

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)

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.

---

**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/760. (See end of Document for details)

---

- (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.
- (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.

**Changes to legislation:** There are currently no known outstanding effects for the  
Commission Implementing Regulation (EU) 2019/760. (See end of Document for details)

---

### *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