

**COMMISSION IMPLEMENTING DECISION (EU) 2017/115****of 20 January 2017****authorising the placing on the market of fermented soybean extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2017) 165)***(Only the English text is authentic)**

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(1) thereof,

Whereas:

- (1) On 8 May 2014, the company Japan Bio Science Laboratory made a request to the competent authorities of Belgium to place fermented soybean extract on the Union market as a novel food ingredient within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97. The application excluded from the use pregnant and lactating women.
- (2) On 1 December 2014, the competent food assessment body of Belgium issued its initial assessment report. In that report it came to the conclusion that fermented soybean extract meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 6 January 2015, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.
- (5) On 22 April 2015, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for fermented soybean extract as novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 28 June 2016, EFSA concluded in its opinion on the safety of fermented soybean extract as a novel food <sup>(2)</sup> that fermented soybean extract used in food supplements intended for adults is safe under the conditions of use proposed by the applicant limiting consumption per day to a maximum dose of 100 mg. That opinion gives sufficient grounds to establish that fermented soybean extract as a novel food ingredient complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (7) In its opinion, EFSA noted that fermented soybean extract contains nattokinase which exhibits *in vitro* fibrinolytic activity and *in vivo* thrombolytic activity in animals when administered parenterally. It is therefore necessary to inform consumers about the need of medical supervision in cases when fermented soybean extract is consumed in combination with medication.
- (8) In its opinion, EFSA concludes that the margin of exposure is sufficient considering the maximum intake level for fermented soybean extract proposed by the applicant.
- (9) In its opinion, EFSA considers that the risk of allergic reaction to fermented soybean extract is similar to that associated with other soy-derived products which are to be labelled pursuant to Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council <sup>(3)</sup>. Therefore, the novel food ingredient should be labelled in accordance with Article 8 of Regulation (EC) No 258/97 and Regulation (EU) No 1169/2011.

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

<sup>(2)</sup> *EFSA Journal* 2016; 14(7): 4541.

<sup>(3)</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (10) Directive 2002/46/EC of the European Parliament and of the Council <sup>(1)</sup> lays down requirements for food supplements. The use of fermented soybean extract should be authorised without prejudice to the provisions of that Directive.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1*

Without prejudice to Directive 2002/46/EC, fermented soybean extract as specified in the Annex to this Decision may be placed on the market in the Union as a novel food ingredient to be used in food supplements in capsule, tablet or powder form intended for the adult population, excluding pregnant and lactating women with a maximum dose of 100 mg fermented soybean extract per day.

*Article 2*

1. The designation of fermented soybean extract authorised by this Decision on the labelling of the foodstuffs containing it shall be 'fermented soybean extract'.
2. Without prejudice to further labelling requirements under Article 8 of Regulation (EC) No 258/97 and Regulation (EU) No 1169/2011, the labelling of food supplements containing fermented soybean extract shall also bear a statement that persons taking medication should only consume the product under medical supervision.

*Article 3*

This Decision is addressed to Japan Bio Science Laboratory Osaka Head Office 1-4-40 Fukushima-ku, Osaka-city Osaka 5533-0003 Japan.

Done at Brussels, 20 January 2017.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

---

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

## ANNEX

## SPECIFICATION OF FERMENTED SOYBEAN EXTRACT

**Description:** Fermented soybean extract is an odourless milk-white coloured powder. It is comprised of 30 % fermented soybean extract powder and 70 % resistant dextrin (as carrier) from corn-starch, which is added during the processing. Vitamin K<sub>2</sub> is removed during the manufacturing process.

Fermented soybean extract contains nattokinase isolated from natto, a foodstuff produced by the fermentation of non-genetically modified soybeans (*Glycine max* (L.)) with a selected strain of *Bacillus subtilis* var. *natto*.

## Specification of the fermented soybean extract

Parameters	Specification value
Nattokinase activity	20 000-28 000 FU <sup>(1)</sup> /g <sup>(2)</sup>
Identity	Confirmable
Condition	No offensive taste or smell
Loss on drying	Not more than 10 %
Vitamin K <sub>2</sub>	Not more than 0,1 mg/kg
Heavy metals	Not more than 20 mg/kg
Lead	Not more than 5 mg/kg
Arsenic	Not more than 3 mg/kg
Total viable aerobic count	Not more than 1 000 CFU <sup>(3)</sup> /g
Yeast and mould	Not more than 100 CFU/g
Coliforms	Not more than 30 CFU/g
Spore-forming bacteria	Not more than 10 CFU/g
Escherichia coli	Absence/25 g
Salmonella sp.	Absence/25 g
Listeria	Absence/25 g

<sup>(1)</sup> FU: Fibrin degradation unit.

<sup>(2)</sup> Assay method as described by Takaoka et al. (2010).

<sup>(3)</sup> CFU: Colony forming unit.