COMMISSION IMPLEMENTING REGULATION (EU) 2020/1822

of 2 December 2020

authorising the placing on the market of chromium-containing yeast (*Yarrowia lipolytica*) 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 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), 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 ([2]) establishing a Union list of authorised novel foods was adopted.

(3) Commission Implementing Regulation (EU) 2019/760 ([3]) authorised, in accordance with Regulation (EU) 2015/2283, the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food to be used 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.

(4) On 22 August 2018, the company Skotan S.A. ('the applicant') introduced an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place chromium-enriched biomass of the yeast *Yarrowia lipolytica* on the Union market as a novel food. The applicant requested for chromium-enriched biomass of the yeast *Yarrowia lipolytica* to be used as a novel food in food supplements, excluding food supplements for infants and young children. The maximum use levels proposed by the applicant are 2 g per day for children from 3 to 9 years of age, and 4 g per day for adolescents and adults.

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 18 February 2019, asking it to provide a scientific opinion by carrying out an assessment for chromium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food.

(6) On 23 January 2020, the Authority adopted its scientific opinion 'Safety of chromium-enriched biomass of *Yarrowia lipolytica* as a novel food pursuant to Regulation (EU) 2015/2283' ([5]). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In its opinion, the Authority concluded that chromium-containing yeast (*Yarrowia lipolytica*) biomass is safe under the proposed uses and use levels, when used in food supplements intended for the general population above 3 years of age.

([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]) *EFSA Journal* 2020;18(3):6005.

(8) The opinion of the Authority gives sufficient grounds to establish that chromium-containing yeast (*Yarrowia lipolytica*) biomass under the proposed conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

(9) Regulation (EU) 2017/2470 should be therefore amended accordingly.

(10) 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. Chromium-containing yeast (*Yarrowia lipolytica*) 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.

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, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'**Chromium-containing yeast (*Yarrowia lipolytica*) biomass**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "chromium-containing yeast (*Yarrowia lipolytica*) biomass" The labelling of food supplements containing chromium-containing yeast (*Yarrowia lipolytica*) biomass shall bear a statement that the food supplements should not be consumed by infants and young children (children under 3 years of age)/children from 3 to 9 years of age (*).	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	2 g/day for children from 3 to 9 years of age, resulting in 46 µg of chromium per day 4 g/day for children from 10 years of age, adolescents and adults, resulting in 92 µg of chromium per day		

(*) Depending on the age group the food supplement is intended for.'

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'**Chromium-containing yeast (*Yarrowia lipolytica*) biomass**	**Description/Definition:** The novel food is the dried and heat-killed chromium-containing biomass of the yeast *Yarrowia lipolytica*. The novel food is produced by fermentation in the presence of chromium chloride followed by a number of purification steps and a heat-killing step of the yeast to ensure the absence of viable *Yarrowia lipolytica* cells in the novel food. **Characteristics/Composition:** Total chromium: 18–23 µg/g Chromium (VI): < 10 µg/kg (i.e. limit of detection) Protein: 40–50 g/100 g Dietary fibre: 24–32 g/100 g Sugars: < 2 g/100 g

	Fat: 6–12 g/100 g Total ash: ≤ 15 % Water: ≤ 5 % Dry matter: ≥ 95 % **Heavy metals:** Lead: ≤ 3,0 mg/kg Cadmium: ≤ 1,0 mg/kg Mercury: ≤ 0,1 mg/kg **Microbiological criteria:** Total aerobic microbial count: ≤ 5×10^3 CFU/g Total yeast and mould count: ≤ 10^2 CFU/g Viable *Yarrowia lipolytica* cells (*): < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g CFU: colony forming units

(*) Applicable at all stages after the heat-treatment step to guarantee the absence of viable *Yarrowia lipolytica* cells and to be first 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 novel food.'