COMMISSION IMPLEMENTING REGULATION (EU) 2021/330

of 24 February 2021

concerning the authorisation of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094 as a feed additive for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding (holder of authorisation: Fertinagro Biotech S.L.)

(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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, two applications were submitted for the authorisation of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The applications concern the extension of use of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094 as a feed additive for pigs for fattening, minor growing porcine species, turkeys for fattening and reared for breeding, to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 3 July 2019 ([2]), 7 January 2020 ([3]) and 28 January 2020 ([4]) that, under the proposed conditions of use, 3-phytase produced by *Komagataella phaffii* CECT 13094 does not have an adverse effect on the health of pigs for fattening, minor growing porcine species, turkeys for fattening and reared for breeding, consumers safety or the environment. It was also concluded that both formulations of the additive should be considered as a respiratory sensitiser and the solid formulation as a dermal 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 concluded that the additive is efficacious as a zootechnical additive in improving the digestibility of the diets in for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It 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 3-phytase shows that the conditions for authorisation of 3-phytase produced by *Komagataella phaffii* CECT 13094, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(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* 2019;17(8):5791.
([3]) *EFSA Journal* 2020;18(7):6205.
([4]) *EFSA Journal* 2020;18(6):6015.

HAS ADOPTED THIS REGULATION:

Article 1

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

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, 24 February 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 of zootechnical additives. Functional group: digestibility enhancers.									
4a25	Fertinagro Biotech S.L.	3-phytase (EC 3.1.3.8)	**Additive composition:** Preparation of 3-phytase (EC 3.1.3.8) produced by *Komagataella phaffii* (CECT 13094) having a minimum activity of: Solid form: 10 000 FTU ([1])/g Liquid form: 1 000 FTU/ml **Characterisation of the active substance:** 3-phytase (EC 3.1.3.8) produced by *Komagataella phaffii* (CECT 13094) **Analytical method** ([2]) For the quantification of 3-phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on phytate – VDLUFA 27.1.4 For the quantification of 3-phytase activity in premixtures: — colorimetric method based on the enzymatic reaction of phytase on phytate – VDLUFA 27.1.3	— Turkeys for fattening — Turkeys reared for breeding purposes — Pigs for fattening — Minor porcine species for fattening	-	500 FTU	-	1. In the directions for use of the additive and premixtures, 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 by inhalation and dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection and gloves.	17.3.2031

			For the quantification of 3-phytase activity in feed materials and compound feed: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024						

(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 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