Commission Regulation (EU) No 168/2011 of 23 February 2011 amending Regulation (EU) No 107/2010 as regards the use of the feed additive Bacillus subtilis ATCC PTA-6737 in feed containing maduramycin ammonium, monensin sodium, narasin, or robenidine hydrochloride (Text with EEA relevance)

COMMISSION REGULATION (EU) No 168/2011

of 23 February 2011

amending Regulation (EU) No 107/2010 as regards the use of the feed additive *Bacillus subtilis* ATCC PTA-6737 in feed containing maduramycin ammonium, monensin sodium, narasin, or robenidine hydrochloride

(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 13(3) 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) Regulation (EC) No 1831/2003 provides for the possibility to modify the authorisation of a feed additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority (the Authority).

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

(4) The holder of the authorisation applied for a modification of the authorisation of *Bacillus subtilis* ATCC PTA-6737 to allow its use in feed containing the coccidiostats maduramycin ammonium, monensin sodium, narasin, or robenidine hydrochloride for chickens for fattening. The holder of the authorisation submitted the relevant data to support this request.

(5) The Authority concluded in its opinion of 7 October 2010 that the additive *Bacillus subtilis* ATCC PTA-6737 is compatible with maduramycin ammonium, monensin sodium, narasin, or robenidine hydrochloride[(3)].

(6) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(7) Regulation (EU) No 107/2010 should therefore be amended accordingly.

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 168/2011. (See end of Document for details)*

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 107/2010 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following 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, 23 February 2011.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 168/2011. (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 NV	*Bacillus subtilis* ATCC PTA-6737	**Additive composition:** Preparation of *Bacillus subtilis* ATCC PTA-6737 containing a minimum of 1×10^{10} CFU/g additive **Characterisation of active substance:** Spores of *Bacillus subtilis* ATCC PTA-6737 **Analytical methods**[a]	—	—	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. May be used in feed containing the permitted coccidiostats: diclazuril, decoquinate, salinomycin sodium, narasin/ nicarbazin, lasalocid A sodium, maduramycin ammonium, monensin sodium,	1.3.2020

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives