COMMISSION IMPLEMENTING DECISION

of 11 December 2014

authorising the placing on the market of *Clostridium butyricum* (CBM 588) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2014) 9345)

(Only the English text is authentic)

(2014/907/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 2 February 2012, the company Miyarisan Pharmaceutical Co. Ltd made a request to the competent authorities of the United Kingdom to place *Clostridium butyricum* (CBM 588) on the market as a novel food ingredient to be used in food supplements.

(2) On 14 May 2013, the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that *Clostridium butyricum* (CBM 588) meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 4 September 2013, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. In accordance with Article 7(1) of Regulation (EC) No 258/97 a Commission Implementing Decision should be made that takes into account the objections raised. The additional explanations provided by the applicant alleviated the concerns to the satisfaction of the Member States and the Commission.

(5) Directive 2002/46/EC of the European Parliament and of the Council ([2]) lays down requirements on food supplements. The use of *Clostridium butyricum* (CBM 588) should be authorised without prejudice to the requirements of that legislation.

(6) 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

Clostridium butyricum (CBM 588) as specified in the Annex may be placed on the market in the Union as a novel food ingredient to be used in food supplements with a maximum dose of $1{,}35 \times 10^8$ CFU per day without prejudice to the specific provisions of Directive 2002/46/EC.

Article 2

The designation of *Clostridium butyricum* (CBM 588) authorised by this Decision on the labelling of the foodstuffs containing it shall be '*Clostridium butyricum* MIYAIRI 588 (CBM 588)' or '*Clostridium butyricum* (CBM 588)'.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) 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).

Article 3

This Decision is addressed to Miyarisan Pharmaceutical Co. Ltd, 1-10-3, Kaminakazato, Kita-Ku, Tokyo 114-0016, Japan.

Done at Brussels, 11 December 2014.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

SPECIFICATION OF *CLOSTRIDIUM BUTYRICUM* (CBM 588)

Definition: *Clostridium butyricum* (CBM 588) is a Gram-positive, spore-forming, obligate anaerobic, non-pathogenic, non-genetically modified bacterium.

Description: White or pale grey tablets with characteristic odour and sweet taste.

Microbiological criteria:

Total viable aerobic count	Not more than 10^3 CFU/g
Escherichia coli	Not detected in 1 g
Staphylococcus aureus	Not detected in 1 g
Pseudomonas aeruginosa	Not detected in 1 g
Yeast and moulds	Not more than 10^2 CFU/g