

II

(Non-legislative acts)

REGULATIONS

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)

(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 set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the micro-organism *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 15 September 2009⁽²⁾ that the *Bacillus subtilis* (ATCC PTA-6737) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can improve the performance of the animals. 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.

(5) The assessment of that preparation 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.

(6) 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ *The EFSA Journal* 2009; 7(9): 1314.

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, 8 February 2010.

For the Commission
The President
José Manuel BARROSO

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	<i>Bacillus subtilis</i> ATCC PTA-6737	<p>Additive composition:</p> <p>Preparation of <i>Bacillus subtilis</i> ATCC PTA-6737 containing a minimum of 1×10^{10} CFU/g additive</p> <p>Characterisation of the active substance:</p> <p>Spores of <i>Bacillus subtilis</i> ATCC PTA-6737</p> <p>Analytical method ⁽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>	Chickens for fattening	—	1×10^7	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. May be used in feed containing the permitted coccidiostats: diclazuril, decoquinate, salinomycin sodium, narasin/nicarbazin and lasalocid A sodium.</p>	1.3.2020

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/html/CRLs/crl_feed_additives/index.htm