COMMISSION IMPLEMENTING REGULATION (EU) 2020/165

of 5 February 2020

concerning the authorisation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 32052 as a feed additive for chickens for fattening, for chickens reared for laying, turkeys for fattening or reared for breeding and for minor poultry species and repealing Regulation (EC) No 786/2007 (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 and renewing such authorisation.

(2) Endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 786/2007 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of that authorisation for the renewal of the authorisation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 32052 (formerly produced by *Paenibacillus lentus* ATCC 55045) as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category 'zootechnical additives' and for a new use for chickens reared for laying, turkeys for fattening or reared for breeding and minor poultry species. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 February 2019 ([3]) that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. It was also concluded that the additive is safe for the target species, consumers of products from animals fed with the additive and the environment. It also concluded that the product should be regarded as a potential 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 additive has a potential to be efficacious in improving digestibility of feed for chickens reared for laying, turkeys for fattening or reared for breeding and minor poultry species.

(5) The assessment of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 32052 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 786/2007 should be repealed.

(7) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045, which are in conformity with the provisions applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until they are exhausted.

(8) 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 Regulation (EC) No 786/2007 of 4 July 2007 concerning the authorisation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell) as a feed additive (OJ L 175, 5.7.2007, p. 8).

([3]) *EFSA Journal* 2019;17(3):5641.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 786/2007 is repealed.

Article 3

Endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045, premixtures and compound feed containing that substance, which are produced and labelled before 26 February 2020 in accordance with the rules applicable before 26 February 2020 may continue to be placed on the market and used until the existing stock are exhausted.

Article 4

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, 5 February 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 Unit of activity/kg of complete feedingstuff with a moisture content of 12 %		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a3i	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 32052) having a minimum activity of $7,2 \times 10^5$ U ([1])/ml Liquid form *Characterisation of the active substance* Endo-1,4-beta-mannanase produced by *Paenibacillus lentus* (DSM 32052) *Analytical method* ([2]) colorimetric method based on the reaction between reducing sugars (mannose equivalent) with 3,5-dinitrosalicylic acid (DNS)	Chickens for fattening Turkeys for fattening Chickens reared for laying Turkeys reared for breeding Minor poultry species for fattening or reared for laying/breeding	-	79 200 U	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to 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 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.	26.2.2030

([1]) One unit of activity (U) is the amount of the enzyme which liberates 0,72 micrograms of reducing sugars (mannose equivalents) from a mannan-containing substrate (locust bean gum) per minute at pH 7,5 and 40 °C.

([2]) 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