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DRAFT

COMMISSION IMPLEMENTING DECISION

of **XXX**

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

(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 ingredients¹, and in particular Article 7 thereof,

Whereas:

- (1) Commission Implementing Decision 2011/762/EU² 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 Commission 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 use levels of yeast beta-glucans meet 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 provided information to address the objections and modified initial request accordingly.
- (6) Directive 2002/46/EC of the European Parliament and of the Council³ lays down requirements for food supplements. Regulation (EC) No 1925/2006 of the European Parliament and of the Council⁴ lays down requirements on the addition of vitamins

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).

and minerals and certain other substances to foods. Regulation (EU) No 609/2013 of the European Parliament and of the Council⁵ on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. These legal acts may apply to the yeast beta-glucans. Therefore yeast beta-glucans should be authorised without prejudice to the requirements of those legislations.

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

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 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.

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,

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

⁵ Regulation (EU) 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, 199/21/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).