

COMMISSION REGULATION (EC) No 203/2009

of 16 March 2009

amending Regulation (EC) No 1137/2007 as regards the use of the feed additive *Bacillus subtilis* (O35) in feed containing decoquinate and narasin/nicarbazin

(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) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedure for granting such authorisation.
- (2) Regulation (EC) No 1831/2003 provides for the possibility to modify 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 use of the micro-organism preparation of *Bacillus subtilis* DSM 17299 (O35) was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1137/2007⁽²⁾.
- (4) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application for a modification of the authorisation of that preparation was submitted to allow its use in feed containing the coccidiostats deco-

quate and narasin/nicarbazin for chickens for fattening. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

- (5) The Authority concluded in its opinion of 22 October 2008 that the compatibility of the additive *Bacillus subtilis* DSM 17299 (O35) with decoquinate and narasin/nicarbazin was established⁽³⁾.
- (6) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (7) Regulation (EC) No 1137/2007 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,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1137/2007 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following that of 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, 16 March 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ OJ L 256, 2.10.2007, p. 5.⁽³⁾ Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the compatibility of the microbial product O35 (*Bacillus subtilis*) with decoquinate and narasin/nicarbazin. *The EFSA Journal* (2008) 840, p. 1.

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 %	CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers.										
4b1821	Chr. Hansen A/S	<i>Bacillus subtilis</i> DSM 17299 (O35)	Additive composition: Preparation of <i>Bacillus subtilis</i> DSM 17299 Containing a minimum of $1,6 \times 10^9$ CFU/g of additive Characterisation of the active substance: <i>Bacillus subtilis</i> DSM 17299 spore concentrate Analytical method (1): Enumeration spread plate method using tryptone soya agar with preheat treatment of feed samples	Chickens for fattening	—	8×10^8	$1,6 \times 10^9$	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The use is permitted in feed containing the permitted coccidiostats: diclazuril, halofuginone, robenidine, decoquinat and narasin/nicarbazin.	22 October 2017	

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