

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

EN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:[*OP, please insert in the EN version in alphabetical order.*]

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Vitamin D₂ mushroom powder	Specified food category	Maximum levels of vitamin D₂ (µg/100 g or 100 ml)	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘UV-treated mushroom powder containing vitamin D ₂ ’. 2. The labelling of food supplements containing vitamin D ₂ mushroom powder shall bear a statement that they should not be consumed by infants.		Authorised on [...] [<i>OP please insert the date dd.mm.yyyy - 20th day following its publication</i>]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Luxidum GmbH, Tempelhof 3, 74594 Kressberg, Germany. During the period of data protection, the novel food vitamin D ₂ mushroom powder is authorised
	Breakfast cereals	2.4			
	Leavened bread and similar products, yeast leavened pastry	2.4			
	Pasta and similar products	2.4			
	Fruit/vegetable juices and nectars	1.2			
	Concentrated or dehydrated fruit/vegetables juices	8.4			
	Yoghurt drinks, probiotic milk-like drinks, flavoured milks	1.2			
	Milk and dairy concentrate	2.4			
	Milk powder, whey powder	24			
	Cream powder	98.4			
	Whey	2.4			

	Dairy dessert and similar products	2.4			<p>for placing on the market within the Union only by Luxidum GmbH, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Luxidum GmbH.</p> <p>End date of the date protection: [...]/<i>OP please insert the date dd.mm.yyyy – after 5 years</i></p>
	Cheese	2.4			
	Food for weight reduction	2.4			
	Meat and dairy imitates	2.4			
	Soups	2.4			
	Dried soups	21.6			
	Puffs/curly-type extruded snack, potato crisps or sticks	2.4			
	Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended but not higher than 15 µg/day			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	15 µg/day			

,

(2) in Table 2 (Specifications), the following entry is inserted: [OP, please insert in the EN version in alphabetical order.]

,

Authorised Novel Food	Specifications
Vitamin D ₂ mushroom powder	<p>Description/Definition: The novel food is produced by controlled exposure of <i>Agaricus bisporus</i> mushrooms powder to UV irradiation.</p> <p>UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under Regulation (EU) 2015/2283.</p> <p>Characteristics/composition: Vitamin D₂ content: 245-460 µg/g Moisture: ≤ 10% Ash: ≤ 12% Water activity: < 0.5 Fat: ≤ 4.5% Total carbohydrates: ≤ 45% Protein: ≤ 36%</p> <p>Heavy metals: Lead: ≤ 0.5 mg/kg Cadmium: ≤ 0.5 mg/kg Mercury: ≤ 0.1 mg/kg Arsenic: ≤ 0.3 mg/kg</p> <p>Mycotoxins: Aflatoxin B1: ≤ 2 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg</p>

	<p>Microbiological criteria:</p> <p>Total aerobic microbial count: $\leq 5\,000$ CFU/g</p> <p>Total yeast and mould count: < 100 CFU/g</p> <p><i>Salmonella</i> spp.: Not detected in 25 g</p> <p><i>Staphylococcus aureus</i>: Not detected in 10 g</p> <p>Coliforms: ≤ 10 CFU/g</p> <p><i>Escherichia coli</i>: Not detected in 10 g</p> <p><i>Listeria monocytogenes</i>: Not detected in 25 g</p> <p>CFU: colony forming units</p>
--	--

CFU: colony forming units. MPN: most probable number.

,