COMMISSION IMPLEMENTING REGULATION (EU) 2018/1565

of 17 October 2018

concerning the authorisation of a preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088) as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species other than laying birds, turkeys for fattening, turkeys reared for breeding, weaned piglets, pigs for fattening and minor porcine species (holder of authorisation Elanco 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 endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088) as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species other than laying birds; turkeys for fattening, turkeys reared for breeding, weaned piglets, pigs for fattening and minor porcine species to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 7 December 2016 ([2]) and 17 April 2018 ([3]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088) does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the additive is considered efficacious for chickens for fattening, turkeys for fattening and weaned piglets, pigs for fattening and minor porcine species. The Authority considered that these conclusions can be extended to chickens reared for laying and turkeys reared for breeding and that they can be extrapolated to minor poultry species for fattening or reared for breeding or 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.

(5) The assessment of the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088) 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.

(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 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in the Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2017;15(1):4677.
([3]) EFSA Journal 2018;16(5):5270.

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, 17 October 2018.

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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a29	Elanco GmbH	Endo-1,4-beta-mannanase EC 3.2.1.78	*Additive composition* Preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088) having a minimum activity of: — $1{,}6 \times 10^8$ U (1)/g solid form; — $5{,}9 \times 10^8$ U/g liquid form. *Characterisation of the active substance* endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 28088) *Analytical methods* (2) For the quantification of endo-1,4-beta-mannanase in the feed additive, premixtures and feedingstuffs: colorimetric methods based on enzymatic hydrolysis and the reaction of reducing sugars (mannose equivalent) with 3,5-dinitrosalicylic acid (DNS)	Chickens for fattening Chickens reared for laying Minor poultry species other than laying birds	—	32 000 U	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks to their 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 skin and breathing protections. 3. For use in weaned piglets until approximately 35 kg.	8 November 2028
				Turkeys for fattening Turkeys reared for breeding		48 000 U			
				Weaned piglets		48 000 U			
				Pigs for fattening Minor porcine species for fattening		32 000 U			

(1) 1 U is the amount of enzyme which liberates 0,72 micrograms of reducing sugars (mannose equivalents) from a mannan-containing substrate (locust bean gum) per minute at pH 7,0 and 40 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports