



2023/2850

21.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2850

of 20 December 2023

concerning the authorisation of a preparation of endo- 1,4-beta-mannanase produced by *Aspergillus niger* CBS 120604 as a feed additive for all poultry species for fattening (holder of authorisation: Kerry Ingredients and Flavours Ltd)

(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 *Aspergillus niger* CBS 120604 as a feed additive. 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 *Aspergillus niger* CBS 120604 as a feed additive for all poultry species for fattening, 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 11 May 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of endo- 1,4-beta-mannanase produced by *Aspergillus niger* CBS 120604 is safe for all poultry species for fattening, consumers and the environment. It also concluded that the preparation of endo- 1,4-beta-mannanase produced by *Aspergillus niger* CBS 120604 is considered an irritant to skin and eyes, and a dermal and respiratory sensitiser. The Authority further concluded that the preparation of endo- 1,4-beta-mannanase produced by *Aspergillus niger* CBS 120604 has the potential to be efficacious at the level of inclusion of 30 U endo- 1,4-beta-mannanase/kg complete feed for all poultry species for fattening. 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) In view of the above, the Commission considers that the preparation of endo- 1,4-beta-mannanase produced by *Aspergillus niger* CBS 120604 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. 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.
- (6) 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⁾ EFSA Journal 2023;21(6):8045.

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, 20 December 2023.

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	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

4a42	Kerry Ingredients and Flavours Ltd	Endo- 1,4-beta-mannanase (EC 3.2.1.78)	<i>Additive composition:</i> Preparation of endo- 1,4-beta-mannanase produced by <i>Aspergillus niger</i> CBS 120604 having a minimum activity of 265 U ⁽¹⁾/g solid form <i>Characterisation of the active substance:</i> Endo- 1,4-beta-mannanase (EC 3.2.1.78) produced by <i>Aspergillus niger</i> CBS 120604 <i>Analytical method ⁽²⁾:</i> Determination of the endo- 1,4-beta-mannanase activity in the feed additive, premixtures and compound feed: colorimetric method based on the enzymatic reaction of endo- 1,4-beta-mannanase on the azurine cross-linked-carob galactomannan substrate	All poultry species for fattening	—	30 U	—	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 potential risks resulting from its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	10 January 2034
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⁽¹⁾ One endo-1,4-beta-mannanase unit (U) is defined as the amount of enzyme required to release one micromole of mannose reducing sugar equivalents per minute at 40°C and pH 4,5.

⁽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