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**COMMISSION IMPLEMENTING DECISION**

**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**

*(notified under document C(2011) 8527)*

**(Only the English text is authentic)**

**(2011/762/EU)**

**(OJ L 313, 26.11.2011, p. 41)**

Corrected by:

► **C1** Corrigendum, OJ L 205, 1.8.2012, p. 20 (2011/762/EU)



# COMMISSION IMPLEMENTING DECISION

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**

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(2011/762/EU)

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) On 23 September 2009 the company Biothera Incorporated made a request to the competent authority of Ireland to place yeast beta-glucans on the market as a novel food ingredient for use in a variety of foods, including beverages, for the general population as well as in food supplements and in foods for particular nutritional uses with the exception of infant formulae and follow-on formulae.
- (2) On 23 December 2009 the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that yeast beta-glucans were acceptable as a novel food ingredient provided that the product specifications and intended use levels are maintained and that the range of foodstuffs is limited to those presented in the application dossier.
- (3) The Commission forwarded the initial assessment report to all Member States on 18 January 2010.
- (4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.
- (5) Therefore, the European Food Safety Authority (EFSA) was consulted on 2 July 2010.
- (6) On 8 April 2011, EFSA in the ‘Scientific Opinion on the safety of “Yeast beta-glucans” as a novel food ingredient’ <sup>(2)</sup> came to the conclusion that yeast beta-glucans were safe under the proposed conditions of use. EFSA opinion did not address in its opinion the safety for children below 1½ years.

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(2)</sup> *EFSA Journal* 2011; 9(5):2137 [22 pp.].

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- (7) On the basis of the EFSA scientific assessment and taking into account 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 <sup>(1)</sup>, 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 <sup>(2)</sup>, Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses <sup>(3)</sup>, Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes <sup>(4)</sup>, Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children <sup>(5)</sup>, it is established that yeast beta-glucans comply with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

Yeast (*Saccharomyces cerevisiae*) beta-glucans as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II, and without prejudice to the provisions of Directive 2002/46/EC, Regulation (EC) No 1925/2006 and Directive 2009/39/EC.

*Article 2*

The designation of yeast (*Saccharomyces cerevisiae*) beta-glucans authorised by this Decision for the labelling of the foodstuffs containing it shall be ‘yeast (*Saccharomyces cerevisiae*) beta-glucans’.

*Article 3*

This Decision is addressed to Biothera Incorporated, 3388 Mike Collins Drive, Eagan, Minnesota, USA, 55121.

<sup>(1)</sup> OJ L 183, 12.7.2002, p. 51.

<sup>(2)</sup> OJ L 404, 30.12.2006, p. 26.

<sup>(3)</sup> OJ L 124, 20.5.2009, p. 21.

<sup>(4)</sup> OJ L 91, 7.4.1999, p. 29.

<sup>(5)</sup> OJ L 339, 6.12.2006, p. 16.



## 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)- $\beta$ -D-glucans.

This novel food is available both in an insoluble and soluble form, isolated from *Saccharomyces cerevisiae*. The insoluble products contain at least 70 % carbohydrate in the form of beta-glucans; the soluble product contains at least 75 % beta-glucans.

The tertiary structure of the glucan cell wall of *Saccharomyces cerevisiae* consists of chains of  $\beta$ -1,3-linked glucose residues, branched by  $\beta$ -1,6-linkages, forming a backbone to which are linked chitin via  $\beta$ -1,4- bonds,  $\beta$ -1,6-glucans and some mannoproteins.

Chemical characteristics yeast (*Saccharomyces cerevisiae*) beta-glucans

	Soluble form	Insoluble form
Total carbohydrate	More than 75 %	More than 70 %
Beta-glucans (1,3/1,6)	More than 75 %	More than 70 %
Ash	less than 4 %	Less than 5 %
Moisture	Less than 8 %	Less than 8 %
Protein	less than 3,5 %	Less than 10 %
Fat	Less than 10 %	Less than 20 %

**▼B***ANNEX II***▼C1****USES OF PURE BETA-GLUCANS FROM YEAST (*SACCHAROMYCES CEREVISIAE*)****▼B**

Food category	Use level
Food supplements, as defined in Directive 2002/46/EC	375 mg (per day as recommended by the manufacturer)
Foods for particular nutritional uses (Parnuts), as defined in Directive 2009/39/EC excluding infant and follow on formula	600 mg (per day as recommended by the manufacturer)
Beverages based on fruit juices	130 mg/100 ml
Fruit-flavoured drinks	80 mg/100 ml
Other beverages	80 mg/100 ml (RTD) 700 mg/100 g (powder)
Cereal bars	600 mg/100 g
Cookie-type biscuits	670 mg/100 g
Cracker-type biscuits	20 mg/100 g
Breakfast cereals	670 mg/100 g
Wholegrain and high fibre instant hot breakfast cereals	150 mg/100 g
Products based on yoghurt, fresh cheese and other dairy desserts	160 mg/100 g
Soups and soup mixes	90 mg/100 g (RTE) 180 mg/100 g (condensed) 630 mg/100 g (powder)
Chocolate and confectionery	400 mg/100 g
Protein bars and powders	600 mg/100 g

Abbreviations: RTD = ready to drink; RTE = ready to eat.