

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1332

of 29 June 2023

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets (holder of the authorisation: Roal Oy), and repealing Regulation (EC) No 902/2009

(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) An enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 was authorised for 10 years as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding by Commission Regulation (EC) No 902/2009 ⁽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 produced by *Trichoderma reesei* CBS 114044 as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets in the additive category 'zootechnical additives' and functional group 'digestibility enhancers'. The preparation is available in solid and liquid formulations. The 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 opinions of 4 October 2019 ⁽³⁾ and 27 January 2021 ⁽⁴⁾ that the preparation remains safe for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets, consumers and the environment. It found that the preparation is non-irritant to skin, and that the tested liquid form is neither irritant to the eyes nor a dermal sensitiser. It further stated that the additive should be considered a potential respiratory sensitiser in all forms. The Authority does 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) The assessment of the preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be renewed as specified in the Annex to this Regulation. 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.
- (6) As a consequence of the renewal of the authorisation of the preparation as a feed additive, Regulation (EC) No 902/2009 should be repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Regulation (EC) No 902/2009 of 28 September 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy) (OJ L 256, 29.9.2009, p. 23).⁽³⁾ EFSA Journal 2019;17(11):5880.⁽⁴⁾ EFSA Journal 2021;19(3):6458.

- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation, it is appropriate to provide 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 the 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

Transitional measures

1. The preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 and premixtures containing it, which are produced and labelled before 20 January 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the preparation referred to in paragraph 1, which are produced and labelled before 20 July 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for food-producing animals.

Article 3

Repeal of Regulation (EC) No 902/2009

Regulation (EC) No 902/2009 repealed.

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, 29 June 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 feed with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers.

4a8i	Roal Oy	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> CBS 114044 having a minimum activity of:</p> <p>solid form: 160 000 BXU ⁽¹⁾/g</p> <p>liquid form: 160 000 BXU/g</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> CBS 114044</p> <p><i>Analytical method ⁽²⁾</i></p> <p>Characterisation of the active substance in the additive and the premixture: reducing sugar assay for endo-1,4- beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield at pH 5,3 and 50 °C;</p> <p>Characterisation of the active substance in the compound feed: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate.</p>	Chickens for fattening and chickens reared for laying	-	8 000 BXU	-	<p>1. In the directions for use of the additive and premixtures, 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 protective equipment, including breathing, skin and eye protection for solid forms, and breathing protection for liquid forms.</p>	20 July 2033
				Turkeys for fattening and turkeys reared for breeding		16 000 BXU			
				Piglets (weaned)		24 000 BXU			

⁽¹⁾ 1 BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50 °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>
