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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2044

of 29 July 2024

amending Implementing Regulation (EU) 2017/2470 as regards the specifications and 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 ([1]), 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 ([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 *Yarrowia lipolytica* yeast biomass as an authorised novel food.

(4) Commission Implementing Regulation (EU) 2019/760 ([3]) 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 ([4]), excluding food supplements for infants and young children.

(5) Commission Implementing Regulation (EU) 2023/938 ([5]) authorised change of the conditions of use of the novel food *Yarrowia lipolytica* yeast biomass, in particular extension of use of the novel food to meal replacements for weight control intended for the adult population.

(6) On 5 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. In particular, the applicant requested to extend the use of *Yarrowia lipolytica* yeast biomass to a number of foods.

(7) On 9 November 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of the extension of use of *Yarrowia lipolytica* yeast biomass as a novel food.

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.

([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

([3]) 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, ELI: http://data.europa.eu/eli/reg_impl/2019/760/oj)

([4]) 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, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

([5]) 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 (OJ L 125, 11.5.2023, p. 16, ELI: http://data.europa.eu/eli/reg_impl/2023/938/oj).

(8) On 26 October 2023, 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' ([6]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority concluded that the proposed extension of use of the novel food *Yarrowia lipolytica* yeast biomass is safe under the proposed conditions of use, and therefore it is appropriate to amend the conditions of use of *Yarrowia lipolytica* yeast biomass.

(10) In its scientific opinion, the Authority noted that given the newly proposed uses of the novel food, that limits for lead, mercury, cadmium and arsenic should be added to the specifications.

(11) The information provided in the application and the opinion of the Authority give sufficient grounds to establish that the changes to the specifications and the conditions of use and of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

(12) It is appropriate that the changes to the conditions of use of the novel food contain the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In this regard, considering additional uses of the novel food it is appropriate to change specific labelling requirement concerning the use of the novel food in food supplements.

(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,

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, 29 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

([6]) EFSA Journal. 2023;21:e8416.

ANNEX

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

(1) in Table 1 (Authorised novel foods), 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	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Yarrowia lipolytica* yeast biomass'. 2. Food supplements containing the novel food should bear a statement that they should not be consumed if other foods with added *Yarrowia lipolytica* 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)			
	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 but not in any case higher than 6 g/day			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	6 g/day			
	Unflavoured milk products	5 g/kg			
	Flavoured fermented milk products	10 g/kg			
	Cheese and cheese products; (excluding desserts)	10 g/kg			
	Nut spreads	30 g/kg			
	Processed potato products	10 g/kg			
	Cocoa and chocolate confectionary	10 g/kg			

	Grains and breakfast cereals	20 g/kg			
	Pasta based products and noodles	10 g/kg			
	Pre-cooked or processed cereals	10 g/kg			
	Bread and rolls	6 g/kg			
	Fine bakery wares	15 g/kg			
	Heat-treated meat products	15 g/kg			
	Herbs and spices; seasonings and condiments	50 g/kg			
	Soups and broths	5 g/kg			
	Sauces	10 g/kg			
	Salads and savoury based sandwich spreads	30 g/kg			
	Yeast and yeast products	30 g/kg			
	Protein products, excluding dairy analogues and beverage whiteners	30 g/kg			
	Flavoured drinks	10 g/l			
	Coffee, coffee extracts	20 g/kg			
	Other non-alcoholic beverages	10 g/l			
	Potato-, cereal-, flour- or starch-based snacks	300 g/kg			
	Processed nuts	20 g/kg			

ELI: http://data.europa.eu/eli/reg_impl/2024/2044/oj

(2) in Table 2 (Specifications), the entry for '*Yarrowia lipolytica* yeast biomass' is replaced by the following:

Authorised novel food	Specification
'*Yarrowia lipolytica* yeast biomass	**Description/Definition:** The novel food is the dried and heat-killed biomass of the yeast *Yarrowia lipolytica*. **Characteristics/Composition:** Protein: 45-55 g/100 g Dietary fibre: 24-30 g/100 g Sugars: < 1 g/100 g Fat: 7-10 g/100 g Total ash: ≤ 12 % Water content: ≤ 5 % Dry matter content: ≥ 95 % **Microbiological criteria:** Total Aerobic Microbial Count: ≤ 5×10^3 CFU/g Total Yeast and Mould Count: ≤ 10^2 CFU/g Viable *Yarrowia lipolytic*a cells[(a)]: < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g Salmonella spp.: Not detected in 25 g **Contaminants**: Lead: ≤ 0,1 mg/kg Mercury: ≤ 0,1 mg/kg Cadmium: ≤ 0,1 mg/kg Arsenic: ≤ 0,15 mg/kg Abbreviations: CFU, colony forming units (a) To be tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable Y. lipolytica cells during packaging and/or storage of the novel food'