Commission Implementing Regulation (EU) 2017/2276 of 8 December 2017 concerning the authorisation of a new use of the preparation of Bacillus subtilis (ATCC PTA-6737) as a feed additive for sows (holder of the authorisation Kemin Europa N.V.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2276

of 8 December 2017

concerning the authorisation of a new use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for sows (holder of the 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 the preparation *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) The application concerns the authorisation of a new use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for sows in order to have a benefit in piglets, to be classified in the additive category ‘zootechnical additives’.

(4) The preparation of *Bacillus subtilis* (ATCC PTA-6737), belonging to the additive category of ‘zootechnical additives’, was authorised for 10 years as a feed additive, for chickens for fattening by Commission Regulation (EU) No 107/2010[(2)], for 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)], for weaned piglets and weaned *Suidae* other than *Sus scrofa domesticus* by Commission Implementing Regulation (EU) No 306/2013[(4)], for turkeys for fattening and turkeys reared for breeding by Commission Implementing Regulation (EU) No 787/2013[(5)] and for laying hens and minor poultry species for laying by Commission Implementing Regulation (EU) 2015/1020[(6)].

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 16 May 2017[(7)] that, under the proposed conditions of use, the preparation of *Bacillus*

subtilis (ATCC PTA-6737) does not have an adverse effect on animal health, human health and the environment. It also concluded that the additive has the potential to improve the growth of piglets from birth to weaning when added to diets of sows from 3 weeks before parturition until weaning of piglets. 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 Plants, Animals, Food and Feed,

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, 8 December 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2276. (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 composition:* Preparation of *Bacillus subtilis* (ATCC PTA-6737) containing a minimum of 1×10^{10} CFU/g additive Solid form *Characterisation of the active substance:* Viable spores of *Bacillus subtilis* (ATCC PTA-6737) *Analytical method*[a] Enumeration: spread plate method using tryptone soya agar	Sows	—	1×10^{8}	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For the use in sows from three weeks before farrowing to whole lactation period. 3. For users of	29.12.2027

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports