



2024/1743

24.6.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1743

of 21 June 2024

concerning the authorisation of a preparation of endo-1,4-beta-mannanase produced with *Thermothelomyces thermophilus* DSM 33149 as a feed additive for all poultry species for fattening and ornamental birds (holder of authorisation: BASF SE)

(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 with *Thermothelomyces thermophilus* DSM 33149. 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 with *Thermothelomyces thermophilus* DSM 33149 as a feed additive for chickens and turkeys for fattening, minor poultry species for fattening and ornamental birds, 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 1 February 2023 ⁽²⁾ that the preparation of endo-1,4-beta-mannanase produced with *Thermothelomyces thermophilus* DSM 33149 is safe for the environment and has the potential to be efficacious in chickens for fattening, turkeys for fattening, minor poultry species for fattening and ornamental birds at a use level of 800 TMU/kg. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 30 January 2024 ⁽³⁾ that the preparation of endo-1,4-beta-mannanase produced with *Thermothelomyces thermophilus* DSM 33149 is safe for the target species at the proposed use level, and for the consumer. The Authority also concluded that the preparation of endo-1,4-beta-mannanase produced with *Thermothelomyces thermophilus* DSM 33149 is not irritant to the eyes or skin. Owing to the proteinaceous nature of the active substance, the additive should be considered a respiratory sensitiser. The Authority was not able to conclude on the potential of the additive to be a skin sensitiser. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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) In view of the above, the Commission considers that the preparation of endo-1,4-beta-mannanase produced with *Thermothelomyces thermophilus* DSM 33149 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening and ornamental birds. 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2023;21(2):7873.

⁽³⁾ EFSA Journal 2024;22:e8632.

- (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

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, 21 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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: zootechnical additives. Functional group: digestibility enhancers.									
4a47	BASF SE	Endo-1,4-beta-mannanase (EC 3.2.1.78)	<i>Additive composition</i> Preparation of endo-1,4-beta-mannanase (EC 3.2.1.78) produced with <i>Thermothelomyces thermophilus</i> DSM 33149 having a minimum activity of: 8 000 TMU/g ⁽¹⁾. Solid form and Liquid form <i>Characterisation of the active substance</i> Endo-1,4-beta-mannanase (EC 3.2.1.78) produced with <i>Thermothelomyces thermophilus</i> DSM 33149 <i>Analytical method</i> ⁽²⁾ For the determination of the endo-1,4-beta-mannanase activity in the feed additive, premixtures and compound feed:	All poultry species for fattening Ornamental birds	-	800 TMU	-	1. In the directions for use of the additive and premixture, 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 the 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.	14 July 2034

			— Enzymatic hydrolysis of dyed carob galactomannan with endo-1,4-beta-mannanase followed by photometry.						
(¹) One Thermostable Mannanase Unit (TMU) is defined as the amount of enzyme that produces reducing carbohydrates having a reducing power corresponding to 1 µM mannose from locust bean gum (0,3 g/100 mL buffer solution) in 1 min at 50 °C and pH 3,5. (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.									