COMMISSION IMPLEMENTING REGULATION (EU) 2021/982

of 17 June 2021

concerning the renewal of the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as a feed additive for pigs and poultry (holder of the authorisation: Roal Oy), and repealing Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011

(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 authorisation.

(2) A preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 was authorised for 10 years as a feed additive for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows by Commission Regulation (EU) No 277/2010 ([2]), for turkeys by Commission Regulation (EU) No 891/2010 ([3]) and for sows by Commission Implementing Regulation (EU) No 886/2011 ([4]).

(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 6-phytase produced by *Trichoderma reesei* CBS 122001 as feed additive for poultry for fattening, breeding and laying, and pigs in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. 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 opinion of 18 November 2020 ([5]) that the applicant had provided data demonstrating that the additive complies with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 does not have an adverse effect on animal health, consumer health or the environment. It also stated that the additive should be considered a potential respiratory sensitiser. Therefore, 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. 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 of 6-phytase produced by *Trichoderma reesei* (CBS 122001) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011 should be repealed.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EU) No 277/2010 of 31 March 2010 concerning the authorisation of 6-phytase as a feed additive for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows (holder of authorisation Roal Oy), (OJ L 86, 1.4.2010, p. 13.).

([3]) Commission Regulation (EU) No 891/2010 of 8 October 2010 concerning the authorisation of a new use of 6-phytase as a feed additive for turkeys (holder of authorisation Roal Oy), (OJ L 266, 9.10.2010, p. 4.).

([4]) Commission Implementing Regulation (EU) No 886/2011 of 5 September 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for sows (holder of authorisation Roal Oy), (OJ L 229, 6.9.2011, p. 5.).

([5]) *EFSA Journal* 2020;18(12):6336.

(7) As regards the composition of this additive, minor changes have been applied to the manufacturing during the last years to improve the fermentation process. Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001, 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

The authorisation of the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 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 the Annex.

Article 2

1. The preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 and premixtures containing it, which are produced and labelled before 8 January 2022 in accordance with the rules applicable before 8 July 2021 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 point 1, which are produced and labelled before 8 July 2022 in accordance with the rules applicable before 8 July 2021 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

Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011 are repealed.

Article 4

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, 17 June 2021.

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: zootechnical additives. Functional group: digestibility enhancers.									
4a12	Roal Oy	6-Phytase (EC 3.1.3.26)	**Additive composition** Preparation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* CBS 122001 with a minimum content of Solid form: 40 000 PPU (1)/g Liquid form: 10 000 PPU/g **Characterisation of active substance** 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) **Analytical method** (2) Colorimetric method quantifying the activity of 6-phytase by measuring released inorganic phosphate from sodium phytate by analysing the colour formed by reduction of a phosphomolybdate complex.	Poultry for fattening and breeding Pigs	-	250 PPU	-	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 their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	8 July 2031
				Poultry for laying		125 PPU			

(1) 1 PPU is the amount of enzyme which liberates 1 µmol of inorganic phosphate from sodium phytate per minute at pH = 5,0 and 37 °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