Official Journal
of the European Union

EN
L series

2024/2682

17.10.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2682

of 16 October 2024

amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food vitamin D_2 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 1852/2001 ([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 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) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes vitamin D_2 mushroom powder as a+n authorised novel food.

(4) Commission Implementing Regulation (EU) 2021/2079 ([3]) authorised the placing on the market of vitamin D_2 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 Regulation (EU) 2015/2283 for a change of the specifications of the novel food vitamin D_2 mushroom powder. The applicant requested to extend the authorised range of vitamin D_2 concentrations in vitamin D_2 mushroom powder to include lower concentrations and to revise the authorised levels of carbohydrates, to delete the different maximum levels for 'carbohydrates' and 'total dietary fibre' and set out a single maximum level for total carbohydrates.

(6) The applicant justified the request for this revision by indicating that current authorised levels of vitamin D_2 content (580-595 µg/g mushroom powder) are very narrow. As a result of subsequent commercial experience and understanding of customer requirements, it became clear that less concentrated formulations are needed in practice as they allow for easier inclusion in final product applications. The requested range of vitamin D_2 to 137,5-595 µg/g dry weight will facilitate reliable addition to a variety of foods and achieve more accurate addition of vitamin D at required final concentrations. The production process remains unchanged regarding its fundamental characteristics: the wavelength of UV light remains in the authorised range; the concentration of vitamin D in the powder is determined by the duration of exposure to UV light. The production of lower concentrations involves less exposure to UV light than the existing higher concentration. To satisfy customer and end user requirements for accurate and consistent addition of vitamin D to final food products, the consistency of treated powders is ensured by careful blending with appropriate proportions of mushroom powder that has not received UV treatment. Untreated mushroom powder used for this purpose is, apart from the absence of vitamin D, identical to the treated powder, thereby eliminating any possible risks that might otherwise be associated with using non-mushroom blending

([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).

material. With regard to the request to set out a single maximum level for total carbohydrates, the applicant indicates that this level would encompass the two separate levels specified in the current authorisation, notably 'carbohydrates' and 'total dietary fibre' that have very tight limits. Therefore, the applicant proposes to replace the existing limits of total dietary fibre and carbohydrates content with a single limit for total carbohydrates of not more than 60%. Moreover, the applicant considers that this approach would have practical benefits that eliminate the uncertainty surrounding the determination of total dietary fibre and carbohydrate separately. The applicant also indicates that other similar approved vitamin D_2 mushroom powders have less restrictive limits on carbohydrates. In that context, the proposed limit of not more than 60% total carbohydrate, is not without precedent.

(7) The Commission considers that the requested update of the Union list concerning the change of the specifications of vitamin D_2 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 D_2 content than previously assessed by the Authority as safe and which supported the authorisation of vitamin D_2 mushroom powder by Regulation (EU) 2021/2079. Furthermore, changes in the production process do not affect safety of the novel food. Moreover, the requested change consisting in setting a single limit for total carbohydrates only combines two of the currently authorised parameters and therefore it does not affect the 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, 16 October 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for vitamin D_2 mushroom powder is replaced by the following:

'Authorised Novel Food	Specification
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: 137-595 µg/g of mushroom powder Ash: ≤ 13,5 % Water activity: < 0,5 Moisture content: ≤ 7,5 % Total carbohydrates: ≤ 60 % 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 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 CFU: colony forming units.'