COMMISSION IMPLEMENTING REGULATION (EU) No 544/2013

of 14 June 2013

concerning the authorisation of a preparation of *Bifidobacterium animalis* ssp. *animalis DSM 16284*, *Lactobacillus salivarius* ssp. *salivarius DSM 16351* and *Enterococcus faecium DSM 21913* as a feed additive for chickens for fattening (holder of authorisation Biomin GmbH)

(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 *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913. 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 a preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 November 2012 [2] that, under the proposed conditions of use, the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 does not have an adverse effect on animal health, human health or the environment, and that it has the potential to improve the performance of chickens 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this 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 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, 14 June 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal 2012*; 10(12):2965.

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 [1]/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1890	Biomin GmbH	*Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913	*Additive composition* Preparation in form of a mixture of: *Bifidobacterium animalis* ssp. *animalis* DSM 16284 containing a minimum of 3×10^9 CFU/g additive *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 containing a minimum of 1×10^9 CFU/g additive *Enterococcus faecium* DSM 21913 containing a minimum of 6×10^9 CFU/g additive Solid preparation (ratio 3:1:6) *Characterisation of active substance* Viable cells of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351, and *Enterococcus faecium* DSM 21913 *Analytical methods* [2] For the enumeration of: *Bifidobacterium animalis* ssp. *animalis* DSM 16284: spread plate method EN 15785 *Lactobacillus salivarius* ssp. *salivarius* DSM 16351: spread plate method EN 15787 *Enterococcus faecium* DSM 21913 spread plate method EN 15788 For the identification: Pulsed Field Gel Electrophoresis (PFGE)	Chickens for fattening	—	1×10^8	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. The additive may be used with feed containing the following coccidiostats: maduramicin ammonium, diclazuril or robenidine hydrochloride. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	5 July 2023

[1] As total content of the mixture.
[2] Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx