

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)

COMMISSION IMPLEMENTING DECISION (EU) 2017/2078

of 10 November 2017

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*(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<sup>(1)</sup>, and in particular Article 7 thereof,

Whereas:

- (1) Commission Implementing Decision 2011/762/EU<sup>(2)</sup> 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

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**Changes to legislation:** There are currently no known outstanding effects for the Commission  
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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<sup>(3)</sup> lays down requirements for food supplements. Regulation (EC) No 1925/2006 of the European Parliament and of the Council<sup>(4)</sup> 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<sup>(5)</sup> 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,

HAS ADOPTED THIS DECISION:

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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](#)).

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2017/2078, Introductory Text.