fatty acids: < 10 % No trans fatty acids (< 0,5 %) No erucic acid (< 0,2 %) More than 50 % of tri-linolenin and di-linolenin-triglycerides Phytosterols composition and level No cholesterol (< 5,0 mg/100 g)
Salatrims	**Description/Definition:** Salatrim is the internationally recognised acronym for (short and long chain acyl triglyceride molecules). Salatrim is prepared by non-enzymatic inter-esterification of triacetin, tripropionin, tributyrin, or their mixtures with hydrogenated canola, soybean, cottonseed, or sunflower oil. Description: Clear, slightly amber liquid to a light coloured waxy solid at room temperature. Free of particulate matter and of foreign or rancid odour. Glycerol ester disribution: Triacylglycerols: > 87 % Diacylglycerols: ≤ 10 % Monoacylglycerols: ≤ 2,0 % Fatty acid composition: MOLE % LCFA (long chain fatty acids): 33-70 % MOLE % SCFA (short chain fatty acids): 30-67 % Saturated long chain fatty acids: < 70 % by weight Trans fatty acids: ≤ 1,0 % Free fatty acids as oleic acid: ≤ 0,5 % Triacylglycerol profile: Triesters (short/long of 0,5 to 2,0): ≥ 90 % Triesters (short/long = 0): ≤ 10 % Unsaponifiable material: ≤ 1,0 % Moisture: ≤ 0,3 % Ash: ≤ 0,1 % Colour: ≤ 3,5 Red (Lovibond) Peroxide value: ≤ 2,0 Meq/Kg

Authorised Novel Food	Specification
***Schizochytrium* sp. oil rich in DHA and EPA**	Acid value: ≤ 0,5 mg KOH/g Peroxide value: ≤ 5,0 meq/kg oil Oxidative stability: All food products containing *schizochytrium* sp. oil rich in DHA and EPA should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC) Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1 % DHA content: ≥ 22,5 % EPA content: ≥ 10 %
***Schizochytrium* sp. (ATCC PTA-9695) oil**	Peroxide value: ≤ 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 %
***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 %
***Schizochytrium* sp. (T18) oil**	Acid value: ≤ 0,5 mg KOH/g Peroxide value: ≤ 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 %

Authorised Novel Food	Specification
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 (*) Identity: Confirmable Condition: No offensive taste or smell Loss on drying: ≤ 10 % Vitamin K2: ≤ 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 (*) Assay method as described by Takaoka et al. (2010).
Spermidine-rich wheat germ extract (*Triticum aestevium*)	**Description/Definition:** Spermidine-rich wheat germ extract is obtained from non-fermented, non-sprouting wheat germs (*Triticum aestevium*) by the process of solid-liquid extraction targeting specifically, but not exclusively polyamines. Spermidine: 0,8-2,4 mg/g Spermine: 0,4-1,2 mg/g Spermidine trichloride < 0,1 µg/g

Authorised Novel Food	Specification
	Putrescine: < 0,3 mg/g Cadaverine: < 0,1 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/25 g *Listeria monocytogenes*: Absence/25 g
Sucromalt	**Description/Definition:** Sucromalt is a complex mixture of saccharides which is produced from sucrose and a starch hydrolysate by means of an enzymatic reaction. In this process, glucose units are attached to saccharides from the starch hydrolysate by means of an enzyme produced by the bacterium *Leuconostoc citreum* or by means of a recombinant strain of the production organism *Bacillus licheniformis*. The resulting oligosaccharides are characterised by the presence of α-(1→6) and α-(l→3) glycosidic compounds. The overall product is syrup, in addition to these oligosaccharides, contains mainly fructose but also the disaccharide leucrose and other disaccharides. Total solids: 75-80 % Moisture: 20-25 % Sulphatase: Max 0,05 % pH: 3,5-6,0 Conductivity < 200 (30 %) Nitrogen < 10 ppm Fructose: 35-45 % d.w. Leucrose: 7-15 % d.w. Other disaccharides: Max 3 % Higher saccharides: 40-60 % d.w
Sugar cane fibre	**Description/Definition:** Sugar Cane Fibre is derived from the dry cell wall or fibrous residue remaining after expression or extraction of sugar juice from sugar cane, of the Saccharum genotype. It consists primarily of cellulose and hemicellulose. The production process consists of several steps, including: chipping, alkaline digestion, removal of lignins and other non-cellulosic components, bleaching of purified fibres, acid washing and neutralization.

Authorised Novel Food	Specification
	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
Sunflower oil extract	**Description/Definition:** The sunflower extract is obtained by a concentration factor of 10 of the unsaponifiable fraction of refined sunflower oil extracted from the seeds of the sunflower, *Helianthus Annuus* L. **Composition:** Oleic acid (C18:1): 20 % Linoleic acid (C18:2): 70 % Unsaponifiable matter: 8,0 % Phytosterols: 5,5 % Tocopherols: 1,1 %
Dried *Tetraselmis chuii* microalgae	**Description/Definition:** The dried product is obtained from the marine microalgae *Tetraselmis chuii*, belonging to the *Chlorodendraceae* family, cultivated in sterile sea water in closed photobioreactors insulated from the outside air.

Authorised Novel Food	Specification
	Purity/Composition: Identified by means of nuclear marker rDNA 18 S (sequence analysed no less than 1 600 base pairs) in the National Centre for Biotechnology information (NCBI) database: Not less than 99,9 % Humidity: ≤ 7,0 % Proteins: 35-40 % Ashes: 14-16 % Carbohydrates: 30-32 % Fibre: 2-3 % Fat: 5-8 % Saturated fatty acids: 29-31 % of total fatty acids Monounsaturated fatty acids: 21-24 % of total fatty acids Polyunsaturated fatty acids: 44-49 % of total fatty acids Iodine: ≤ 15 mg/kg
***Therapon barcoo*/Scortum**	**Description/Definition:** Scortum/Therapon barcoo is a species of fish in the family Terapontidae. It is an endemic fresh water species from Australia. It is now reared in fish farms. Taxonomic Identification: Class: Actinopterygii > order: Perciformes > family: Terapontidae > genus: Therapon or Scortum Barcoo Composition of fish flesh: Protein (%): 18-25 Moisture (%): 65-75 Ash (%): 0,5-2,0 Energy (KJ/Kg): 6 000-11 500 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

Authorised Novel Food	Specification
D-Tagatose	**Description/Definition:** Tagatose is produced by isomerization of galactose by means of chemical or enzymatic conversion, or by epimerization of fructose by means of enzymatic conversion. These are single-step conversions. Appearance: White or almost white crystals Chemical name: D-tagatose Synonym: D-*lyxo*-Hexulose CAS number: 87-81-0 Chemical formula: $C_6H_{12}O_6$ Formula weight: 180,16 (g/mol) **Purity:** Assay: ≥ 98 % on a dry weight basis Loss on drying: ≤ 0,5 % (102 °C, 2 hours) Specific Rotation: $[\alpha]20_D$: – 4 to – 5,6° (1 % aqueous solution) (*) Melting range: 133-137 °C **Heavy metals:** Lead: ≤ 1,0 mg/kg (**) (*) 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 (**) 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' (*).
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. **Definition:** Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)- dihydroquercetin] Chemical formula: $C_{15}H_{12}O_7$ Molecular mass: 304,25 Da CAS No: 480-18-2 **Specifications:** *Physical parameter* Moisture: ≤ 10 %

Authorised Novel Food	Specification
	Compound analysis Taxifolin (m/m): ≥ 90,0 % of the dry weight ***Heavy Metals, Pesticide*** Lead: ≤ 0,5 mg/kg Arsenic: ≤ 0,02 mg/kg Cadmium: ≤ 0,5 mg/kg Mercury: ≤ 0,1 mg/kg Dichlorodiphenyltrichloroethane (DDT): ≤ 0,05 mg/kg ***Residual solvents*** Ethanol: < 5 000 mg/kg ***Microbiological criteria*** Total Plate Count (TPC): ≤ 10^4 CFU/g Enterobacteria: ≤ 100/g Yeast and Mould: ≤ 100 CFU/g *Escherichia coli*: Absence/1 g *Salmonella*: Absence/10 g *Staphylococcus aureus*: Absence/1 g *Pseudomonas*: Absence/1 g **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 %.

Authorised Novel Food	Specification
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 by a multistep enzymatic process. The commercial product is the dihydrate. Virutally odourless, white or almost white crystals with a sweet taste Synonyms: α,α-trehalose Chemical name: α-D-glucopyranosyl-α-D-glucopyranoside, dihydrate CAS No.: 6138-23-4 (dihydrate) Chemical formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$ (dihydrate) Formula weight: 378,33 (dihydrate) Assay: ≥ 98 % on the dry basis Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5 (1), 'Instrumental methods' **Method of assay:** Principle: trehalose is identified by liquid chromatography and quantified by comparison to a reference standard containing standard trehalose Preparation of sample solution: weigh accurately about 3 g of dry sample into a 100 ml volumetric flask and add about 80 ml of purified, deionised water. Bring sample to complete dissolution and dilute to mark with purified deionised water. Filter through a 0,45 micron filter Preparation of standard solution: dissolve accurately weighed quantities of dry standard reference trehalose in water to obtain a solution having known concentration of about 30 mg of trehalose per ml. Apparatus: liquid chromatography equipped with a refractive index detector and integrating recorder Conditions: Column: Shodex Ionpack KS-801 (Showa Denko Co.) or equivalent — length: 300 mm — diameter: 10 mm — temperature: 50 °C Mobile phase: water flow rate: 0,4 ml/min Injection volume: 8 µl Procedure: inject separately equal volumes of the sample solution and the standard solution into the chromatograph. Record the chromatograms and measure the size of response of the trehalose peak Calculate the quantity, in mg, of trehalose in 1 ml of the sample solution by the following formula: % trehalose = $100 \times (R_U/R_S)\ (W_S/W_U)$

Authorised Novel Food	Specification
	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: [α]D20 + 199° (5 % aqueous solution) Melting point: 97 °C (dihydrate) **Purity:** Loss on drying: ≤ 1,5 % (60 °C, 5 h) Total ash: ≤ 0,05 % **Heavy metals:** Lead: ≤ 1,0 mg/kg
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: 5-10 µg/100 g fresh weight at the expiration of shelf life
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 1 800 000-3 500 000 IU vitamin D/100 g (450-875 µg/g). Tan-coloured, free-flowing granules

Authorised Novel Food	Specification
	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: ≤ 10^3/g *Escherichia coli*: ≤ 10/g *Salmonella*: Absence in 25 g
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 (*) Yeast in dough: 1-5 g/100 g (**) (*) EN 12821, 2009, European Standard. (**) Recipe calculation.
UV-treated milk	**Description/Definition:** UV-treated milk is cow's milk (whole and semi-skimmed) to which a treatment with ultraviolet (UV) radiation via turbulent flow is applied after pasteurisation. The treatment of the pasteurised milk with UV radiation results in an increase in the vitamin D_3 (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin D_3. UV radiation: A process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1 045 J/l.

Authorised Novel Food	Specification
	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 (*): 0,5-3,2 µg/100 g (**) Semi-skimmed milk (*): 0,1–1,5 µg/100 g (**) (*) 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). (**) HPLC
Vitamin K_2 (menaquinone)	This novel food is produced by a synthetic or microbiological process. ***Specification of synthetic Vitamin K_2 (menaquinone-7)*** Chemical Name: (all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaheptaenyl)-3-methyl-1,4-naphtalenedione CAS Number: 2124-57-4 Molecular formula: $C_{46}H_{64}O_2$ Molecular weight: 649 g/mol 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 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. It is presented in an oil suspension that primarily contains MK-7 and MK-6 to a smaller extent. 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 $C_{31}H_{40}O_2$.

Authorised Novel Food	Specification
Wheat bran extract	**Description/Definition:** White crystalline powder obtained by enzymatic extraction from *Triticum aestivum* L. bran, rich in arabinoxylan oligosaccharides Dry matter: Min. 94 % Arabinoxylan oligosaccharides: Min 70 % of dry matter Average degree of polymerisation of arabinoxylan oligosaccharides: 3-8 Ferulic acid (bound to arabinoxylan oligosaccharides): 1-3 % of dry matter Total poly/oligosaccharides: Min 90 % Protein: Max 2 % of dry matter Ash: Max 2 % of dry matter **Microbiological parameters:** Mesophilic bacteria – total count: Max 10 000/g Yeasts: Max 100/g Fungi: Max 100/g *Salmonella*: Absence in 25 g *Bacillus cereus*: Max 1 000/g *Clostridium perfringens*: Max 1 000/g
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)-β-D-glucans. Beta-glucans consist of a backbone of β-1-3-linked glucose residues that are branched by β-1-6-linkages, to which chitin and mannoproteins are linked by β-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 β-1,3-linked glucose residues, branched by β-1,6-linkages, forming a backbone to which are linked chitin via β-1,4- bonds, β-1,6-glucans and some mannoproteins. This novel food is available in three different forms: soluble, insoluble and insoluble in water, but dispersible in many liquid matrices. **Chemical characteristics yeast (*Saccharomyces cerevisiae*) beta-glucans:** **Soluble form:** Total carbohydrates: > 75 %

Authorised Novel Food	Specification
	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)-β-D-Glucans: > 80 % Ash: < 2,0 % Moisture: < 6,0 % Protein: < 4,0 % Total fat: < 3,0 % **Microbiological data:** Total plate count: < 1 000 CFU/g Enterobacteriaceae: < 100 CFU/g Total coliforms: < 10 CFU/g Yeast: < 25 CFU/g Mould: < 25 CFU/g *Salmonella*: Absence in 25 g *Escherichia coli*: Absence in 1 g *Bacillus cereus*: < 100 CFU/g *Staphylococcus aureus*: Absence in 1 g **Heavy metals:** Lead: < 0,2 mg/g Arsenic: < 0,2 mg/g

Authorised Novel Food	Specification
	Mercury: < 0,1 mg/g Cadmium: < 0,1 mg/g
Zeaxanthin	**Description/Definition:** Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid. The synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base ('beadlets') with added α-tocopherol and ascorbyl palmitate or as a corn oil suspension with added α-tocopherol. Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules. Orange-red crystalline powder with little or no odour. Chemical formula: $C_{40}H_{56}O_2$ CAS No: 144-68-3 Molecular weight: 568,9 daltons **Physical-chemical properties:** Loss on drying: < 0,2 % *All*-trans zeaxanthin: > 96 % Cis-zeaxanthin: < 2,0 % Other carotenoids: < 1,5 % Triphenylphosphine oxid (CAS No 791-28-6): < 50 mg/kg
Zinc L-pidolate	**Description/Definition:** Zinc L-pidolate is a white to off-white powder, with characteristic odour. International non-proprietary name (INN): L-pyroglutamic acid, Zinc salt Synonyms: Zinc 5-oxoproline, Zinc pyroglutamate, Zinc pyrrolidone carboxylate, Zinc PCA, L-Zinc pidolate CAS No.: 15454-75-8 Molecular formula: $(C_5H_6NO_3)_2$ 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 %

Authorised Novel Food	Specification
	Heavy metals: Lead: ≤ 3,0 ppm Arsenic: ≤ 2,0 ppm Cadmium: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm **Microbiological criteria:** Total viable mesophilic count: ≤ 1 000 CFU/g Yeasts and moulds: ≤ 100 CFU/g Pathogen: Absence

(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)

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2017/2330 of 14 December 2017 concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006

(Official Journal of the European Union L 333 of 15 December 2017)

On page 41, the text of Commission Implementing Regulation (EU) 2017/2330 should read as follows:

'**COMMISSION IMPLEMENTING REGULATION (EU) 2017/2330**

of 14 December 2017

concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The iron compounds Ferric chloride hexahydrate, Ferric oxide, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate were authorised without a time limit by Commission Regulation (EC) No 1334/2003 ([3]) and Commission Regulation (EC) No 479/2006 ([4]) in accordance with Directive 70/524/EEC. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of Ferric chloride hexahydrate, Ferric oxide, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an application was submitted for Iron dextran as feed additive for piglets. The applicants requested that those additives be classified in the additive category 'nutritional additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11).
([4]) Commission Regulation (EC) No 479/2006 of 23 March 2006 as regards the authorisation of certain additives belonging to the group compounds of trace elements (OJ L 86, 24.3.2006, p. 4).

(4) Due to scientific considerations, the European Food Safety Authority ('the Authority') recommended in its opinions of 19 June 2013 ([1]), 30 January 2014 ([2]), 5 March 2014 ([3]), 28 April 2014 ([4]) and 27 January 2016 ([5]) to rename Ferric as Iron(III) and Ferrous as Iron(II), in order to avoid potential misunderstandings. The Authority also recommended splitting Iron(II) chelate of amino acids into the following two groups, in view of its chemical characteristics: Iron(II) chelate of amino acids hydrate and Iron(II) chelate of protein hydrolysates.

(5) The Authority concluded that, under the proposed conditions of use, Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate do not have an adverse effect on animal health, consumer safety and the environment. Considering the capacities to be respiratory, eye and skin irritants due to the presence of Nickel in each iron (II) and iron (III) compound, appropriate protective measures should be taken with respect to the handling of the additives concerned and premixtures containing them, in order to avoid that safety concerns for the users would arise.

(6) In its opinions of 24 January 2017 ([6]), the Authority concluded that, under the proposed conditions of use, Iron dextran does not have an adverse effect on animal health, consumer safety and the environment, and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(7) The Authority further concluded that Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates, Iron(II) chelate of glycine hydrate and Iron dextran are effective sources of iron; however, the bioavailability of Iron(II) carbonate varies significantly and is considered to be lower than that for Iron(II) sulphate. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran for piglets shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied, except for water for drinking. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation and their use via water for drinking should be prohibited.

(9) As a result of the granting new authorisations for 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferrous sulphate monohydrate' and 'Ferrous chelate of glycine, hydrate' by this Regulation and of the denial of the authorisation for 'Ferric oxide', the entries of these substances in Regulations (EC) No 479/2006 and (EC) No 1334/2003 should be deleted.

(10) As the Authority could not conclude in its opinions of 24 May 2016 ([7]) on the safety of ferric oxide for the target species, the additive and feed containing it should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.

(11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for Ferric chloride hexahydrate, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate as authorised by Regulation (EC) No 1334/2003 and Regulation (EC) No 479/2006, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

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

([1]) EFSA Journal 2013;11(7):3287.
([2]) EFSA Journal 2014;12(2):3566.
([3]) EFSA Journal 2014;12(3):3607.
([4]) EFSA Journal 2015;13(5):4109.
([5]) EFSA Journal 2016;14(2):4396.
([6]) EFSA Journal 2017;15(2):4701.
([7]) EFSA Journal 2016;14(6):4508.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Special conditions of use

The authorised substances specified in the Annex as additives belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements' shall not be used in water for drinking.

Article 3

Denial

The authorisation for ferric oxide is hereby denied and the substance shall no longer be used as nutritional feed additive.

Article 4

Amendment to Regulation (EC) No 1334/2003

In the Annex to Regulation (EC) No 1334/2003, from the entry E1 on the element Iron-Fe the following additives, their chemical formulas and descriptions are deleted: 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferrous sulphate monohydrate' and 'Ferric oxide'.

Article 5

Amendment to Regulation (EC) No 479/2006

In the Annex to Regulation (EC) No 479/2006, the entry E1 on the additive 'Ferrous chelate of glycine, hydrate' is deleted.

Article 6

Transitional measures

1. The substances 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous chelate of glycine hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferric oxide' and 'Ferrous sulphate monohydrate' as authorised by Commission Regulation (EC) No 1334/2003 and Commission Regulation (EC) No 479/2006, and premixtures containing those substances, which are produced and labelled before 4 July 2018 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 4 January 2019 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 4 January 2020 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 7

Entry into force

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.

Done at Brussels, 14 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
Category of nutritional additives. Functional group: compounds of trace elements									
3b101		Iron(II) carbonate (siderite)	*Additive composition:* Powder sourced from mined ore, containing siderite, with a minimum content of 70 % $FeCO_3$ and of 39 % total iron *Characterisation of the active substance:* Chemical formula: $FeCO_3$ CAS Number: 563–71–3 *Analytical methods* (1): For the identification of iron and carbonate in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: — X-Ray diffraction. For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species except piglets, calves, chicken up to 14 days and turkey up to 28 days	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) carbonate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).					4. In the labelling of the additive and premixtures containing it, the following shall be indicated: "Iron(II) carbonate should not be used as iron source for young animals due to its limited bioavailability."	

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
3b102	—	Iron(III) chloride hexahydrate	*Additive composition:* Iron(III) chloride hexahydrate, as a powder with a minimum content of 19 % iron. *Characterisation of the active substance:* Chemical formula: $FeCl_3 \cdot 6H_2O$ CAS Number: 10025–77–1 *Analytical methods* (1): For the identification of iron and chloride in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: — X-Ray diffraction. For the quantification of the ferric chloride hexahydrate in the feed additive: — titration with sodium thiosulfate (Ph. Eur Monograph 1515). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(III) chloride hexahydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a liquid premixture. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
3b103	—	Iron(II) sulphate monohydrate	*Additive composition:* Iron(II) sulphate monohydrate, as powder or granules with a minimum content of 29 % iron. *Characterisation of the active substance:* Chemical formula: $FeSO_4 \cdot H_2O$ CAS Number: 17375–41–6 *Analytical methods* (1): For the identification of iron and sulphate in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: — X-Ray diffraction. For the quantification of the iron(II) sulphate monohydrate in the feed additive: — titration with ammonium and cerium nitrate (Ph. Eur Monograph 0083); or — titration with potassium dichromate (EN 889). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) sulphate monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
3b104	—	Iron(II) sulphate heptahydrate	*Additive composition:* Iron(II) sulphate heptahydrate, as a powder with a minimum content of 18 % iron. *Characterisation of the active substance:* Chemical formula: $FeSO_4 \cdot 7H_2O$ CAS Number: 7782–63–0 *Analytical methods* (1): For the identification of iron and sulphate in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: X-Ray diffraction. For the quantification of the iron(II) sulphate heptahydrate in the feed additive: — titration with ammonium and cerium nitrate (Ph. Eur Monograph 0083); or — titration with potassium dichromate (EN 889). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) sulphate heptahydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
3b105		Iron(II) fumarate	*Additive composition:* Iron(II) fumarate, as a powder with a minimum content of 30 % iron. *Characterisation of the active substance:* Chemical formula: $C_4H_2FeO_4$ CAS Number: 141–01–5 *Analytical methods* (1): For the quantification of the Iron(II) fumarate in the feed additive: — titration with cerium sulphate (Ph. Eur Monograph 0902). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) fumarate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						
3b106	—	Iron(II) chelate of amino acids hydrate	*Additive composition:* Iron(II) amino acid complex where the iron and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 9 % iron.	All animal species	—	—	Ovine: 500 (total [2]) Bovines and poultry: 450 (total [2]) Piglets up to one week before weaning: 250 mg/day (total [2])	1. Iron(II) chelate of amino acids may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			Characterisation of the active substance: Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate. Maximum of 10 % of the molecules exceeding 1 500 Da. *Analytical methods* (1): For the quantification of amino acid content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex III, F). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).				Pet animals: 600 (total (2)) Other species: 750 (total (2))	3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						
3b107	—	Iron(II) chelate of protein hydrolysates	*Additive composition:* Iron(II) chelate of protein hydrolysates as a powder with a minimum content of 10 % iron. Minimum of 50 % iron chelated.	All animal species	—	—	Ovine: 500 (total [2]) Bovines and poultry: 450 (total [2]) Piglets up to one week before weaning: 250 mg/day (total [2])	1. Iron(II) chelate of protein hydrolysates may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			Characterisation of the active substance: Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate. *Analytical methods* (1): For the quantification of protein hydrolysates content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex III, F). For the qualitative verification of the chelation of the iron in the feed additive: — Fourier Transformed Infrared (FTIR) spectroscopy followed by multivariate regression methods (to be updated by EURL) (3). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or				Pet animals: 600 (total (2)) Other species: 750 (total (2))	3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
3b108	—	Iron(II) chelate of glycine hydrate	*Additive composition:* Iron(II) chelate of glycine, hydrate, as a powder with a minimum content of 15 % iron. Moisture: maximum 10 %. *Characterisation of the active substance:* Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of glycine. *Analytical methods* (1): For the quantification of the glycine content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex III, F). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) chelate of glycine hydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
3b110		Iron dextran 10 %	*Additive composition:* Colloidal, aqueous solution of iron dextran with 25 % iron dextran (10 % total iron, 15 % dextran), 1,5 % sodium chloride, 0,4 % phenol and 73,1 % water *Characterisation of the active substance:* Iron dextran Chemical formula: $(C_6H_{10}O_5)n \cdot [Fe(OH)_3]m$ IUPAC name: ferric hydroxide dextran (α,3-α1,6 glucan) complex CAS Number: 9004-66-4 *Analytical methods* (1): For the characterisation of the feed additive: — British and US Pharmacopeia Iron Dextran monographs. For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	Suckling piglets	—	—	200 mg/day once in the first week of life and 300 mg/day once in the second week of life	1. For users of the additive, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive shall be used with appropriate personal protective equipment. 2. Indicate in the instructions of use: — "The additive shall be fed only individually directly via a complementary feed." — "The additive shall not be administered to piglets deficient in vitamin E and/or selenium." — "The simultaneous use of other iron compounds shall be avoided during the administration period (first 2 weeks of life) of iron dextran 10 %."	4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or						

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
(2) The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.
(3) The method might be supplemented with another method. In this case, the Reference Laboratory will update its evaluation report and publish the applicable method on: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports'

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