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

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1559

of 26 October 2020

amending Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods

(Text with EEA relevance)

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 12 thereof,

Whereas:

(1) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission was to establish, by 1 January 2018, the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council[(2)].

(2) The Union list of novel foods authorised or notified under Regulation (EC) No 258/97 was established by Commission Implementing Regulation (EU) 2017/2470[(3)].

(3) Commission Implementing Regulation (EU) 2018/1023[(4)] corrected the initial Union list of novel foods established in the Annex to Implementing Regulation (EU) 2017/2470 by replacing that Annex. In the meantime eight Commission Implementing Regulations (EU) 2018/460[(5)], (EU) 2018/461[(6)], (EU) 2018/462[(7)], (EU) 2018/469[(8)], (EU) 2018/991[(9)], (EU) 2018/1011[(10)], (EU) 2018/1018[(11)], (EU) 2018/1032[(12)] had been adopted authorising placing on the market of novel foods or extending the use of novel foods respectively. Those Implementing Regulations also updated the Union list. However, those novel foods and extensions of the use of novel foods no longer appear in the list, as replaced by Implementing Regulation (EU) 2018/1023.

(4) For reasons of clarity and legal certainty, the Union list of novel foods set out in the Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended to include those novel foods and extensions of the use of novel foods in the Union list again. Since those novel foods and extensions of the use of novel foods were included in the Union list until the entry into force of Implementing Regulation (EU) 2018/1023 on 13 August 2018, this Regulation should apply as of that date.

(5) 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

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 13 August 2018.

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

Done at Brussels, 26 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

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**
'***Ecklonia cava* phlorotannins**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "*Ecklonia cava* Phlorotannins". Food supplements containing *Ecklonia cava* phlorotannins shall bear the following statement: (a) This food supplement should not be consumed by children/ adolescents under the age of twelve/ fourteen/ eighteen(*) years.	
	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		

			(b)	This food supplement should not be consumed by persons with thyroid disease or by persons who are aware of or have been identified as being at risk of developing thyroid disease.
			(c)	This food supplement should not be consumed if other food supplements containing iodine are also consumed.
			(*)	Depending on the age group

			the food supplement is intended for.’	

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

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

	(*) When used in milk products Taxifolin-rich extract may not replace in whole or in part, any milk constituent		

(c) the entry for ‘L-ergothioneine’ is replaced by the following:

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

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

Extract of three herbal roots (*Cynanchum*	*Specified food category*	*Maximum levels*	The designation of the novel food on the

***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 (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai)". The labelling of food supplements containing the extract of mixture of the three herbal roots shall bear a statement in close proximity to the list of ingredients indicating that it should not be consumed by individuals with known celery allergy.

(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	*Specified food category*	*Maximum levels*	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	

	EC intended for adult population		be "Hen egg white lysozyme hydrolysate".	

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

UV-treated mushrooms (*Agaricus bisporus*)	*Specified food category*	*Maximum levels of vitamin D_2*	1.	The designation on the label of the novel food as such or of the foodstuffs containing it shall be "UV-treated mushrooms (*Agaricus bisporus*)".
	Mushrooms (*Agaricus bisporus*)	20 µg of vitamin D_2/100 g fresh weight	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".

(g) the entry for 'UV- treated baker's yeast (*Saccharomyces cerevisiae*)' is replaced by the following:

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			
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dried yeast	1.	The designation of the novel food on the

				labelling of the foodstuffs shall be "Vitamin D yeast" or "Vitamin D_2 yeast".
			2.	The labelling of the novel food shall bear a statement that the foodstuff is only intended for baking and that it should not be eaten raw.
			3.	The labelling of the novel food shall bear instructions for use for the final

			consumers so that a maximum concentration of 5 µg/100 g of vitamin D_2 in final home# baked products is not exceeded.

(h) the entry for '*Schizochytrium* sp. (T18) oil' is replaced by the following:

***Schizochytrium* sp. (T18) oil**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae *Schizochytrium* sp.".
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	
	Spreadable fats and dressings	600 mg/100 g	
	Breakfast cereals	500 mg/100 g	
	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	In accordance with the	

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:

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

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

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

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

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

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

(d) 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	**Description/Definition** Hen egg white lysozyme hydrolysate is obtained from

	hen egg white lysozyme by an enzymatic process, using subtilisin from *Bacillus licheniformis*. The product is a white to light yellow powder. **Specification** Protein (TN(*) x 5,30): 80-90 % Tryptophan: 5-7 % Ratio Tryptophan/LNAA(**): 0,18-0.25 Degree of hydrolysis: 19-25 % Moisture: < 5 % Ash: < 10 % Sodium: < 6 % **Heavy metals** Arsenic: < 1 ppm Lead: < 1 ppm Cadmium: < 0,5 ppm Mercury: < 0,1 ppm **Microbiological criteria** Total aerobic count: < 10^3 CFU/g Total combined yeasts/moulds count: < 10^2 CFU/g Enterobacteria: < 10 CFU/g *Salmonella* spp: Absence in 25 g *Escherichia coli*: Absence in 10 g *Staphylococcus aureus*: Absence in 10 g *Pseudomonas aeruginosa*: Absence in 10 g * TN: total nitrogen ** LNAA: large neutral amino acids

(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 D_2** Chemical name: (3β,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol Synonym: Ergocalciferol

	CAS No: 50-14-6 Molecular weight: 396,65 g/mol **Contents** Vitamin D_2 in the final product: 5-20 µg/100 g fresh weight at the expiration of shelf life.

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

UV-treated baker's yeast (*Saccharomyces cerevisiae*)	**Description/Definition** Baker's yeast (*Saccharomyces cerevisiae*) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D_2 (ergocalciferol). Vitamin D_2 content in the yeast concentrate varies between 800 000-3 500 000 IU vitamin D/100 g (200-875 µg/g). The yeast 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. **Vitamin D_2** Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol Synonym: Ergocalciferol CAS No.: 50-14-6 Molecular weight: 396,65 g/mol **Microbiological criteria for the yeast concentrate** Coliforms: $\leq 10^3$/g *Escherichia coli*: $\leq$ 10/g *Salmonella*: Absence in 25 g

(**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).

(**3**) 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 (OJ L 351, 30.12.2017, p. 72).

(**4**) Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (OJ L 187, 24.7.2018, p. 1).

(**5**) Commission Implementing Regulation (EU) 2018/460 of 20 March 2018 authorising the placing on the market of *Ecklonia cava* phlorotannins as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 78, 21.3.2018, p. 2).

(**6**) Commission Implementing Regulation (EU) 2018/461 of 20 March 2018 authorising an extension of use of taxifolin-rich extract as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 78, 21.3.2018, p. 7).

(**7**) Commission Implementing Regulation (EU) 2018/462 of 20 March 2018 authorising an extension of use of L-ergothioneine as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 78, 21.3.2018, p. 11).

(**8**) Commission Implementing Regulation (EU) 2018/469 of 21 March 2018 authorising the placing on the market of an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 79, 22.3.2018, p. 11).

(**9**) Commission Implementing Regulation (EU) 2018/991 of 12 July 2018 authorising the placing on the market of hen egg white lysozyme hydrolysate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 177, 13.7.2018, p. 9).

(**10**) Commission Implementing Regulation (EU) 2018/1011 of 17 July 2018 authorising an extension of use levels of UV-treated mushrooms as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 181, 18.7.2018, p. 4).

(**11**) Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018 authorising an extension of use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 183, 19.7.2018, p. 9).

(**12**) Commission Implementing Regulation (EU) 2018/1032 of 20 July 2018 authorising the extension of use of oil from the micro algae *Schizochytrium* sp. as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 185, 23.7.2018, p. 9).

Status:
Point in time view as at 26/10/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1559.