

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)

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) 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'⁽²⁾ 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.

(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⁽³⁾, 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⁽⁴⁾, Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses⁽⁵⁾, Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes⁽⁶⁾, Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children⁽⁷⁾, 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.

⁽²⁾ EFSA Journal 2011; 9(5):2137 [22 pp.].

⁽³⁾ OJ L 183, 12.7.2002, p. 51.

⁽⁴⁾ OJ L 404, 30.12.2006, p. 26.

⁽⁵⁾ OJ L 124, 20.5.2009, p. 21.

⁽⁶⁾ OJ L 91, 7.4.1999, p. 29.

⁽⁷⁾ OJ L 339, 6.12.2006, p. 16.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

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.

Done at Brussels, 24 November 2011.

For the Commission
John DALLI
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.

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 β -1,3-linked glucose residues, branched by β -1,6-linkages, forming a backbone to which are linked chitin via β -1,4- bonds, β -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 %

ANNEX II

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.