COMMISSION IMPLEMENTING REGULATION (EU) 2021/2079

of 26 November 2021

authorising the placing on the market of vitamin D_2 mushroom powder 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

(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) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) establishing a Union list of authorised novel foods was adopted.

(3) On 29 July 2019, the company MBio, Monaghan Mushrooms ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 to place vitamin D_2 mushroom powder on the Union market as a novel food. The applicant requested vitamin D_2 mushroom powder to be used in number of foods intended for the general population. The applicant also requested the novel food to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), excluding in food supplements for infants, and in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), excluding foods for special medical purposes intended for infants. During the application process, the applicant agreed to exclude children under 3 years of age from the request for authorisation of the novel food in food supplements.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) 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).

([3]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

([4]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

(4) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of original data submitted in support of the application, namely, data concerning the production process ([5]); compositional data: particle size ([6]), physico-chemical properties ([7]), vitamin D analysis ([8]), nutritional analysis ([9]), vitamin D_2 analysis ([10]), vitamin D analysis validation ([11]), stability studies ([12]), toxicological analysis ([13]), data concerning tachysterol and lumisterol ([14]), ergosterol ratio analysis ([15]), vitamin D ratio analysis ([16]), data concerning ergosterol ([17]); specifications of fresh mushrooms ([18]); data concerning allergenicity ([19]).

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 24 January 2020, requesting it to provide a scientific opinion by carrying out an assessment of the safety of vitamin D_2 mushroom powder as a novel food.

(6) On 24 February 2021, the Authority adopted its scientific opinion on the 'Safety of Vitamin D_2 mushroom powder (*Agaricus bisporus*) as a novel food pursuant to Regulation (EU) 2015/2283' ([20]). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In that opinion, the Authority concluded that vitamin D_2 mushroom powder is safe at the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that vitamin D_2 mushroom powder under the specific conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) A labelling requirement should be provided in order to properly inform the consumers that infants and children under 3 years of age should not consume food supplements containing vitamin D_2 mushroom powder.

(9) In its opinion, the Authority considered that the data concerning the production process and compositional data served as a basis to establish the safety of the novel food. On this basis, the Commission considers that the conclusions on the safety of vitamin D_2 mushroom powder could not have been reached without that data.

(10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to those data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to those data under national law, and that therefore third parties cannot lawfully access or use those data or refer to those data.

(12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data concerning the production process; compositional data: particle size, physico-chemical properties, vitamin D analysis, nutritional analysis, vitamin D_2 analysis, vitamin D analysis validation, stability

([5]) 2.3.1 Production Process Confidential_Final.
([6]) Annex 1 Particle Size Report.
([7]) Annex 3 NIZO Report physico-chemical properties.
([8]) Annex 4 COA vitamin D analysis.
([9]) Annex 5 COA nutritional analysis.
([10]) Annex 7 MBio SOP Vitamin D_2 analysis.
([11]) Annex 8 MBio Vit. D analysis validation report.
([12]) Annex 9 Stability Study Report UCC; Annex 14 COA Vit. D stability study; Annex 24 Stability study Report CampdenBRI; Annex 25 Stability study report meat free product; Annex 29 COAs Stability Meat free.
([13]) Annex 16 COA Toxicological analysis.
([14]) Annex 17 Report Tachysterol and lumisterol.
([15]) Annex 20 COA Ergosterol ratio analysis.
([16]) Annex 21 COA Vitamin D ratio analysis.
([17]) Annex 22 MBio Ergosterol.
([18]) Annex 13 COA fresh mushrooms analysis.
([19]) Annex 12 MBio Allergen Policy.
([20]) EFSA Journal 2021;19(4):6516.

studies, toxicological analysis, data concerning tachysterol and lumisterol, ergosterol ratio analysis, vitamin D ratio analysis, data concerning ergosterol contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, should not be used by the Authority for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place vitamin D_2 mushroom powder on the market within the Union during that period.

(13) However, restricting the authorisation of vitamin D_2 mushroom powder and the reference to the data contained in the applicant's file for the sole use of the applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such an authorisation under Regulation (EU) 2015/2283.

(14) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(15) 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

1. The vitamin D_2 mushroom powder as specified in the Annex shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of 5 years from 19 December 2021 only the initial applicant:

Company: MBio, Monaghan Mushrooms,

Address: Tullygony, Tyholland, Co. Monaghan, Ireland,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 or with the agreement of MBio, Monaghan Mushrooms.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The data contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of 5 years from 19 December 2021 without the agreement of MBio, Monaghan Mushrooms.

Article 3

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

Article 4

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

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

Done at Brussels, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

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:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Vitamin D_2 mushroom powder	*Specified food category*	*Maximum levels of vitamin D_2*	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 and children under 3 years of age.		Authorised on 19 December 2021. 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. During the period of data protection, the novel food vitamin D_2 mushroom powder is authorised for placing on the market within the Union 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. End date of the date protection: 19 December 2026.'
	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 the manufacturer)			
	Meat analogues	2,1 µg/100 g			
	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			

	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			
	Food supplements as defined in Directive 2002/46/EC excluding food supplements intended for infants and young children	15 µg of vitamin D_2/day			

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specifications
'**Vitamin D_2 mushroom powder**	**Description/Definition:** The novel food is mushroom powder produced from the dried whole *Agaricus bisporus* mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to UV irradiation. 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. **Characteristics/composition:** Vitamin D_2 content: 580-595 µg/g of mushroom powder Ash: ≤ 13,5 % Water activity: < 0,5 Moisture content: ≤ 7,5 % Carbohydrates: ≤ 35,0 % Total Dietary Fibre: ≥ 15 % Crude protein (N × 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: ≤ 0,10 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria:** Total plate count: ≤ 5 000 CFU ([a]) Total yeast and mould count: < 100 CFU/g *E. 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'

([a]) CFU: colony forming units.