

COMMISSION IMPLEMENTING DECISION

of 9 August 2011

authorising the placing on the market of fermented black bean extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council*(notified under document C(2011) 5645)***(Only the English text is authentic)**

(2011/497/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 8 July 2008 the company Cantox Health Sciences International on behalf of CBC Co. Ltd (Japan) made a request to the competent authorities of United Kingdom to place fermented black bean extract on the market as a novel food ingredient for use in food supplements.
- (2) On 28 January 2009 the competent food assessment body of United Kingdom issued its initial assessment report. In that report it came to the conclusion that fermented black bean extract was acceptable as a novel food ingredient provided that the product specifications and use levels are maintained.
- (3) The Commission forwarded the initial assessment report to all Member States on 5 February 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 19 August 2009.
- (6) On 8 April 2011, EFSA in the 'Scientific Opinion on the safety of a "fermented black bean extract" (Touchi) as a Novel Food ingredient' ⁽²⁾ came to the conclusion that fermented black bean extract was safe under the proposed use and conditions of use.
- (7) On the basis of the scientific assessment, it is established that fermented black bean extract complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97, without prejudice to the specific provisions of 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⁾ and to 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 certain other substances to foods ⁽⁴⁾.

- (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

Fermented black bean extract as specified in the Annex may be placed on the market in the Union as a novel food ingredient in food supplements without prejudice to the specific provisions of Directive 2002/46/EC and Regulation (EC) No 1925/2006, with a maximum intake of 4,5 g per day.

Article 2

The designation of the authorised fermented black bean extract by this Decision on the labelling of the foodstuff containing it shall be 'fermented black bean (Soya) extract' or 'fermented Soya extract'.

Article 3

This Decision is addressed to CBC Co. Ltd, 2-15-13, Tsukima, Chuo-ku, Tokyo 104-0052, JAPAN.

Done at Brussels, 9 August 2011.

For the Commission

John DALLI

Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ EFSA Journal 2011; 9(5):2136. [20 pp.]

⁽³⁾ OJ L 183, 12.7.2002, p. 51.

⁽⁴⁾ OJ L 404, 30.12.2006, p. 26.

ANNEX

SPECIFICATIONS OF FERMENTED BLACK BEAN EXTRACT

Description:

Fermented black bean extract (Touchi extract) is a fine light-brown protein-rich powder obtained by water extraction of small soybeans (*Glycine max*) fermented with *Aspergillus oryzae*. The extract contains an α -glucosidase inhibitor.

Chemical characteristics of fermented black bean extract	
fat	Not more than 1 %
protein	Not less than 55 %
water	Not more than 7 %
ash	Not more than 10 %
carbohydrate	Not less than 20 %
α -glucosidase inhibitory activity	IC ₅₀ min 0,025 mg/ml
Soy isoflavone	Not more than 0,3 g/100 g