

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

(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 the authorisation of a preparation of *Bacillus amyloliquefaciens* CECT 5940 (Ecobiol and Ecobiol plus), as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) From the Opinion of the European Food Safety Authority (the Authority) of 16 July 2008⁽²⁾ it results that, on the basis of the data provided by the manufacturer, *Bacillus amyloliquefaciens* CECT 5940 (Ecobiol and Ecobiol plus) does not have an adverse effect on animal health, human health or the environment and that it is efficacious in stabilising the gut flora. The Authority further concluded

that *Bacillus amyloliquefaciens* CECT 5940 (Ecobiol and Ecobiol plus) 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 the preparation does not have an adverse effect on chicken for fattening. 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 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.

Done at Brussels, 18 December 2008.

For the Commission
Androulla VASSILOU
Member of the Commission

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ 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 safety and efficacy of Ecobiol® (*Bacillus amyloliquefaciens*) as feed additives for chickens for fattening. The EFSA Journal (2008) 773, pp. 1-13.

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 feedstuff with a moisture content of 12 %	CFU/kg of complete feedstuff with a moisture content of 12 %			
Category of zootechnical additives: Functional group: gut flora stabilisers										
4b1822	NOREL SA	<i>Bacillus amylo-loliquefaciens</i> CECT 5940 (Ecobiol and Ecobiol plus)	<p>Additive composition:</p> <p>Ecobiol: Preparation of <i>Bacillus amylo-loliquefaciens</i> CECT 5940 containing a minimum concentration of 1×10^9 CFU/g</p> <p>Ecobiol plus: Preparation of <i>Bacillus amylo-loliquefaciens</i> CECT 5940 containing a minimum concentration of 1×10^{10} CFU/g</p> <p>Characterisation of the active substance:</p> <p>Spores of <i>Bacillus amylo-loliquefaciens</i> CECT 5940</p> <p>Analytical method (1): Enumeration: spread plate method using tryptone soya agar following a heat treatment.</p> <p>Identification: pulsed-field gel electrophoresis (PFGE).</p>	Chickens for fattening	—	1×10^9	1×10^9	1×10^9	<p>1. In the directions for use of the additive and premixtures, indicate the storage temperature, storage life, and stability to pelleting.</p> <p>2. For safety: it is recommended to use safety masks during mixing.</p> <p>3. The simultaneous use with coccidiostats is not permitted.</p>	8.1.2019

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