

COMMISSION REGULATION (EC) No 164/2008

of 22 February 2008

amending Regulation (EC) No 1444/2006 as regards the minimum content of the feed additive *Bacillus subtilis* C-3102 (Calsporin)

(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 13(3) thereof,

Whereas:

(1) The additive *Bacillus subtilis* C-3102 (Calsporin) was authorised under certain conditions in accordance with Regulation (EC) No 1831/2003. Commission Regulation (EC) No 1444/2006⁽²⁾ authorised that additive for ten years for use for chickens for fattening, linking the authorisation to the holder of authorisation for putting that additive into circulation.

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

(3) The holder of the authorisation of the feed additive *Bacillus subtilis* C-3102 (Calsporin) has submitted an

application which proposes changing the terms of the authorisation by reducing the minimum content of that additive.

(4) In its opinion adopted on 18 September 2007, the Authority has proposed to reduce the minimum content of active substance from 1×10^9 CFU to 5×10^8 CFU because there is evidence of efficacy at the lowest dose proposed⁽³⁾.

(5) Regulation (EC) No 1444/2006 should therefore be amended accordingly.

(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 Annex to Regulation (EC) No 1444/2006 is replaced by 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, 22 February 2008.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽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 271, 30.9.2006, p. 19.

⁽³⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on Safety and efficacy of Calsporin, a preparation of *Bacillus subtilis*, as a feed additive for chickens for fattening in accordance with Regulation (EC) No 1831/2003. *The EFSA Journal* (2007) 543, 1-8.

ANNEX

ANNEX

Identification number of the additive	Name of the holder of the 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 feedstuff 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	<i>Bacillus subtilis</i> C-3102 DSM 15544 (Calsporin)	Additive composition: Preparation of <i>Bacillus subtilis</i> C-3102 (DSM 15544) containing a minimum of 1×10^{10} CFU/g of additive Characterisation of the active substance: Viable spores of <i>Bacillus subtilis</i> 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-micarbazin 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