Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018 authorising an extension of use of UV-treated baker's yeast (Saccharomyces cerevisiae) 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) 2018/1018

of 18 July 2018

authorising an extension of use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) 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 submit a draft implementing act authorising the placing on the Union market of a novel food and updating the Union list.

(4) Commission Implementing Decision 2014/396/EU[(3)] authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[(4)] and following the European Food Safety Authority's Opinion[(5)], the placing on the market of UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food ingredient to be used in certain foods, including yeast-leavened breads and rolls and yeast-leavened fine bakery wares, as well as in food supplements.

(5) On 6 December 2016, the company Lallemand Bio-Ingredients made a request to the competent authority of Denmark for an extension of use and use levels of UV-treated baker's yeast (*Saccharomyces cerevisiae*). The application requested to extend the use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) to additional food categories,

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1018. (See end of Document for details)*

namely, pre-packed fresh and dry yeast for home baking and in food supplements without indication of maximum permitted levels. In addition, the applicant requested to amend the lower specification of the vitamin D_2 content in the yeast concentrate from 1 800 000 IU (450 µg/g) to 800 000 IU (200 µg/g).

(6) 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.

(7) While the request for an extension of uses and use levels of UV-treated baker's yeast (*Saccharomyces cerevisiae*) 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.

(8) On 30 June 2017, the competent authority of Denmark issued its initial assessment report. In that report it came to the conclusion that the extension of uses and proposed maximum use levels of UV-treated baker's yeast (*Saccharomyces cerevisiae*) meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(9) On 7 July 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 methods employed to adequately identify potential mutants, lack of justification on safety grounds to support the removal of the maximum level for food supplements, lack of information on storage stability for the new form of the novel food, lack of information on the accreditation of laboratories, and as to whether the intake of the novel food might exceed the tolerable upper intake levels for vitamin D set up by EFSA[(6)].

(10) In view of the comments made by the other Member States, the applicant provided additional explanations which alleviated their concerns to the satisfaction of the Member States and the Commission. Those explanations give sufficient grounds to establish that the extension of use and use levels of UV-treated baker's yeast (*Saccharomyces cerevisiae*) complies with Article 12(1) of Regulation (EU) 2015/2283.

(11) Directive 2002/46/EC of the European Parliament and of the Council[(7)] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council[(8)] lay down specific provisions for the use of vitamins and minerals when added to food supplements and food. The extension of use of UV-treated baker's yeast should be authorised without prejudice to those specific provisions.

(12) 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1018. (See end of Document for details)*

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 the substance UV-treated baker's yeast (*Saccharomyces cerevisiae*) 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.

3 The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC and Regulation (EC) No 1925/2006.

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, 18 July 2018.

For the Commission

The President

Jean-Claude JUNCKER