

SCHEDULE 5

Regulation 6

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of vitamin D₂ mushroom powder as a novel food

1. In Commission Implementing Regulation (EU) 2017/2470, the Annex (list of novel foods) is amended as follows.

2. In Table 1 (authorised novel foods), after the entry for “Vitamin D₂ mushroom powder” insert the following entry—

“Vitamin D₂ mushroom powder”	<i>Specified food category</i>	<i>Maximum levels of vitamin D₂</i>	The designation of the novel food on the labelling of food containing it is “UV-treated mushroom powder containing vitamin D ₂ ”. The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D ₂ mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.	Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D ₂ mushroom powder is authorised for placing on the market, within Wales, only by MBio, Monaghan Mushrooms unless a subsequent
	Breakfast cereals	2.1 µg/100 g		
	Yeast-leavened bread and similar pastries	2.1 µg/100 g		
	Grain products and pasta and similar products	2.1 µg/100 g		
	Fruit / vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by		

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	the manufacturer)			
Meat analogues	2.1 µg/100 g			applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of MBio, Monaghan Mushrooms. The data protection will expire at the end of 14 May 2028.
Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
Extruded vegetable snack	2.1 µg/100 g			
Meal replacement for weight control	2.1 µg/100 g			
Food for special medical purposes as defined in Regulation (EU) No 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and children under 3 years of age	15 µg of vitamin D ₂ /day”			

3. In Table 2, (specifications), after the entry for “Vitamin D₂ mushroom powder” insert the following entry—

“Vitamin D ₂ mushroom powder	Description/Definition
	The novel food is mushroom powder produced from dried whole <i>Agaricus bisporus</i> mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to ultraviolet light.

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Characteristics/Composition

Vitamin D₂ content: 580-595 µg/g of mushroom powder

Ash: ≤ 13.5%

Water activity: < 0.5

Moisture content: ≤ 7.5%

Carbohydrates: ≤ 35%

Total dietary fibre: ≥ 15%

Crude protein (N x 6.25): ≥ 22%

Fat: ≤ 4.5%

Heavy metals

Lead: ≤ 0.5 mg/kg

Cadmium: ≤ 0.5 mg/kg

Mercury: ≤ 0.1 mg/kg

Arsenic: ≤ 0.3 mg/kg

Mycotoxins

Aflatoxin B1: ≤ 0.1 µg/kg

Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg

Microbiological criteria

Total plate count: ≤ 5000 CFU

Total yeast and mould count: ≤ 100 CFU/g

Escherichia coli: < 10 CFU/g

Salmonella spp.: Absence in 25 g

Staphylococcus aureus: ≤ 10 CFU/g

Coliforms: ≤ 10 CFU/g

Listeria spp.: Absence in 25 g

Enterobacteriaceae: < 10 CFU/g

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CFU: Colony Forming Units”.