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,

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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

ANNEX

additive of authorisation descriptiof, analytical method complete feedingstuff with a moisture content of 12 % of authorisation Category of zootechnical additives. Functional group: gut flora stabilisers dotted to the subtilis 1 × 10 ⁷ — 1. 1.3.2 4b1823 Kemin Subtilis Bacillus subtilis Kuidisise flore pra-6737 1 × 10 ⁷ — 1. 1.3.2 4b1823 Kemin Subtilis Category of zootechnical additives. Subtilis Category of zootechnical additives. Subtilis 1 × 10 ⁷ — 1. 1.3.2 4b1823 Kemin Subtilis Subtilis ATCC PTA-6737 1 × 10 ⁷ — 1. 1.3.2 6 PTA-6737 Of Bacillus Subtilis 1 × 10 ⁷ — 1. 1. 1. 7 Flore Bacillus Subtilis ATCC PTA-6737 1 × 10 ⁷ — 1. 1. 1. 8 ATCC PTA-6737 Got 1 × 10 ¹⁰ 1 × 1	End	10 ther	ınMaxim	uminim	Maxim		e Compo	Additiv	ca Nixom e	
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plate dicla method deco using salin tryptone sodi soya agar nicar	directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. May be used in feed containing the permitted coccidiostats: diclazuril, decoquinate, salinomycin sodium, narasin/ nicarbazin, lasalocid	2.		1 × 10 ⁷	tion: ion 7 ng n erisation ce: 7 cal * Enumera spread plate method using tryptone soya agar with	Additive formposi Pattepaing of Bacillus Subtilis ATCC PTA-673 containin a minimur of 1 × 10 ¹⁰ CFU/ g additive Charact of active substand Spores of Bacillus ATCC PTA-673 ATCC		Bacillus subtilis ATCC	Kemin Europa	

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

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heat-	sodium,
treatment	maduramycin
of	ammonium,
feed	monensin
samples	sodium,
Identification:	narasin
pulsed-	or
field	robenidine
gel	hydrochloride.
electrophoresis	
(PFGE)	
method	

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

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- (**1**) OJ L 268, 18.10.2003, p. 29.
- (**2**) OJ L 36, 9.2.2010, p. 1.
- (**3**) EFSA Journal 2010; 8(10):1863.