

COMMISSION IMPLEMENTING REGULATION (EU) 2022/196**of 11 February 2022****authorising an extension of use and the change of the specifications 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 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⁾ has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes UV-treated baker's yeast (*Saccharomyces cerevisiae*) as an authorised novel food.
- (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 to be used in certain foods, including yeast-leavened breads and rolls and yeast-leavened fine bakery wares, as well as in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁶⁾.
- (5) Commission Implementing Regulation (EU) 2018/1018 ⁽⁷⁾ authorised in accordance with Regulation (EU) 2015/2283 an extension of use and use levels of the novel food UV-treated baker's yeast (*Saccharomyces cerevisiae*). In particular, the use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) has been extended to additional food categories, namely, pre-packed fresh or dry yeast for home baking and food supplements without indication of maximum permitted levels, and an amendment of the vitamin D₂ content in the yeast concentrate.

⁽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.

⁽⁶⁾ 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).

⁽⁷⁾ 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 (OJ L 183, 19.7.2018, p. 9).

- (6) On 15 May 2020, the company Lallemand Bio-Ingredients Division ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 for an extension of the use of the novel food UV-treated baker's yeast (*Saccharomyces cerevisiae*). The applicant requested to extend the use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) to a number of additional foods intended for the general population. The applicant also requested the novel food to be used in foods intended for infants and young children.
- (7) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 20 July 2020, requesting it to provide a scientific opinion on the extension of use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food.
- (8) On 28 April 2021, the Authority adopted its scientific opinion 'Safety of extended uses of UV-treated baker's yeast as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁸⁾. That scientific opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (9) In its opinion, the Authority concluded that UV-treated baker's yeast (*Saccharomyces cerevisiae*) is safe under the proposed conditions of use. Therefore, the opinion of the Authority gives sufficient grounds to establish that UV-treated baker's yeast (*Saccharomyces cerevisiae*), under the specific conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (10) In accordance with Commission Directive 2006/125/EC ⁽⁹⁾, vitamin D is not to be added to baby foods. Due to its vitamin D₂ content, UV-treated baker's yeast (*Saccharomyces cerevisiae*) should not be authorised for use in baby foods. Furthermore, in accordance with Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽¹⁰⁾ vitamins may not be added to unprocessed foodstuffs. Therefore, UV-treated baker's yeast (*Saccharomyces cerevisiae*) should not be authorised for the proposed use in amphibians, reptiles, snails, insects, algae and prokaryotes organisms, and in fungi, mosses and lichens.
- (11) In accordance with the Authority's opinion, the UV-treated baker's yeast (*Saccharomyces cerevisiae*) must be inactivated for use in infant formula and follow-on formula, processed cereal-based food and foods for special medical purposes as defined by Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽¹¹⁾, and therefore it is appropriate to amend the specifications of the novel food.
- (12) The information provided in the application and in the Authority's opinion gives sufficient grounds to establish that the changes to the specifications and the conditions of use of the novel food fulfil the conditions for its placing on the market in accordance with Article 12 of Regulation (EU) 2015/2283.
- (13) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁸⁾ EFSA Journal 2021;19(6):6602.

⁽⁹⁾ Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version) (OJ L 339, 6.12.2006, p. 16).

⁽¹⁰⁾ 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).

⁽¹¹⁾ 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).

HAS ADOPTED THIS REGULATION:

Article 1

1. The entry in the Union list of authorised novel foods in the Annex to Implementing Regulation (EU) 2017/2470, referring to the novel food UV-treated baker's yeast (*Saccharomyces cerevisiae*), is amended as specified in the Annex to this Regulation.
2. 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.

Article 2

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, 11 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

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	Data protection
“UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)	<i>Specified food category</i>	<i>Maximum levels of vitamin D₂</i>	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/100 g			
	Yeast-leavened fine bakery wares	5 µg/100 g			
	Food supplements as defined in Directive 2002/46/EC	In accordance with Directive 2002/46/EC			
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dried yeast	1. The designation of the novel food on the labelling of the foodstuffs shall be ‘vitamin D yeast’ or ‘vitamin D ₂ 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 D ₂ in final home-baked products is not exceeded.		
	Dishes, incl. ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘vitamin D yeast’ or ‘vitamin D ₂ yeast’”		
	Soups and salads	5 µg/100 g			
	Fried or extruded cereal, seed or root-based products	5 µg/100 g			

Infant formula and follow-on formula as defined by Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
Processed cereal-based food as defined by Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
Processed fruit products	1,5 µg/100 g			
Processed vegetables	2 µg/100 g			
Bread and similar products	5 µg/100 g			
Breakfast cereals	4 µg/100 g			
Pasta, doughs and similar products	5 µg/100 g			
Other cereal based products	3 µg/100 g			
Spices, seasonings, condiments, sauce ingredients, dessert sauces/toppings	10 µg/100 g			
Protein products	10 µg/100 g			
Cheese	2 µg/100 g			
Dairy dessert and similar products	2 µg/100 g			
Fermented milk or fermented cream	1,5 µg/100 g			
Dairy powders and concentrates	25 µg/100 g			
Milk based products, whey and cream	0,5 µg/100 g			

	Meat and dairy analogues	2,5 µg/100 g			
	Total diet replacement for weight control as defined by Regulation (EU) No 609/2013	5 µg/100 g			
	Meal replacements for weight control	5 µg/100 g			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			

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

Authorised Novel Food	Specifications
"UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)"	<p>Description/Definition 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 shall be inactivated for use in infant formula and follow-on formula, processed cereal-based food and foods for special medical purposes as defined by Regulation (EU) No 609/2013, while for use in other foods the yeast may or may not be inactivated. 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. Tan-coloured, free-flowing granules.</p> <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: ≤ 10³/g <i>Escherichia coli</i>: ≤ 10/g <i>Salmonella</i>: Absence in 25 g"</p>