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.) (Text with EEA relevance)

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.)

(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 turkeys for fattening and turkeys reared for breeding, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that preparation of *Bacillus subtilis* (ATCC PTA-6737) was authorised for 10 years 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)] and for weaned piglets and weaned Suidae other than *Sus scrofa domesticus* by Commission Implementing Regulation (EU) No 306/2013[(4)].

(5) The European Food Safety Authority (‘the Authority’) in its opinion of 13 March 2013[(5)] confirmed its previous conclusions that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (ATCC PTA-6737) is presumed safe for animal and human health and the environment. The Authority also concluded that the additive has the potential to improve the zootechnical performance in turkeys for fattening and that this conclusion can be extended to turkeys reared for breeding. The Authority does not

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 787/2013. (See end of Document for details)*

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, 16 August 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 787/2013. (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 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	*Turkeys for fattening and breeding*	—	1×10^{8}	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. The use is permitted in feed containing the authorised coccidiostats: diclazuril, robenidine hydrochloride, lasalocid A sodium, maduramicin ammonium, or monensin sodium, on conditions	6 September 2023

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