

**COMMISSION IMPLEMENTING REGULATION (EU) 2019/760****of 13 May 2019****authorising the placing on the market of *Yarrowia lipolytica* yeast biomass 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> establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising placing on the Union market of a novel food and on the updating of the Union list.
- (4) On 10 April 2017, the company Skotan S.A. ('the Applicant') made a request in accordance with Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(3)</sup> to the competent authority of Poland to place *Yarrowia lipolytica* yeast biomass on the Union market as a novel food within the meaning of point (d) of Article 1(2) of that Regulation. The application requested for *Yarrowia lipolytica* yeast biomass to be used in food supplements. The maximum use levels proposed by the applicant are 3 g per day for children from 3 to 9 years of age, and 6 g per day thereafter.
- (5) On 15 November 2017, the competent authority of Poland issued its initial assessment report. In that report, it came to the conclusion that *Yarrowia lipolytica* yeast biomass meets the criteria for novel foods set out in Article 3(1) of Regulation (EC) No 258/97.
- (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 placing *Yarrowia lipolytica* yeast biomass on the Union market as a novel food 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) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 22 June 2018, asking it to provide a scientific opinion by carrying out an assessment for *Yarrowia lipolytica* yeast biomass as a novel food.
- (9) On 17 January 2019, the Authority adopted the 'Scientific Opinion on the safety of *Yarrowia lipolytica* yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283' <sup>(4)</sup>. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

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

<sup>(4)</sup> EFSA Journal 2019;17(2):5594.

- (10) The opinion of the Authority gives sufficient grounds to establish that *Yarrowia lipolytica* yeast biomass in the proposed use and use levels, when used in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (11) Directive 2002/46/EC of the European Parliament and of the Council <sup>(5)</sup> lays down requirements on food supplements. The use of *Yarrowia lipolytica* yeast biomass should be authorised without prejudice to the requirements of that Directive.
- (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. *Yarrowia lipolytica* yeast biomass as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
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 to this Regulation.
3. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

*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, 13 May 2019.

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

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<sup>(5)</sup> 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).

## ANNEX

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

(1) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
<i>Yarrowia lipolytica</i> yeast biomass	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be “ <i>Yarrowia lipolytica</i> yeast heat-killed biomass”	
	Food Supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	6 g/day for children from 10 years of age, adolescents and general adult population 3 g/day for children from 3 to 9 years of age		

(2) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

'Authorised Novel Food	Specification
<i>Yarrowia lipolytica</i> yeast biomass	<p><b>Description/Definition:</b> The novel food is the dried and heat-killed biomass of the yeast <i>Yarrowia lipolytica</i>.</p> <p><b>Characteristics/Composition:</b> Protein : 45-55 g/100 g Dietary fibre: 24-30 g/100 g Sugars: &lt; 1,0 g/100 g Fat: 7-10 g/100 g Total ash: ≤ 12 % Water content: ≤ 5 % Dry matter content: ≥ 95 %</p> <p><b>Microbiological criteria:</b> Total Aerobic Microbial Count: ≤ 5 × 10<sup>3</sup> CFU/g Total Yeast and Mould Count: ≤ 10<sup>2</sup> CFU/g Viable <i>Yarrowia lipolytica</i> cells <sup>(1)</sup>: &lt; 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g</p>

<sup>(1)</sup> To be tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable *Yarrowia lipolytica* cells during packaging and/or storage of the NF