## ATODLEN 5

Rheoliad 6

Diwygiadau i'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi powdr madarch fitamin D<sub>2</sub> fel bwyd newydd

**1.** Yn Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470, mae'r Atodiad (rhestr o fwydydd newydd) wedi ei ddiwygio fel a ganlyn.

**2.** Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer "Vitamin  $D_2$  mushroom powder" mewnosoder y cofnod a ganlyn—

"Vitamin mushroom	D <sub>2</sub> Specified foo category		of the novel	Included in the
powder	Breakfast cereals	10 0	food on the labelling of food containing it	list on 15 May 2023.
	Yeast-leavened bread an similar pastries	bread and	is "UV-treated mushroom powder	This inclusion
	and pasta an	Grain products 2.1 µg/100 g and pasta and similar products		is based on proprietary scientific
		5 ×	00 of food ed supplements, or as defined as in the Food he Supplements (Wales)	evidence and scientific data protected in accordance
	and analogue	and analogues g (market other than as such	ed vitamin D <sub>2</sub> or mushroom as powder must	with Article 26 of Regulation (EU) 2015/2283.
		Dairy products 1.1 µg/1 and analogues as beverages as such reconstituted instructed by t manufacturer)	ed by infants and or children under 3 as years of age.	Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland,
	Milk and dain powders		ed or as	Co. Monaghan, Ireland, H18 FW95.
	Meat analogues	Meat analogues 2.1 µg/100 g		During
	Soups	Soups 2.1 µg/1 ml (market		period of data

	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 <sub>2</sub> /day"

protection, vitamin  $D_2$ mushroom powder is authorised for placing on the market, within Wales, only by MBio, Monaghan Mushrooms 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 MBio, Monaghan Mushrooms. The data protection will

					expire at the end of 14 May 2028.
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3. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer "Vitamin  $D_2$  mushroom powder" mewnosoder y cofnod a ganlyn—

"Vitamin D <sub>2</sub> 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.
	Characteristics/Composition
	Vitamin D <sub>2</sub> content: 580-595 $\mu$ g/g of mushroom powder
	Ash: ≤ 13.5%
	Water activity: < 0.5
	Moisture content: $\leq 7.5\%$
	Carbohydrates: $\leq 35\%$
	Total dietary fibre: $\geq 15\%$
	Crude protein (N x 6.25): $\geq$ 22%
	Fat: ≤ 4.5%
	Heavy metals
	Lead: $\leq 0.5 \text{ mg/kg}$
	Cadmium: $\leq 0.5 \text{ mg/kg}$
	Mercury: $\leq 0.1 \text{ mg/kg}$
	Arsenic: $\leq 0.3 \text{ mg/kg}$
	Mycotoxins
	Aflatoxin B1: $\leq 0.1 \ \mu g/kg$
	Aflatoxins (sum of B1 + B2 + G1 + G2): $< 4 \mu g/kg$
	Microbiological criteria

Total plate count:  $\leq 5000 \text{ CFU}$ Total yeast and mould count:  $\leq 100 \text{ CFU/g}$ Escherichia coli: < 10 CFU/gSalmonellaspp.: Absence in 25 gStaphylococcus aureus:  $\leq 10 \text{ CFU/g}$ Coliforms:  $\leq 10 \text{ CFU/g}$ Listeria spp.: Absence in 25 gEnterobacteriaceae: < 10 CFU/gCFU: Colony Forming Units".