COMMISSION IMPLEMENTING REGULATION (EU) 2019/914

of 29 May 2019

concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying (holder of authorisation HuvePharma NV)

(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 licheniformis* DSM 28710. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying, to be classified in the additive category 'zootechnical additives'.

(4) The preparation of *Bacillus licheniformis* DSM 28710, belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for chickens for fattening and chickens reared for laying by Commission Implementing Regulation (EU) 2017/1904 ([2]).

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 November 2018 ([3]) that, under the proposed conditions of use, the preparation of Bacillus licheniformis DSM 28710 does not have an adverse effect on animal health or the environment. It also concluded that the additive is considered as a potential respiratory sensitiser and that no conclusion could be drawn on skin or eyes sensitisation or irritation by the additive. 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 additive has a potential to be efficacious in feed to gain ratio in turkeys for fattening at the recommended dose and that this conclusion can be extended to turkeys reared for breeding and to minor poultry species for fattening and those reared for laying. 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.

(6) The assessment of the preparation of *Bacillus licheniformis* DSM 28710 shows that the conditions for authorisation, as 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.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Implementing Regulation (EU) 2017/1904 of 18 October 2017 concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation Huvepharma NV) (OJ L 269, 19.10.2017, p. 27).
([3]) *EFSA Journal* 2019;17(1):5536.

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, 29 May 2019.

For the Commission

The President

Jean-Claude JUNCKER

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									
4b1828	HuvePharma NV	*Bacillus licheniformis* DSM 28710	*Additive composition* Preparation of *Bacillus licheniformis* DSM 28710 containing a minimum of $3{,}2 \times 10^9$ CFU/g of additive Solid form *Characterisation of the active substance* Viable spores of *Bacillus licheniformis* DSM 28710 *Analytical method* (1) For the enumeration of *Bacillus licheniformis* DSM 28710 in additive, premixture and feedingstuffs: — Spread plate method EN 15784 For the identification of *Bacillus licheniformis* DSM 28710: — Pulsed Field Gel Electrophoresis (PFGE)	Turkeys for fattening Turkeys reared for breeding Minor poultry species for fattening or reared for laying	—	$1{,}6 \times 10^9$	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The use is permitted in feed for turkeys containing one of the following authorised coccidiostats: diclazuril, halofuginone, robenidine, lasalocid, maduramicin, or monensin. 3. The use is permitted in feed for minor poultry species for fattening or reared for laying containing one of the following authorised coccidiostats: diclazuril or lasalocid. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalator or eyes exposure cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	25 June 2029

(1) 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