COMMISSION IMPLEMENTING REGULATION (EU) 2023/4

of 3 January 2023

authorising the placing on the market of vitamin D_2 mushroom powder as a novel food and amending 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(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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]) has established a Union list of novel foods.

(3) On 21 February 2020, the company Monterey Mushrooms Inc ('the applicant') submitted an application for an authorisation to the Commission in accordance with 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 for vitamin D_2 mushroom powder to be used in a number of foods intended for the general population. The applicant also requested the novel food to be used in food supplements for infants from 7 to 11 months of age, as well as in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), excluding food supplements for infants and young children, 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, and total diet replacement for weight control as defined in Regulation (EU) No 609/2013. During the application process, the applicant withdrew the request for authorisation of the novel food in food supplements for infants from 7 to 11 months of age.

(4) On 21 February 2020, the applicant also made 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 on the identity of vitamin D_2 mushroom powder ([5]), certificates of analysis and batch data ([6]), the stability reports ([7]), and the intakes assessment report ([8]).

(5) On 5 February 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of vitamin D_2 mushroom powder as a novel food.

([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).

([5]) Annex I Identity of High Vitamin D2 Mushroom Powder.

([6]) Annex II Certificates of Analysis and Batch Data.

([7]) Annex III Stability Reports.

([8]) Annex V Intakes Assessment Report.

(6) On 26 April 2022, the Authority adopted its scientific opinion on the 'Safety of vitamin D_2 mushroom powder as a Novel food pursuant to Regulation (EU) 2015/2283 (NF 2019/1471)' ([9]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that the vitamin D_2 mushroom powder is safe at the proposed uses and use levels. Therefore, that scientific opinion gives sufficient grounds to establish that the vitamin D_2 mushroom powder under the specific conditions of use fulfils the conditions for its placing on the market in accordance 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 scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on scientific data on the identity of the novel food, batch analysis information, the respective certificates of analysis and the stability studies without which it could not have assessed the novel food and reached its conclusion.

(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 they held proprietary and exclusive rights of reference to the scientific data on the identity of the novel food, batch analysis information, the respective certificates of analysis and the stability studies at the time they submitted the application.

(12) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data on the identity of vitamin D_2 mushroom powder ([10]), certificates of analysis and batch data ([11]) and stability reports ([12]) should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place vitamin D_2 mushroom powder on the market within the Union during a period of five years from the entry into force of this Regulation.

(13) However, restricting the authorisation of vitamin D_2 mushroom powder and the reference to the scientific data contained in the applicant's file for the sole use by them does not prevent subsequent 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.

(14) It is appropriate that the inclusion of vitamin D_2 mushroom powder as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(15) Vitamin D_2 mushroom powder should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([9]) *EFSA Journal* 2022;20(6):7326.
([10]) Annex I Identity of High Vitamin D2 Mushroom Powder.
([11]) Annex II Certificates of Analysis and Batch Data.
([12]) Annex III Stability Reports.

HAS ADOPTED THIS REGULATION:

Article 1

1. The vitamin D_2 mushroom powder is authorised to be placed on the market within the Union.

The vitamin D_2 mushroom powder shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

Article 2

Only the company Monterey Mushrooms Inc ([13]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 24 January 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Monterey Mushrooms Inc.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Monterey Mushrooms Inc.

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, 3 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

([13]) Address: 260 Westgate Drive Watsonville, CA 95076, the United States.

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 (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 and children under 3 years of age.		Authorised on 24 January 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Monterey Mushrooms Inc, 260 Westgate Drive Watsonville, CA 95076, the United States. 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 Monterey Mushrooms Inc, 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 Monterey Mushrooms Inc. End date of the date protection: 24 January 2028.'
	Milk analogues	1,1			
	Dairy analogues other than milks	2,2			
	Breakfast cereals and cereal bars	2,2			
	Soups	2,2			
	Dried soups	22,5			
	Whey powder	14,1			
	Fruit/vegetable juices and nectars	1,1			
	Fruit/vegetable juice powder	12,4			
	Fruit/vegetable juice concentrate (liquid)	3,4			
	Soft drinks marketed in relation to physical exercise and fermented non-alcoholic drinks (with exclusion of dairy fermented drinks)	1,1			
	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			

	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	15 µg/day			
	Meal replacements for weight control	5 µg/meal			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	15 µg/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 produced by controlled exposure of sliced/diced *Agaricus bisporus* mushrooms to UV irradiation followed by dehydration and grinding into a powder. 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: 125–375 µg/g Moisture: ≤ 7 % Ash: ≤ 13,5 % Water activity: < 0,5 Fat: ≤ 4,5 % Total carbohydrates: ≤ 60 % Protein: ≤ 40 % **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: ≤ 2 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria:** Total aerobic microbial count: ≤ 5 000 CFU/g Total yeast and mould count: < 100 CFU/g Coliforms: < 100 MPN/g

	Salmonella spp.: Absence in 25 g *Staphylococcus aureus*: Absence in 10 g *Escherichia coli*: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g CFU: colony forming units. MPN: most probable number.'