

ANNEX

The Annex is amended as follows.

(1) Table 1 (Authorised novel foods) is amended as follows:

(a) the following entry is inserted between the entry for ‘*Echium plantagineum* oil’ and the entry for ‘Egg membrane hydrolysate’:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
‘ <i>Ecklonia cava</i> phlorotannins	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “ <i>Ecklonia cava</i> Phlorotannins”. Food supplements containing <i>Ecklonia cava</i> phlorotannins shall bear the following statement:	
	Food supplements as defined in Directive 2002/46/EC intended for the general population, excluding children under the age of 12 years	163 mg/day for adolescents from 12 to 14 years of age 230 mg/day for adolescents above 14 years of age 263 mg/day for adults		

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		(b) This food supplement should not be consumed by persons with thyroid disease or by persons who are aware of or have been identified as being at risk of developing thyroid disease.
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		(c) This food supplement should not be consumed if other food supplements containing iodine are also consumed.
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		(*) Depending on the age group
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			the food supplement is intended for.'
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(b) the entry for 'Taxifolin-rich extract' is replaced by the following:

Taxifolin-rich extract	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "taxifolin-rich extract"
	Yogurt plain/ Yogurt with fruits ^(*)	0,020 g/kg	
	Kephir ^(*)	0,008 g/kg	
	Buttermilk ^(*)	0,005 g/kg	
	Milk powder ^(*)	0,052 g/kg	
	Cream ^(*)	0,070 g/kg	
	Sour cream ^(*)	0,050 g/kg	
	Cheese ^(*)	0,090 g/kg	
	Butter ^(*)	0,164 g/kg	
	Chocolate confectionery	0,070 g/kg	
	Non-alcoholic beverages	0,020 g/L	
	Food supplements as defined in Directive 2002/46/EC intended for the general population, excluding infants, young children, children and adolescents younger than 14 years	100 mg/day	

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(*)	When used in milk products Taxifolin-rich extract may not replace in whole or in part, any milk constituent	
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(c) the entry for ‘L-ergothioneine’ is replaced by the following:

L-ergothioneine	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “L-ergothioneine”
	Alcohol-free beverages	0,025 g/kg	
	Milk-based drinks	0,025 g/kg	
	“Fresh” milk products(*)	0,040 g/kg	
	Cereal bars	0,2 g/kg	
	Chocolate confectionery	0,25 g/kg	
	Food supplements as defined in Directive 2002/46/EC	30 mg/day for general population (excluding pregnant and lactating women) 20 mg/day for children older than 3 years	
	(*)	When used in milk products L-ergothioneine may not replace in whole or in part, any milk constituent	

(d) the following entry is inserted between the entry for ‘L-ergothioneine’ and the entry for ‘Ferric sodium EDTA’:

Extract of three herbal roots (<i>Cynanchum</i>)	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the

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wilfordii Hemsley, Phlomis umbrosa Turcz. and Angelica gigas Nakai)	Food supplements as defined in Directive 2002/46/EC for adult population	175 mg/day	labelling of the foodstuffs containing it shall be “extract of three herbal roots (<i>Cynanchum wilfordii</i> Hemsley, <i>Phlomis umbrosa</i> Turcz. and <i>Angelica gigas</i> Nakai)”. The labelling of food supplements containing the extract of mixture of the three herbal roots shall bear a statement in close proximity to the list of ingredients indicating that it should not be consumed by individuals with known celery allergy.
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(e) the following entry is inserted between the entry for ‘Lycopene oleoresin from tomatoes’ and the entry for ‘Magnesium citrate malate’:

Hen egg white lysozyme hydrolysate	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of food supplements containing it shall
	Food supplements as defined in Directive 2002/46/	1000 mg/day	

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	EC intended for adult population		be “Hen egg white lysozyme hydrolysate”.
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- (f) the entry for ‘UV-treated mushrooms (*Agaricus bisporus*)’ is replaced by the following:

UV-treated mushrooms (<i>Agaricus bisporus</i>)	<i>Specified food category</i>	<i>Maximum levels of vitamin D₂</i>	
	Mushrooms (<i>Agaricus bisporus</i>)	20 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 (<i>Agaricus bisporus</i>)”.
			2. The designation on the label of the novel food as such or of the foodstuffs containing it shall be accompanied by

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			indication that a “controlled light treatment was used to increase vitamin D levels” or “UV treatment was used to increase vitamin D ₂ levels”.
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- (g) the entry for ‘UV- treated baker’s yeast (*Saccharomyces cerevisiae*)’ is replaced by the following:

UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)	<i>Specified food category</i>	<i>Maximum levels of vitamin D₂</i>	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		
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dried yeast	1. The designation of the novel food on the

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| | | | labelling of the foodstuffs shall be “Vitamin D yeast” or “Vitamin D ₂ yeast”. |
| | | 2. | The labelling of the novel food shall bear a statement that the foodstuff is only intended for baking and that it should not be eaten raw. |
| | | 3. | The labelling of the novel food shall bear instructions for use for the final |

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			consumers so that a maximum concentration of 5 µg/100 g of vitamin D ₂ in final home# baked products is not exceeded.
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(h) the entry for ‘*Schizochytrium* sp. (T18) oil’ is replaced by the following:

<i>Schizochytrium</i> sp. (T18) oil	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “Oil from the microalgae <i>Schizochytrium</i> 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	

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	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	In accordance with the

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

(2) Table 2 (Specifications) is amended as follows:

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- (a) the following entry is inserted between the entry for ‘*Echium plantagineum* oil’ and the entry for ‘Egg membrane hydrolysate’:

Authorised Novel Food	Specification
‘ <i>Ecklonia cava</i> phlorotannins	<p>Description/Definition <i>Ecklonia cava</i> phlorotannins are obtained via alcohol extraction from the edible marine alga <i>Ecklonia cava</i>. The extract is a dark brown powder, rich in phlorotannins, polyphenolic compounds found as secondary metabolites in certain brown algae species.</p> <p>Characteristics/Composition Phlorotannin content: 90 ± 5 % Antioxidant activity: > 85 % Moisture: < 5 % Ash: < 5 %</p> <p>Microbiological criteria Total viable cell count: $< 3\ 000$ CFU/g Mould/yeast: < 300 CFU/g Coliforms: Negative to test <i>Salmonella</i> spp.: Negative to test <i>Staphylococcus aureus</i>: Negative to test</p> <p>Heavy metals and Halogens Lead: $< 3,0$ mg/kg Mercury: $< 0,1$ mg/kg Cadmium: $< 3,0$ mg/kg Arsenic: $< 25,0$ mg/kg Inorganic Arsenic: $< 0,5$ mg/kg Iodine: $150,0 - 650,0$ mg/kg CFU: Colony Forming Units’</p>

- (b) the entry for ‘Definition’ for ‘Taxifolin-rich extract’ is replaced by the following:

Taxifolin-rich extract	Definition
	<p>Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)-dihydroquercetin] and with no more than 2 % of the cis-form</p>

- (c) the following entry is inserted between the entry for ‘L-ergothioneine’ and the entry for ‘Ferric sodium EDTA’:

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<p>Extract of three herbal roots (<i>Cynanchum wilfordii</i> Hemsley, <i>Phlomis umbrosa</i> Turcz. and <i>Angelica gigas</i> Nakai)</p>	<p>Description/Definition The mixture of the three herbal roots is yellowish brown fine powder produced by hot-water extraction, concentration by evaporation, and spray drying</p> <p>Composition of the extract of mixture of the 3 herbal roots <i>Cynanchum wilfordii</i> root: 32,5 % (w/w) <i>Phlomis umbrosa</i> root: 32,5 % (w/w) <i>Angelica gigas</i> root: 35,0 % (w/w)</p> <p>Specifications Loss on drying: NMT 100 mg/g</p> <p>Assay Cinnamic acid: 0,012 – 0,039 mg/g Shanzhiside methyl ester: 0,20 – 1,55 mg/g Nodakenin: 3,35 – 10,61 mg/g Methoxsalen: < 3 mg/g Phenols: 13,0 – 40,0 mg/g Coumarins: 13,0 – 40,0 mg/g Iridoids: 13,0 – 39,0 mg/g Saponins: 5,0 – 15,5 mg/g</p> <p>Nutritive components Carbohydrates: 600 – 880 mg/g Proteins: 70 – 170 mg/g Fats: < 4 mg/g</p> <p>Microbiological parameters Total viable plate count: < 5000 CFU/g Total mold and yeast: < 100 CFU/g Coliform bacteria: < 10 CFU/g <i>Salmonella</i>: Negative/25 g <i>Escherichia coli</i>: Negative/25 g <i>Staphylococcus aureus</i>: Negative/25 g</p> <p>Heavy metals Lead: < 0,65 mg/kg Arsenic: < 3,0 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 1,0 mg/kg CFU: Colony Forming Units</p>
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- (d) the following entry is inserted between the entry for ‘Lycopene oleoresin from tomatoes’ and the entry for ‘Magnesium citrate malate’:

<p>Hen egg white lysozyme hydrolysate</p>	<p>Description/Definition Hen egg white lysozyme hydrolysate is obtained from</p>
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hen egg white lysozyme by an enzymatic process, using subtilisin from *Bacillus licheniformis*. The product is a white to light yellow powder.

Specification

Protein (TN(*) x 5,30): 80-90 %

Tryptophan: 5-7 %

Ratio Tryptophan/LNAA(**): 0,18-0.25

Degree of hydrolysis: 19-25 %

Moisture: < 5 %

Ash: < 10 %

Sodium: < 6 %

Heavy metals

Arsenic: < 1 ppm

Lead: < 1 ppm

Cadmium: < 0,5 ppm

Mercury: < 0,1 ppm

Microbiological criteria

Total aerobic count: < 10³ CFU/g

Total combined yeasts/moulds count: < 10² CFU/g

Enterobacteria: < 10 CFU/g

Salmonella spp: Absence in 25 g

Escherichia coli: Absence in 10 g

Staphylococcus aureus: Absence in 10 g

Pseudomonas aeruginosa: Absence in 10 g

* TN: total nitrogen

** LNAA: large neutral amino acids

- (e) the entry for 'UV-treated mushrooms (*Agaricus bisporus*)' is replaced by the following:

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 D₂

Chemical name:
(3β,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol

Synonym: Ergocalciferol

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CAS No: 50-14-6
 Molecular weight: 396,65 g/mol
Contents
 Vitamin D₂ in the final product:
 5-20 µg/100 g fresh weight at the expiration of shelf life.

- (f) the entry for ‘UV- treated baker’s yeast (*Saccharomyces cerevisiae*)’ is replaced by the following:

UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)	<p>Description/Definition Baker’s yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D₂ (ergocalciferol). Vitamin D₂ content in the yeast concentrate varies between 800 000-3 500 000 IU vitamin D/100 g (200-875 µg/g). The yeast may be inactivated. The yeast concentrate is blended with regular baker’s yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking. Tan-coloured, free-flowing granules.</p> <p>Vitamin D₂ 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</p> <p>Microbiological criteria for the yeast concentrate Coliforms: ≤ 10³/g <i>Escherichia coli</i>: ≤ 10/g <i>Salmonella</i>: Absence in 25 g</p>
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