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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specifications 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 1852/2001¹, 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) 2017/2470² 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) 2019/760³ 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 Council⁴, excluding food supplements for infants and young children.

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 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).

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).

- (5) Commission Implementing Regulation (EU) 2023/938⁵ 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.
- (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 conditions of use and the specifications 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 contains 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 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.

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).

⁶ EFSA Journal. 2023;21:e8416.

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,

For the Commission
The President
Ursula VON DER LEYEN