COMMISSION IMPLEMENTING DECISION (EU) 2017/2078

of 10 November 2017

authorising an extension of use of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2017) 7391)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) Commission Implementing Decision 2011/762/EU ([2]) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of yeast beta-glucans as a novel food ingredient to be used in certain foods and foodstuffs, including beverages, as well as in food supplements and in food for special medical purposes, and total diet replacement for weight control.

(2) On 25 April 2016, the company Leiber GmbH made a request to the competent authority of Ireland for extension of uses and use levels of yeast beta-glucans as a novel food ingredient. In particular, they asked to extend the use of yeast beta-glucans to additional food categories and to increase maximum use levels of yeast beta-glucans per day for food categories already authorised by Implementing Decision 2011/762/EU.

(3) On 7 November 2016, the competent authority of Ireland issued its initial assessment report. In that report, it came to the conclusion that the extension of uses and proposed maximum use levels of yeast beta-glucans meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(4) On 15 November 2016, the Commission forwarded the initial assessment report to the other Member States.

(5) Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. The applicant consequently modified the request concerning the food categories and use levels proposed. That change and additional explanations by the applicant alleviated the concerns to the satisfaction of the Member States and the Commission.

(6) Directive 2002/46/EC of the European Parliament and of the Council ([3]) lays down requirements for food supplements. Regulation (EC) No 1925/2006 of the European Parliament and of the Council ([4]) lays down requirements on the addition of vitamins and minerals and certain other substances to foods. Regulation (EU) No 609/2013 of the European Parliament and of the Council ([5]) lays down general compositional and information requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. Those acts may apply to the yeast beta-glucans. Therefore yeast beta-glucans should be authorised without prejudice to the requirements of that and of any other legislation applying in parallel to Regulation (EC) No 258/97.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) OJ L 43, 14.2.1997, p. 1.

([2]) Commission Implementing Decision 2011/762/EU of 24 November 2011 authorising the placing on the market of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 313, 26.11.2011, p. 41).

([3]) 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).

([4]) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

([5]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC, and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 12.6.2013, p. 35).

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to the provisions of Directive 2002/46/EC, Regulation (EC) No 1925/2006 and Regulation (EU) No 609/2013, yeast (*Saccharomyces cerevisiae*) beta-glucans as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II to this Decision.

Article 2

The designation of yeast (*Saccharomyces cerevisiae*) beta-glucans authorised by this Decision on the labelling of the foodstuffs shall be 'yeast (*Saccharomyces cerevisiae*) beta-glucans'.

Article 3

This Decision is addressed to Leiber GmbH, Hafenstraße 24, 49565 Bramsche, Germany.

Done at Brussels, 10 November 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATIONS OF YEAST (*SACCHAROMYCES CEREVISIAE*) BETA-GLUCANS

Description

Beta-glucans are complex, high molecular mass (100–200 kDa) polysaccharides, found in the cell wall of many yeasts and cereals. The chemical name for 'yeast beta-glucans' is (1-3), (1-6)-β-D-glucans.

Beta-glucans consist of a backbone of β-1-3-linked glucose residues that are branched by β-1-6-linkages, to which chitin and mannoproteins are linked by β-1-4-bonds.

This novel food is a highly purified (1,3)-(1,6)-β-D-glucan isolated from yeast *Saccharomyces cerevisiae*, insoluble in water, but dispersible in many liquid matrices.

Specifications of yeast (*Saccharomyces cerevisiae*) beta-glucans

Parameter	Specifications values
Solubility	*Insoluble in water but dispersible in many liquid matrices*
Chemical data	
(1,3)-(1,6)-β-D-Glucan	> 80 %
Ash	< 2 %
Moisture	< 6 %
Protein	< 4 %
Total fat	< 3 %
Microbiological data	
Total plate count	< 1 000 CFU/g
Enterobacteriaceae	< 100 CFU/g
Total coliforms	< 10 CFU/g
Yeast	< 25 CFU/g
Mould	< 25 CFU/g
Salmonella ssp.	Absent in 25 g
Escherichia coli	Absent in 1 g
Bacillus cereus	< 100 CFU/g
Staphylococcus aureus	Absent in 1 g
Heavy metals	
Lead	< 0,2 mg/g
Arsenic	< 0,2 mg/g
Mercury	< 0,1 mg/g
Cadmium	< 0,1 mg/g

ANNEX II

AUTHORISED USES OF YEAST (*SACCHAROMYCES CEREVISIAE*) BETA-GLUCANS

Food category	Maximum level of yeast beta-glucans
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1,275 g/day for children older than 12 years and general adult population 0,675 g/day for children younger than 12 years
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	1,275 g/day
Food for special medical purposes as defined in Regulation (EU) No 609/2013, excluding food for special medical purposes intended for infants and young children	1,275 g/day
Beverages based on fruit and/or vegetable juices including concentrate and dehydrated juices	1,3 g/kg
Fruit-flavoured drinks	0,8 g/kg
Cocoa beverages preparation powder	38,3 g/kg (powder)
Cereal bars	6 g/kg
Breakfast cereals	15,3 g/kg
Wholegrain and high fibre instant hot breakfast cereals	1,5 g/kg
Cookie-type biscuits	2,2 g/kg
Cracker-type biscuits	6,7 g/kg
Milk based beverages	3,8 g/kg
Fermented milk products	3,8 g/kg
Milk product analogues	3,8 g/kg
Other beverages	0,8 g/kg (ready to drink)
Dried milk/milk powder	25,5 g/kg
Soup and soup mixes	0,9 g/kg (ready to eat) 1,8 g/kg (condensed) 6,3 g/kg (powder)
Chocolate and confectionary	4 g/kg
Protein bars and powder	19,1 g/kg
Jam, marmalade and other fruit spreads	11,3 g/kg