



2023/2645

29.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2645

of 28 November 2023

concerning the authorisation of a preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618 as a feed additive for all poultry species for fattening and reared for laying or breeding, weaned piglets, weaned piglets of minor porcine species, pigs for fattening and minor porcine species for fattening (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 an 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 33618 as a feed additive available in a solid formulation and a liquid formulation. 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 endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618 as a feed additive for all poultry species for fattening and reared for laying or breeding, weaned piglets, weaned piglets of minor porcine species, pigs for fattening and minor porcine species for fattening ('the target species'), requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 February 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618 is safe for the target species, for the consumers and for the environment. The Authority also concluded that the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618 is not irritant to the skin and eyes but is regarded as a dermal sensitiser and a potential respiratory sensitiser. The Authority further concluded that the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618 has a potential to be efficacious at 32 000 U/kg complete feed in chickens for fattening, chickens reared for laying, minor poultry species for fattening or reared for laying or breeding, pigs for fattening and minor porcine species for fattening, and at 48 000 U/kg complete feed in turkeys for fattening, turkeys reared for breeding, weaned piglets and weaned piglets of minor porcine species. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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 applicant informed the Commission by a letter of 10 July 2023 of their intention to propose a re-formulation of the liquid formulation of the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618, and requested that the authorisation process of the solid formulation of that additive be continued separately.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2023;21(2):7878.

- (6) In view of the above, the Commission considers that the solid formulation of the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 33618 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of the solid formulation of that preparation should be authorised for the target species. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) 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

Authorisation

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 that Annex.

Article 2

Entry into force

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, 28 November 2023.

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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a45	Elanco GmbH	Endo-1,4-beta-mannanase (EC 3.2.1.78)	<p><i>Additive composition:</i></p> <p>Preparation of endo-1,4-beta-mannanase produced by <i>Paenibacillus lentus</i> DSM 33618 having a minimum activity of $1,60 \times 10^5$ U (°)/g, and ≤ 1 % food-grade mineral oil</p> <p>Solid form.</p> <p><i>Characterisation of the active substance:</i></p> <p>Endo-1,4-beta-mannanase (EC 3.2.1.78) produced by <i>Paenibacillus lentus</i> DSM 33618</p>	<p>Chickens for fattening</p> <p>Chickens reared for laying</p> <p>Minor poultry species for fattening</p> <p>Minor poultry species reared for laying or breeding</p> <p>Pigs for fattening</p> <p>Minor porcine species for fattening</p>	—	32 000 U	—	<p>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.</p>	19 December 2033
			<p><i>Analytical method (°):</i></p> <p>For the quantification of endo-1,4-beta-mannanase activity in the feed additive, premixtures and compound feed: colorimetric methods based on enzymatic hydrolysis and the reaction of reducing sugars (mannose equivalent) with 3,5-dinitrosalicylic acid (DNS)</p>	<p>Turkeys for fattening</p> <p>Turkeys reared for breeding</p> <p>Weaned piglets</p> <p>Weaned piglets of minor porcine species</p>		48 000 U			

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- (¹) One unit of endo-1,4-beta-mannanase activity (U) is the amount of the enzyme which generates 0,72 micrograms of reducing sugars per minute from a mannose containing substrate at pH 7,0 and 40 °C.
- (²) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en
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