

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

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 (<i>Yarrowia lipolytica</i>) biomass	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "chromium-containing yeast (<i>Yarrowia lipolytica</i>) biomass" The labelling of food supplements containing chromium-containing yeast (<i>Yarrowia lipolytica</i>) 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 (<i>Yarrowia lipolytica</i>) biomass	<p>Description/Definition: The novel food is the dried and heat-killed chromium-containing biomass of the yeast <i>Yarrowia lipolytica</i>. 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 <i>Yarrowia lipolytica</i> cells in the novel food.</p> <p>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</p>

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 × 10³ CFU/g

Total yeast and mould count: ≤ 10² 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.'