

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, 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 D₂ 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.

⁽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⁾ Commission Implementing Decision 2014/396/EU of 24 June 2014 authorising the placing on the market of UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 186, 26.6.2014, p. 108).

⁽⁴⁾ 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).

⁽⁵⁾ Scientific Opinion on the safety of vitamin D-enriched UV-treated baker's yeast, *EFSA Journal* 2014; 12(1):3520.

- (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 ⁽¹⁾.
- (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 ⁽²⁾ and Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽³⁾ 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:

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*.

⁽¹⁾ EFSA Journal 2012;10(7):2813

⁽²⁾ 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).

⁽³⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

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

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

(1) the entry for 'UV-treated baker's yeast (*Saccharomyces cerevisiae*)' 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
'UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)'	Specified food category	Maximum levels of vitamin D₂	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Vitamin D yeast" or "Vitamin D ₂ yeast"	
	Yeast-leavened breads and rolls	5 µg of vitamin D ₂ /100 g		
	Yeast-leavened fine bakery wares	5 µg of vitamin D ₂ /100 g		
	Food supplements as defined in Directive 2002/46/EC		<ol style="list-style-type: none"> 1. The designation of the novel food on the labelling of the foodstuffs shall be "Vitamin D yeast" or "Vitamin D₂ yeast". 2. The labelling of the novel food shall bear a statement that the foodstuff is only intended for baking and that it should not be eaten raw. 3. The labelling of the novel food shall bear instructions for use for the final consumers so that a maximum concentration of 5 µg/100 g of vitamin D₂ in final home-baked products is not exceeded.⁷ 	
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dried yeast		

(2) the entry for 'UV-treated baker's yeast (*Saccharomyces cerevisiae*)' in Table 2 (Specifications) is replaced by the following:

Authorised Novel Food	Specification
'UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)'	<p>Description/Definition:</p> <p>Baker's yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D₂ (ergocalciferol). Vitamin D₂ content in the yeast concentrate varies between 800 000-3 500 000 IU vitamin D/100 g (200-875 µg/g). The yeast may be inactivated.</p> <p>The yeast concentrate is blended with regular baker's yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking.</p> <p>Tan-coloured, free-flowing granules.</p>

Authorised Novel Food	Specification
	<p>Vitamin D₂: Chemical name: (5Z,7E,22E)-(3S)-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>Microbiological criteria for the yeast concentrate: Coliforms: $\leq 10^3$/g <i>Escherichia coli</i>: ≤ 10/g <i>Salmonella</i>: Absence in 25 g'</p>