

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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 107/2010 of 8 February 2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (holder of authorisation Kemin Europa NV) (OJ L 36, 9.2.2010, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) No 885/2011 of 5 September 2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (holder of authorisation Kemin Europa N.V.) (OJ L 229, 6.9.2011, p. 3).

⁽⁴⁾ 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.) (OJ L 91, 3.4.2013, p. 5).

⁽⁵⁾ Commission Implementing Regulation (EU) No 787/2013 of 16 August 2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Kemin Europa N.V.) (OJ L 220, 17.8.2013, p. 15).

⁽⁶⁾ Commission Implementing Regulation (EU) 2015/1020 of 29 June 2015 concerning the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kemin Europa NV) (OJ L 163, 30.6.2015, p. 22).

⁽⁷⁾ EFSA Journal 2017; 17(5):4855.

- (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

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.	<i>Bacillus subtilis</i> ATCC PTA-6737	<p><i>Additive composition:</i></p> <p>Preparation of <i>Bacillus subtilis</i> (ATCC PTA-6737) containing a minimum of 1×10^{10} CFU/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable spores of <i>Bacillus subtilis</i> (ATCC PTA-6737)</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: spread plate method using tryptone soya agar with pre heat-treatment of feed samples.</p> <p>Identification: pulsed-field gel electrophoresis (PFGE) method.</p>	Sows	—	1×10^8	—	<ol style="list-style-type: none"> 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 the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 	29.12.2027
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⁽¹⁾ 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>