

COMMISSION REGULATION (EC) No 1143/2007

of 1 October 2007

amending Regulation (EC) No 256/2002 as regards the authorisation of the feed additive preparation of *Bacillus cereus* var. *toyoi*, belonging to the group of microorganisms

(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) The preparation *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012), belonging to the group of 'microorganisms', was authorised in accordance with Council Directive 70/524/EEC⁽²⁾, in particular, by Commission Regulation (EC) No 256/2002⁽³⁾ without a time limit for use for piglets, until two months, and for sows, from one week prior to farrowing until weaning. This additive was subsequently entered in the Community Register of Feed Additives as an existing product, in accordance with Article 10 of Regulation (EC) No 1831/2003.

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application for an amendment of the authorisation of that preparation was submitted to allow its use in feed for sows from service to weaning. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 7 March 2007 that the preparation *Bacillus cereus* var. *toyoi* NCIMB 40112/CNCM I-1012 does not have an adverse effect on animal health, human health or the environment⁽⁴⁾. It further concluded that the preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. 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 provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(6) Regulation (EC) No 256/2002 should therefore be amended accordingly.

(7) 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

Annex III to Regulation (EC) No 256/2002 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*.

⁽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 270, 14.12.1970, p. 1. Directive repealed by Regulation (EC) No 1831/2003.

⁽³⁾ OJ L 41, 13.2.2002, p. 6.

⁽⁴⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product Toyocerin (*Bacillus cereus* var. *Toyoi*) as feed additive for sows in accordance with Regulation (EC) No 1831/2003. Adopted on 7 March 2007. The EFSA Journal (2007) 458, 1-9.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 October 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

ANNEX III

Microorganisms

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	CFU/kg of complete feedingstuff		Other provisions	End of period of authorisation
					Minimum content	Maximum content		
Microorganisms								
E 1701	<i>Bacillus cereus</i> var. <i>toyoi</i> NCIMB 40112/ CNCM I-1012	Preparation of <i>Bacillus cereus</i> var. <i>toyoi</i> containing a minimum of 1×10^{10} CFU/g additive	Piglets	Two months	1×10^9	1×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit
			Sows	From service to weaning	$0,5 \times 10^9$	2×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit