Commission Implementing Regulation (EU) 2020/1395 of 5 October 2020 concerning the renewal of the authorisation of Bacillus amyloliquefaciens CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of authorisation Evonik Nutrition & Care GmbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1395

of 5 October 2020

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(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 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 and renewing such authorisation.

(2) *Bacillus amyloliquefaciens* CECT 5940 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1292/2008[(2)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive for the renewal of the authorisation for chickens for fattening, and for a new authorisation for chickens reared for laying, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Articles 7(3) and 14(2) of that Regulation.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 January 2020[(3)] that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority confirmed its previous conclusions that *Bacillus amyloliquefaciens* CECT 5940 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that it is not an irritant to skin/eye or a skin sensitiser but should be considered a potential respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to

users of the additive. The Authority also concluded that the additive has the potential to be efficacious in chickens reared for laying.

(5) The assessment of *Bacillus amyloliquefaciens* CECT 5940 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1292/2008 should be repealed.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’ for chickens reared for laying, and for the same category and functional group for chickens for fattening is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 1292/2008 is repealed.

Article 3

This Regulation shall enter into force on the twentieth 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, 5 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1395. (See end of Document for details)*

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	Evonik Nutrition & Care GmbH	*Bacillus amyloliquefaciens* CECT 5940	***Additive composition*** Preparation of *Bacillus amyloliquefaciens* CECT 5940 containing a minimum of: — Solid forms	Chickens for fattening Chickens reared for laying		1×10^9		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.	26.10.2030
			Characterisation of active substance Spores of *Bacillus amyloliquefaciens* CECT 5940	1×10^9 CFU/g additive				2. May be used in feed containing the permitted coccidiostats: diclazuril, monensin sodium, or nicarbazin.	
			Analytical method[a] Enumeration: spread plate method using tryptone					3. For users of the additive and premixtures, feed business operators	

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports