

DECISIONS

COMMISSION DECISION

of 2 February 2011

authorising the placing on the market of a mycelial extract from *Lentinula edodes* (Shiitake mushroom) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2011) 442)

(Only the English text is authentic)

(2011/73/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 19 December 2007 the company GlycaNova Norge AS made a request to the competent authorities of the United Kingdom to place a mycelial extract from the Shiitake mushroom (*Lentinula edodes* formerly *Lentinus edodes*) on the market as a novel food ingredient.
- (2) On 3 November 2008 the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that the use of the mycelial extract from *Lentinula edodes* as a food ingredient was acceptable.
- (3) The Commission forwarded the initial assessment report to all Member States on 7 January 2009.
- (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 24 September 2009.
- (6) On 9 July 2010, EFSA (Panel on Dietetic Products, Nutrition and Allergies) in the 'Scientific opinion on the safety of "*Lentinula edodes* extract" as a novel food ingredient'⁽²⁾ came to the conclusion that the mycelial

extract from *Lentinula edodes* was safe under the proposed conditions of use and the proposed levels of intake.

- (7) On the basis of the scientific assessment, it is established that mycelial extract from *Lentinula edodes* complies 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

The mycelial extract from *Lentinula edodes* as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses listed in Annex II.

Article 2

The designation of the mycelial extract from *Lentinula edodes* authorised by this Decision on the labelling of the foodstuff containing it shall be 'extract from the mushroom *Lentinula edodes*' or 'extract from the Shiitake mushroom'.

Article 3

This Decision is addressed to GlycaNova Norge AS, Oraveien 2, 1630 Gamle Fredrikstad, Norway.

Done at Brussels, 2 February 2011.

For the Commission

John DALLI

Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ EFSA Journal 2010; 8(7): 1685.

ANNEX I

Specifications of the mycelial extract from *Lentinula edodes***Description:**

The novel food ingredient is a sterile aqueous extract obtained from the mycelium of *Lentinula edodes* cultivated in a submerged fermentation. It is a light brown, slightly turbid liquid.

Lentinan is a β -(1-3) β -(1-6)-D-glucan which has a molecular weight of approximately 5×10^5 Daltons, a degree of branching of 2/5 and a triple helical tertiary structure.

Composition of the mycelial extract from *Lentinula edodes*

Moisture	98 %
Dry matter	2 %
Free glucose	less than 20 mg/ml
Total Protein (*)	less than 0,1 mg/ml
N-containing constituents (**)	less than 10 mg/ml
Lentinan	0,8 – 1,2 mg/ml
(*) Bradford method	
(**) Kjeldahl method	

ANNEX II

Uses of the mycelial extract from *Lentinula edodes*

Use group	Maximum level of mycelial extract from <i>Lentinula edodes</i>
Bread products	2 ml/100 g
Soft drinks	0,5 ml/100 ml
Ready prepared meals	2,5 ml per meal
Foods based on yoghurt	1,5 ml/100 ml
Food supplements (as defined in Directive 2002/46/EC ⁽¹⁾)	2,5 ml per day dose

(¹) OJ L 183, 12.7.2002, p. 51.