II

*(Non-legislative acts)*

# REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/1163

**of 6 August 2020**

**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) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the update of the Union list.

(4) On 17 July 2018, the company Oakshire Naturals, LP. ('the applicant') submitted a request 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 application concerns the use of vitamin $D_2$ mushroom powder in a variety of foods and beverages for consumption by the general population, in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]) excluding those intended for infants, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]), intended for individuals above 7 months of age.

([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]) 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]) 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).

(5) The applicant also introduced a request to the Commission for protection of proprietary data for scientific data submitted in support of the application, namely, the specifications for the raw materials and processing aids ([5]), the certificates of analysis and batch data of vitamin $D_2$ mushroom powder ([6]), and the vitamin $D_2$ mushroom powder stability reports ([7]).

(6) On 18 October 2018, the Commission consulted the European Food Safety Authority ('the Authority') asking it to carry out an assessment of vitamin $D_2$ mushroom powder as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 28 November 2019, the Authority adopted its scientific opinion 'Safety of vitamin $D_2$ mushroom powder as a novel food pursuant to Regulation (EU) 2015/2283' ([8]). That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority concluded that vitamin $D_2$ mushroom powder is safe under the proposed uses and uses levels, when used in a variety of foods and beverages, in foods for special medical purposes excluding those intended for infants, and when used in food supplements intended for the general population above the age of 1 year. The Authority also noted, that in situations of high consumption of other foods containing or being fortified with vitamin D, the intake by infants of 7 to 12 months of food supplements containing the vitamin $D_2$ mushroom powder at levels equivalent to 10 µg of vitamin D, could result in combined overall intakes of vitamin D, which would exceed the Tolerable Upper Intake Levels ('UL') for vitamin D ([9]). It is therefore appropriate to conclude that the intake of vitamin D from food supplements containing the vitamin $D_2$ mushroom powder at levels equivalent to 10 µg of vitamin D by infants 7 to 12 months of age, may not be in accordance with the conditions set out in Article 7 of Regulation (EU) 2015/2283 and such use should therefore not be authorised for this novel food.

(9) Therefore the scientific opinion gives sufficient grounds to establish that vitamin $D_2$ mushroom powder, under the proposed uses and uses levels, and when used in food supplements intended for the general population above the age of one year, complies with Article 12(1) of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority considered that the data from the specifications for the raw materials and processing aids, the certificates of analysis and batch data of vitamin $D_2$ mushroom powder and the vitamin $D_2$ mushroom powder stability reports 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 the data from the report of these studies.

(11) Following the receipt of the Authority's scientific opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary data from Annex I (Raw materials and processing aids), Annex II (Certificates of Analysis and batch data) and Annex III (Stability reports) as regards vitamin $D_2$ mushroom powder, and to clarify their claim to an exclusive right of reference to these reports and studies, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

(12) The applicant declared that, at the time the application was submitted, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use these studies.

(13) The Commission assessed all the information provided by the applicant and considered that the latter has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the data from these studies contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the applicant for a period of five years.

([5]) Oakshire Naturals 2017 (unpublished).
([6]) Oakshire Naturals 2016 (unpublished).
([7]) Oakshire Naturals 2018 (unpublished).
([8]) *EFSA Journal* 2020; 18(1): 5948.
([9]) *EFSA Journal* 2018; 16(8): 5365.

(14) However, restricting the authorisation of vitamin $D_2$ mushroom powder and of the reference to the scientific 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 lawfully obtained information supporting the authorisation under this Regulation.

(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. Vitamin $D_2$ mushroom powder as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established by Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the applicant:

— Company: Oakshire Naturals, LP.

— Address: PO Box 388, Kennett Square, Pennsylvania 19348, United States

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 that novel food without reference to the data protected pursuant to Article 2 or with the agreement of Oakshire Naturals, LP.

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 to this Regulation.

*Article 2*

The studies and reports contained in the applicant's file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as fulfilling the requirements 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 Oakshire Naturals, LP.

*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, 6 August 2020.

*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 in alphabetical order:

| 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 $D_2$ ([a])* | The designation of the novel food on the labelling of the foodstuffs containing it shall be "UV-treated mushroom powder containing vitamin D" or "UV-treated mushroom powder containing vitamin $D_2$"<br>The labelling of food supplements containing vitamin $D_2$ mushroom powder shall bear a statement that they should not be consumed by infants | | Authorised on 27 August 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br>Applicant: Oakshire Naturals, LP., PO Box 388 Kennett Square, Pennsylvania 19348, 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 Oakshire Naturals, LP., 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 Oakshire Naturals, LP.<br>End date of the data protection: 27 August 2025. |
| | Breakfast cereals | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Yeast-leavened bread and pastries | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Grain products and pastas | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Fruit juice and fruit/vegetable blend beverages | 1,125 µg of vitamin $D_2$/100 mL | | | |
| | Milk and dairy products (excluding fluid milks) | 2,25 µg of vitamin $D_2$/100 g/1,125 µg of vitamin $D_2$/100 mL (beverages) | | | |
| | Cheese (excluding cottage cheese, ricotta cheese, and hard-grating cheeses) | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Meal replacement bars and beverages | 2,25 µg of vitamin $D_2$/100 g/1,125 µg of vitamin $D_2$/100 mL (beverages) | | | |
| | Dairy analogues | 2,25 µg of vitamin $D_2$/100 g/1,125 µg of vitamin $D_2$/100 mL (beverages) | | | |
| | Meat analogues | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Soups and broths | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Extruded vegetable snacks | 2,25 µg of vitamin $D_2$/100 g | | | |
| | Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 excluding those intended for infants | 15 µg/day | | | |
| | Food supplements as defined in Directive 2002/46/EC intended for the general population excluding infants | 15 µg/day | | | |

([a]) The minimum specification for vitamin D content in vitamin $D_2$ mushroom powder of 1 000 µg vitamin $D_2$/gram of mushroom powder is used.'

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

| Authorised Novel Food | Specification |
|---|---|
| **'Vitamin $D_2$ mushroom powder** | **Description/Definition**<br>Vitamin $D_2$ mushroom powder is a granular powder made from homogenised *Agaricus bisporus* mushrooms that have been exposed to UV light.<br>The mushrooms are washed, homogenised and suspended in water to produce a mushroom slurry. The mushroom slurry is passed under a UV lamp. The slurry is then filtered, dried and ground, producing vitamin $D_2$ mushroom powder.<br>UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under the novel food regulation.<br>**Characteristics/Composition**<br>Vitamin $D_2$ content: 1 000–1 300 µg/g of mushroom powder (*)<br>Moisture: ≤ 10,0 %<br>Ash: ≤ 13,5 %<br>**Heavy Metals**<br>Lead (as Pb): ≤ 0,5 mg/kg<br>Cadmium: ≤ 0,5 mg/kg<br>Mercury: ≤ 0,1 mg/kg<br>Arsenic: ≤ 0,3 mg/kg<br>**Mycotoxins**<br>Aflatoxins (sum of B1+B2+G1+G2): < 4 µg/kg<br>**Microbiological criteria:**<br>Total plate count: ≤ 5 000 CFU (**)/g<br>Yeast and mould: ≤ 100 CFU/g<br>*Salmonella* sp.: Absent in 25 g<br>*Staphylococcus aureus*: ≤ 10 CFU/g<br>*Escherichia coli*: ≤ 10 CFU/g<br>Coliforms: ≤ 10 CFU/g<br>*Enterobacteriaceae*: ≤ 10 CFU/g<br>*Listeria monocytogenes*: Absent in 25 g |

(*) Converted from International Units (IU) using the conversion factor of 0,025 µg = 1 IU.
(**) CFU: Colony Forming Units.'.