

**COMMISSION IMPLEMENTING REGULATION (EU) 2018/1011****of 17 July 2018****authorising an extension of use levels of UV-treated mushrooms 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 and Commission Regulation (EC) No 1852/2001 <sup>(1)</sup>, 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 <sup>(2)</sup> was adopted, which establishes a Union list of authorised novel foods.
- (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 updating the Union list.
- (4) Commission Implementing Decision (EU) 2017/2355 <sup>(3)</sup> authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(4)</sup>, the placing on the market of UV-treated mushrooms as a novel food.
- (5) On 23 July 2015, the companies Banken Champignons Group BV and J.K. Holding BV made a request to the competent authority of the Netherlands to place UV-treated mushrooms (*Agaricus bisporus*) with increased levels of vitamin D<sub>2</sub> on the Union market as a novel food within the meaning of point (f) of Article 1(2) of Regulation (EC) No 258/97.
- (6) With Implementing Regulation (EU) 2017/2470 that authorisation became generic in January 2018. As the application of this company concerns mushrooms with higher vitamin D<sub>2</sub> content, this Regulation should be considered as an authorisation for the extension of use.
- (7) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018, shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (8) While the request for placing UV-treated mushrooms (*Agaricus bisporus*) with increased levels of vitamin D<sub>2</sub> on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (9) On 20 September 2017, the competent authority of the Netherlands issued its initial assessment report. In that report it came to the conclusion that the UV-treated mushrooms (*Agaricus bisporus*) with increased levels of vitamin D<sub>2</sub> meet the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> Commission Implementing Decision (EU) 2017/2355 of 14 December 2017 authorising the placing on the market of UV-treated mushrooms as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 336, 16.12.2017, p. 52).

<sup>(4)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (10) On 5 October 2017, the Commission forwarded the initial assessment report to the other Member States. Comments were made by the other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to ensure that the tolerable upper intake levels of vitamin D set up by EFSA <sup>(1)</sup> are not exceeded.
- (11) In view of the comments made by the other Member States, the applicant provided additional explanations which alleviated the concerns to the satisfaction of the Member States and the Commission.
- (12) Those explanations give sufficient grounds to establish that UV-treated mushrooms (*Agaricus bisporus*) with increased levels of vitamin D<sub>2</sub> at the proposed use levels, comply with Article 12(1) of Regulation (EU) 2015/2283.
- (13) Point 1 of Part A of the Annex VI to Regulation (EU) No 1169/2011 of the European Parliament and of the Council <sup>(2)</sup> requires that the name of the food includes or is accompanied by particulars as to the specific treatment that the food has undergone in all cases where omission of such information could mislead the consumers. As consumers do not normally expect mushrooms to be subject to UV treatments, the name of this food shall include or be accompanied by such information in order to avoid misleading consumers.
- (14) 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 entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to UV-treated mushrooms shall be amended as specified in the annex to this Regulation.
2. The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

*Article 2*

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

*Article 3*

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, 17 July 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

<sup>(1)</sup> *EFSA Journal* 2012;10(7):2813

<sup>(2)</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

## ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the entry for 'UV-treated mushrooms (*Agaricus bisporus*)' in Table 1 (Authorised novel foods) is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
<b>'UV-treated mushrooms (<i>Agaricus bisporus</i>)'</b>	<i>Specified food category</i>	<i>Maximum levels of vitamin D<sub>2</sub></i>	1. The designation on the label of the novel food as such or of the foodstuffs containing it shall be "UV-treated mushrooms ( <i>Agaricus bisporus</i> )". 2. The designation on the label of the novel food as such or of the foodstuffs containing it shall be accompanied by indication that a "controlled light treatment was used to increase vitamin D levels" or 'UV treatment was used to increase vitamin D <sub>2</sub> levels'.'	
	Mushrooms ( <i>Agaricus bisporus</i> )	20 µg of vitamin D <sub>2</sub> /100 g fresh weight		

(2) the entry for 'UV-treated mushrooms (*Agaricus bisporus*)' in Table 2 (Specifications) is replaced by the following:

Authorised Novel Food	Specification
<b>'UV-treated mushrooms (<i>Agaricus bisporus</i>)'</b>	<p><b>Description/Definition:</b>            Commercially grown <i>Agaricus bisporus</i> to which UV light treatment is applied to harvested mushrooms.            UV radiation: a process of radiation in ultraviolet light within the wavelength of 200-800 nm.</p> <p><b>Vitamin D<sub>2</sub>:</b>            Chemical name: (3β,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol            Synonym: Ergocalciferol            CAS No: 50-14-6            Molecular weight: 396,65 g/mol</p> <p><b>Contents:</b>            Vitamin D<sub>2</sub> in the final product: 5-20 µg/100 g fresh weight at the expiration of shelf life.'</p>