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COMMISSION REGULATION (EC) No 1444/2006

of 29 September 2006

concerning the authorisation of *Bacillus subtilis* C-3102 (Calsporin) as a feed additive

(Text with EEA relevance)

(OJ L 271, 30.9.2006, p. 19)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 164/2008 of 22 February 2008	L 50	6	23.2.2008

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concerning the authorisation of *Bacillus subtilis* C-3102 (Calsporin) as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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. That application was accompanied by the particulars and documents required under Article 7 (3) of that Regulation.

(3) The application concerns authorisation of the preparation *Bacillus subtilis* C-3102 (Calsporin) a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The method of analysis included in the application for authorisation in accordance with Article 7(3)(c) of Regulation (EC) No 1831/2003 concerns the determination of the active substance of the feed additive in feed. The method of analysis referred to in the Annex to this Regulation is therefore not to be understood as a Community method of analysis within the meaning of Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([2]).

(5) The European Food Safety Authority (the Authority) concluded in its opinion of 8 March 2006 that *Bacillus subtilis* C-3102 (Calsporin) does not have an adverse effect on animal health, human health or the environment ([3]). It further concluded that *Bacillus subtilis* C-3102 (Calsporin) does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that preparation can improve the zootechnical parameters in chickens for fattening. It does not consider that there is a need for specific requirements of post market monitoring. The opinion of the Authority recommends appropriate

([1]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

([2]) OJ L 165, 30.4.2004, as corrected by OJ L 191, 28.5.2004, p. 1. Regulation as amended by Commission Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3).

([3]) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product Calsporin a preparation of *Bacillus subtilis* C-3102, as a feed additive for chickens for fattening in accordance with Regulation (EC) No 1831/2003. Adopted on 8 March 2006. *The EFSA Journal* (2006) 336, p. 1 to 15.

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measures for user safety. This opinion also verifies 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. The assessment of that preparation shows that the conditions for authorisation, 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.

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.

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ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	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									
4b1820	Calpis Co., Ltd Represented in the Community by Orffa International Holding BV	*Bacillus subtilis* C-3102 DSM 15544 (Calsporin)	Additive composition: Preparation of *Bacillus subtilis* C-3102 (DSM 15544) containing a minimum of 1×10^{10} CFU/g of additive Characterisation of the active substance: Viable spores of *Bacillus subtilis* C-3102 (DSM 15544) Analytical method (1) Enumeration spread plate method using tryptone soya agar with preheat treatment of feed samples	Chickens for fattening	—	5×10^8	1×10^9	1. For user safety: breathing protection during handling and safety glasses. 2. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 3. The use is permitted in feed containing the permitted coccidiostats: monensin sodium, salinomycin sodium, semduramycin sodium, lasalocid sodium, maduramycin ammonium, narasin-nicarbazin and diclazuril.	20 October 2016

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