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

(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

(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 $\beta$-(1-3)$\beta$-(1-6)-D-glucan which has a molecular weight of approximately $5 \times 10^5$ Daltons, a degree of branching of 2/5 and a triple helical tertiary structure.

<table>
<thead>
<tr>
<th>Composition of the mycelial extract from <em>Lentinula edodes</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture (g/100 g)</td>
</tr>
<tr>
<td>Dry matter (%)</td>
</tr>
<tr>
<td>Free glucose (mg/ml)</td>
</tr>
<tr>
<td>Total Protein (*) (Bradford method)</td>
</tr>
<tr>
<td>N-containing constituents (Kjeldahl method) (mg/ml)</td>
</tr>
<tr>
<td>Lentinan (mg/ml)</td>
</tr>
</tbody>
</table>

---

ANNEX II

**Uses of the mycelial extract from *Lentinula edodes***

<table>
<thead>
<tr>
<th>Use group</th>
<th>Maximum level of mycelial extract from <em>Lentinula edodes</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bread products</td>
<td>2 ml/100 g</td>
</tr>
<tr>
<td>Soft drinks</td>
<td>0.5 ml/100 ml</td>
</tr>
<tr>
<td>Ready prepared meals</td>
<td>2.5 ml per meal</td>
</tr>
<tr>
<td>Foods based on yoghurt</td>
<td>1.5 ml/100 ml</td>
</tr>
<tr>
<td>Food supplements (as defined in Directive 2002/46/EC ((^{(1)}))</td>
<td>2.5 ml per day dose</td>
</tr>
</tbody>
</table>