Commission Implementing Regulation (EU) 2020/161 of 5 February 2020 concerning the renewal of the authorisation of Bacillus subtilis DSM 17299 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1137/2007 (holder of authorisation Chr. Hansen A/S) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/161

of 5 February 2020

concerning the renewal of the authorisation of *Bacillus subtilis* DSM 17299 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1137/2007 (holder of authorisation Chr. Hansen A/S)

(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 subtilis* DSM 17299 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1137/2007[(2)].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Bacillus subtilis* DSM 17299 as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 2 April 2019[(3)] that the applicant has provided data demonstrating that the additive complies with the existing conditions of authorisation. The Authority confirmed its previous conclusions that *Bacillus subtilis* DSM 17299 is considered safe for the target species, consumers of products from animals fed with the additive and the environment. It also concluded that there is a potential for users to be exposed via inhalation and that no conclusion could be drawn on the potential for skin and eyes irritancy and dermal sensitisation. Therefore the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive

(5) The assessment of *Bacillus subtilis* DSM 17299 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 subtilis* DSM 17299 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1137/2007 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’, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 1137/2007 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 February 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) 2020/161. (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									
4b1821	Chr. Hansen A/S	*Bacillus subtilis* DSM 17299	**Additive composition** Preparation of *Bacillus subtilis* DSM 17299, containing a minimum of 1,6 × 10^{10} CFU/g of additive Solid form	Chickens for fattening	—	8×10^{8}	—	1. 26 February 2030 2.	
			Characterisation of the active substance Viable spore of *Bacillus subtilis* DSM 17299						
			Analytical method[a] Enumeration spread plate method using						

Additional conditions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.

The use is permitted in feed containing one of the following authorised coccidiostats: diclazuril, halofuginone, robenidine, decoquinate,

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