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.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 885/2011

of 5 September 2011

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(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 the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737). The 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 the preparation 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, to be classified in the additive category ‘zootechnical additives’.

(4) The use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) was authorised for 10 years for chickens for fattening by Commission Regulation (EU) No 107/2010[(2)].

(5) New data were submitted in support of the application for the authorisation of *Bacillus subtilis* (ATCC PTA-6737) for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches. The European Food Safety Authority (the Authority) concluded in its opinion of 15 March 2011[(3)] that, under the proposed conditions of use, *Bacillus subtilis* (ATCC PTA-6737) does not have an adverse effect on animal health, consumer health or the environment, and that the use of this preparation can improve the zootechnical performance of

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 885/2011. (See end of Document for details)*

the animal species. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment 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 this 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 enters into force on the 20th day following its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 5 September 2011.

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 885/2011. (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)	*Composition:* Preparation of *Bacillus subtilis* (ATCC PTA-6737) containing a minimum of 1×10^{10} CFU/g *Characterisation of the active substance:* Spores of *Bacillus subtilis* (ATCC PTA-6737) *Analytical method*[a]: Enumeration: spread plate method using tryptone soya agar with	Chickens for fattening, turkeys, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening, Ostriches	—	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. The use is allowed in feed containing one of the authorised coccidiostats: diclazuril, decoquinate, salinomycin sodium, narasin/ nicarbazin, lasalocid A sodium, maduramycin ammonium,	26 September 2021

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