

COMMISSION REGULATION (EU) No 336/2011

of 7 April 2011

amending Regulation (EC) No 1292/2008 as regards the use of the feed additive *Bacillus amyloliquefaciens* CECT 5940 in feed containing diclazuril, monensin sodium and nicarbazin

(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 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 procedures for granting such authorisation.
- (2) Regulation (EC) No 1831/2003 provides for the possibility to modify the authorisation of a feed 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 amyloliquefaciens* CECT 5940 was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1292/2008 of 18 December 2008 concerning the authorisation of *Bacillus amyloliquefaciens* CECT 5940 (Ecobiol and Ecobiol Plus) as a feed additive⁽²⁾.
- (4) The holder of the authorisation submitted an application for a modification of the authorisation of this additive to allow its use in feed containing the coccidiostats

monensin sodium, diclazuril, nicarbazin, robenidine hydrochloride, salinomycin sodium, lasalocid sodium, narasin/nicarbazin, maduramycin ammonium, decoquinate or semduramicin sodium for chickens for fattening. The holder of the authorisation submitted the relevant data to support its request.

- (5) The Authority concluded in its opinion of 9 November 2010 that the additive *Bacillus amyloliquefaciens* CECT 5940 is compatible with diclazuril, monensin sodium and nicarbazin⁽³⁾.
- (6) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (7) Regulation (EC) No 1292/2008 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 1292/2008 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*.

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

Done at Brussels, 7 April 2011.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ OJ L 340, 19.12.2008, p. 36.⁽³⁾ EFSA Journal 2010; 8(12):1918.

ANNEX

The Annex to Regulation (EC) No 1292/2008 is replaced by the following:

‘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									
4b1822	Norel SA	<i>Bacillus amylo-liquefaciens</i> CECT 5940	<i>Additive composition</i> Preparation of <i>Bacillus amyloliquefaciens</i> CECT 5940 containing a minimum of 1 × 10 ⁹ CFU/g additive <i>Characterisation of active substance</i> Spores of <i>Bacillus amyloliquefaciens</i> CECT 5940 <i>Analytical methods</i> ⁽¹⁾ Enumeration: spread plate method using tryptone soya agar following a heat treatment. Identification: pulsed-field gel electrophoresis (PFGE) method.	Chickens for fattening	—	1 × 10 ⁹	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. May be used in feed containing the permitted coccidiostats: diclazuril, monensin sodium, or nicarbazin. 3. For safety reasons: breathing protection; glasses and gloves shall be used during handling	8.1.2019

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