Commission Implementing Regulation (EU) No 306/2013 of 2 April 2013 concerning the authorisation of a preparation of Bacillus subtilis (ATCC PTA-6737) for weaned piglets and weaned Suidae other than Sus scrofa domesticus (holder of authorisation Kemin Europa N.V.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 306/2013

of 2 April 2013

concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) for weaned piglets and weaned Suidae other than *Sus scrofa domesticus* (holder of authorisation Kemin Europa N.V.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of a preparation of *Bacillus subtilis* (ATCC PTA-6737). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a new use of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for weaned piglets and weaned Suidae other than *Sus scrofa domesticus*, to be classified in the additive category ‘zootechnical additives’.

(4) The use of a preparation of *Bacillus subtilis* (ATCC PTA-6737) was authorised for 10 years for chickens for fattening by Commission Regulation (EU) No 107/2010[(2)] and chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches by Commission Implementing Regulation (EU) No 885/2011[(3)].

(5) The European Food Safety Authority (‘the Authority’) in its opinion of 25 April 2012[(4)] confirmed its previous conclusions that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (ATCC PTA-6737) is presumed safe for all animal species, consumers of the products of any animals given the additive and the environment. Although three trials performed by the applicant showed at least one significantly improved parameter in comparison with control groups, the Authority was unable to establish a minimum effective dose as proposed by the applicant, because

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 306/2013. (See end of Document for details)*

of conflicting results at different dose levels tested. Two trials showed significant improvements with a dose of 1×10^7CFU/kg but not at 5×10^7CFU/kg feed. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the preparation of *Bacillus subtilis* (ATCC PTA-6737) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 April 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 306/2013. (See end of Document for details)*

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive**	**Composition, chemical formula, description, analytical method**	**Species, or category of animal**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1823	Kemin Europa N.V.	*Bacillus subtilis* (ATCC PTA-6737)	*Additive consisting of* Viable spores of *Bacillus subtilis* (ATCC PTA-6737) *Analytical method*[a]	(Weaned) piglets and (weaned) *Sus scrofa domesticus*	—	1×10^7	—	(1) In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. (2) For use in (weaned) piglets up to approximately 35 kg.	23 April 2023

Composition, chemical formula, description, analytical method

Preparation
Viable spores of *Bacillus subtilis* (ATCC PTA-6737) containing a minimum of 1×10^{10} CFU/g additive

Characterisation of the active substance
Viable spores of *Bacillus subtilis* (ATCC PTA-6737)

Analytical method[a]
Enumeration: spread plate method using tryptone soya agar

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx