Commission Implementing Regulation (EU) 2020/1755 of 24 November 2020 concerning the authorisation of a preparation of Bacillus coagulans DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds (holder of authorisation Biochem Zusatzstoffe Handels- und Produktionsges. mbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1755

of 24 November 2020

concerning the authorisation of a preparation of *Bacillus coagulans* DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds (holder of authorisation Biochem Zusatzstoffe Handels- und Produktionsges. mbH)

(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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Bacillus coagulans* DSM 32016. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of *Bacillus coagulans* DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds, to be classified in the category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 25 May 2020[(2)] that, under the proposed conditions of use, the preparation of *Bacillus coagulans* DSM 32016 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that is not a skin/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. 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. The Authority also concluded that the preparation has the potential to be efficacious as zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of

analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Bacillus coagulans* DSM 32016 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the product 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 Plants, Animals, Food and Feed,

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 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, 24 November 2020.

For the Commission

The President

Ursula VON DER LEYEN

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									
4b1900	Biochem Zusatzstoffe Handels- und Produktionsges. mbH	*Bacillus coagulans* DSM 32016	*Additive composition* Preparation of *Bacillus coagulans* DSM 32016 containing a minimum of 2×10^{10} CFU/g additive Solid form	Suckling and weaned Suidae piglets		1×10^{9}		1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.	15.12.2030
			Characterisation of the active substance Viable spores of cells of *Bacillus coagulans* DSM 32016	Poultry for fattening				2. May be used in feed containing the following permitted coccidiostats: halofuginone and diclazuril.	
			Analytical method[a] Enumeration in the feed additive, premixtures	Ornamental birds				3. For users of the	

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

			and feedingstuffs: Spread plate method on MRS agar (based on EN 15787 method). Identification: Pulsed Field Gel Electrophoresis (PFGE).						additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.

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

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) *EFSA Journal* 2020;18(6):6158.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1755.