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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food vitamin D₂ mushroom powder

(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 1852/2001¹, 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) 2017/2470² has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes vitamin D₂ mushroom powder as an authorised novel food.
- (4) Commission Implementing Regulation (EU) 2021/2079³ authorised the placing on the market of vitamin D₂ mushroom powder as a novel food to be used in a number of foods.
- (5) On 29 March 2024, the company MBio, Monaghan Mushrooms ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of

¹ OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

³ Commission Implementing Regulation (EU) 2021/2079 of 26 November 2021 authorising the placing on the market of vitamin D₂ 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 (OJ L 426, 29.11.2021, p. 16, ELI: http://data.europa.eu/eli/reg_impl/2021/2079/oj).

Regulation (EU) 2015/2283 for a change of the specifications of the novel food vitamin D₂ mushroom powder. The applicant requested to extend the range of vitamin D₂ concentrations to include lower levels and to revise levels of carbohydrates.

- (6) The applicant justified the request for this revision by indicating that the change of the specifications for vitamin D₂ mushroom powder concerns extending the range of vitamin D₂ concentrations to include lower levels and to revise levels of total carbohydrates, while other parameters of the specifications remain identical. Current levels of vitamin D₂ content (580-595 µg/g mushroom powder) are very narrow. Moreover, commercial experience and market requirements have identified a need for the permitted range to encompass much lower concentrations of vitamin D. Therefore, the applicant requests to change permitted range of vitamin D₂ to 137.5-595 µg /g dry weight. Furthermore, the applicant indicates that certain parameters, notably carbohydrate and dietary fibre, have very tight limits. Therefore, the applicant proposes to replace the existing limits for dietary fibre and carbohydrate with total carbohydrates that should not be more than 60%. Moreover, the applicant considers that this approach would have practical benefits that eliminate the uncertainty surrounding the determination of fibre and carbohydrate separately.
- (7) The Commission considers that the requested update of the Union list concerning the change of the specifications of vitamin D₂ mushroom powder proposed by the applicant, is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The requested change of the specifications concerns lower levels of vitamin D₂ than previously assessed by the Authority as safe and which supported the authorisation of vitamin D₂ mushroom powder by Commission Implementing Regulation (EU) 2021/2079. Moreover, change regarding expressing carbohydrates only combines parameters without affecting safety of the novel food.
- (8) The information provided in the application gives sufficient grounds to establish that the changes to the specifications of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (9) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (10) 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

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

Article 2

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,

For the Commission
The President
Ursula VON DER LEYEN