

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/938****of 10 May 2023****amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Yarrowia lipolytica* yeast biomass****(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 <sup>(1)</sup>, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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> has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes *Yarrowia lipolytica* yeast biomass as an authorised novel food.
- (4) Commission Implementing Regulation (EU) 2019/760 <sup>(3)</sup> authorised the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food for use in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council <sup>(4)</sup>, excluding food supplements for infants and young children.
- (5) On 27 July 2020, the company Skotan S.A. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the conditions of use of the novel food *Yarrowia lipolytica* yeast biomass. The applicant requested to extend the use of *Yarrowia lipolytica* yeast biomass to meal replacements for weight control intended for the adult population. The applicant also requested a change of the labelling of the designation of the novel food.
- (6) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 21 December 2020, requesting it to provide a scientific opinion on the change of conditions of use of the novel food *Yarrowia lipolytica* yeast biomass.
- (7) On 1 July 2022, the Authority adopted its scientific opinion on the 'Safety of an extension of use of *Yarrowia lipolytica* yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283' <sup>(5)</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority concluded that the proposed change is safe under the proposed conditions of use, and therefore it is appropriate to amend the conditions of use of *Yarrowia lipolytica* yeast biomass.

<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> 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 (OJ L 125, 14.5.2019, p. 13).

<sup>(4)</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).

<sup>(5)</sup> EFSA Journal 2022;20(7):7450.

- (9) In line with the conditions of use of meal replacements for weight control containing *Yarrowia lipolytica* yeast biomass as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers through an appropriate label that the meal replacements for weight control containing *Yarrowia lipolytica* yeast biomass should only be consumed by persons above 18 years of age and should not be used if food supplements with added *Yarrowia lipolytica* yeast biomass are consumed on the same day.
- (10) The information provided in the application and the opinion of the Authority give sufficient grounds to establish that the changes to the conditions of use and the labelling of the designation (removal of the term 'heat-killed') of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (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*

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

*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, 10 May 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Yarrowia lipolytica yeast biomass' 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
'Yarrowia lipolytica yeast biomass	<i>Specified food category</i>	<i>Maximum levels</i>	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Yarrowia lipolytica yeast biomass".  2. The labelling of meal replacements for weight control containing <i>Yarrowia lipolytica</i> yeast biomass shall bear a statement that they should only be used by persons above 18 years of age and should not be used if food supplements containing <i>Yarrowia lipolytica</i> yeast biomass are consumed on the same day.		
	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			
	Meal replacements for weight control for the adult population	3 g/meal (maximum 2 meals/day up to a maximum of 6 g/day)			