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)

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[(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)] 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[(3)] authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[(4)], 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_2 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_2 content, this Regulation should be considered as an authorisation for the extension of use.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1011. (See end of Document for details)*

(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_2 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_2 meet the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(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[(5)] 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_2 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[(6)] 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