



2024/221

15.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/221

of 12 January 2024

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive for all poultry species for fattening, all poultry species for laying and weaned piglets (holder of authorisation: DSM Nutritional Products) and amending Implementing Regulation (EU) No 403/2013

(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 an authorisation.
- (2) A preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, was authorised for 10 years as a feed additive for poultry for fattening and for laying and for weaned piglets by Commission Implementing Regulation (EU) No 403/2013 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 May 2023 ⁽³⁾ that the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, remains safe for poultry for fattening and for laying and for weaned piglets, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, should be considered a potential respiratory sensitiser. In absence of data the Authority could not conclude on the potential of that preparation to cause skin and eye irritation or dermal sensitisation. It also indicated that there is no need for assessing the efficacy of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, in the context of the renewal of the authorisation. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 403/2013 of 2 May 2013 concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 (holder of authorisation DSM Nutritional Products) (OJ L 121, 3.5.2013, p. 26).

⁽³⁾ EFSA Journal 2023;21(6):8043.

- (5) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive, Implementing Regulation (EU) No 403/2013 should be amended.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (8) 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

Renewal of authorisation

The authorisation of the preparation 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

Amendment to Implementing Regulation (EU) No 403/2013

Implementing Regulation (EU) No 403/2013 is amended as follows:

- (1) Article 1 is deleted;
- (2) the Annex is deleted.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 4 August 2024 in accordance with the rules applicable before 4 February 2024 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 4 February 2025 in accordance with the rules applicable before 4 February 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 12 January 2024.

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

4a1602i	DSM Nutritional Products	Endo-1,4-beta-xylanase (EC 3.2.1.8) Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) Endo-1,4-beta-glucanase (EC 3.2.1.4)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by <i>Trichoderma reesei</i> ATCC 74444, having a minimum activity of: — Endo-1,4-beta-xylanase 2 700 U ⁽¹⁾/ml or g additive — Endo-1,3(4)-beta-glucanase 700 U ⁽²⁾/ml or g additive — Endo-1,4-beta-glucanase 800 U ⁽³⁾/ml or g additive Liquid or solid form. <i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8), endo-1,4-beta-glucanase (EC 3.2.1.6) and endo-1,3(4)-beta-glucanase (EC 3.2.1.4), produced by <i>Trichoderma reesei</i> ATCC 74444 <i>Analytical method ⁽⁴⁾</i> — For the determination of endo-1,4-beta-xylanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the wheat arabinoxylan substrate.	All poultry species for fattening other than turkeys for fattening	—	Endo-1,4-beta-xylanase: 135 U Endo-1,3(4)-beta-glucanase: 35 U Endo-1,4-beta-glucanase: 40 U	—	- In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. - 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, eye and skin protective equipment.	4 February 2034
				All poultry species for laying		Endo-1,4-beta-xylanase: 216 U Endo-1,3(4)-beta-glucanase: 56 U Endo-1,4-beta-glucanase: 64 U			
				Turkeys for fattening Piglets (weaned)		Endo-1,4-beta-xylanase: 270 U Endo-1,3(4)-beta-glucanase: 70 U Endo-1,4-beta-glucanase: 80 U			

			— For the determination of endo-1,3(4)-beta-glucanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the barley betaglucan substrate. — For the determination of endo-1,4-beta-glucanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxy-methyl-cellulose substrate. — For the determination of endo-1,4-beta-xylanase in pre-mixtures and compound feed: colorimetric method based on the enzymatic reaction on the azo-xylan (birchwood) substrate. — For the determination of endo-1,3(4)-beta-glucanase in premixtures and compound feed: colorimetric method based on the enzymatic reaction on the azo-barley-glucan substrate. — For the determination of endo-1,4-beta-glucanase in pre-mixtures and compound feed: colorimetric method based on the enzymatic reaction on the azo-carboxy-methyl-cellulose substrate.						
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(¹) One endo-1,4-beta-xylanase unit (U) is the amount of enzyme which releases 1 micromole of reducing sugar (xylose equivalent) per minute from wheat arabinoxylan at 40 °C and pH 5,0.
(²) One endo-1,3(4)-beta-glucanase unit (U) is the amount of enzyme which releases 1 micromole of reducing sugar (glucose equivalent) per minute from barley beta-glucan at 40 °C and pH 5,0.
(³) One endo-1,4-beta-glucanase unit (U) is the amount of enzyme which releases 1 micromole of reducing sugar (glucose equivalent) per minute from carboxy-methyl-cellulose at 40 °C and pH 5,0.
(⁴) 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.