

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1410**of 27 August 2021****concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds (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 Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds, to be classified in the category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2021 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Bacillus licheniformis* DSM 28710 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that in the absence of data, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but that it is 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 of *Bacillus licheniformis* DSM 28710 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 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 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(3):6449.

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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: zootechnical additives. Functional group: gut flora stabilisers

4b1828	Huvepharma NV	<i>Bacillus licheniformis</i> DSM 28710	Additive composition Preparation of <i>Bacillus licheniformis</i> DSM 28710 containing a minimum of: $3,2 \times 10^9$ CFU/g of additive Solid form	Laying hens Minor poultry species for laying	-	$1,6 \times 10^9$	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the following permitted coccidiostats: diclazuril and lasalocid A sodium. 3. 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, inhalation 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, including skin, eyes and breathing protection.	19.9.2031
			Characterisation of the active substance: Viable spores of <i>Bacillus licheniformis</i> DSM 28710	Poultry species for breeding except turkeys					
			Analytical method ⁽¹⁾ For the enumeration of <i>Bacillus licheniformis</i> DSM 28710 in additive, premixture and feedingstuffs: — Spread plate method EN 15784 For the identification of <i>Bacillus licheniformis</i> DSM 28710: — Pulsed Field Gel Electrophoresis (PFGE)	Ornamental birds					

⁽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>