

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1453

of 1 September 2022

concerning the authorisation of 6-phytase produced by *Komagataella pastoris* (DSM 23036) as a feed additive for all avian species and for all pigs and repealing Implementing Regulation (EU) No 98/2012 (holder of authorisation Huvepharma EOOD)

(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) 6-phytase produced by *Komagataella pastoris* (DSM 23036) was authorised for 10 years as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows by Commission Regulation (EU) No 98/2012 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of that authorisation for the renewal of the authorisation of 6-phytase produced by *Komagataella pastoris* (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows, to be classified in the additive category 'zootechnical additives', and for a new use of that additive for all avian species and all pigs. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 March 2022 ⁽³⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority further concluded that the additive is safe for animal health, consumer health and environment and that it is a respiratory sensitizer. 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 concluded that the additive has a potential to be efficacious for all avian species and all pigs.
- (5) The assessment of 6-phytase produced by *Komagataella pastoris* (DSM 23036) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) Due to the renewal of the authorisation of 6-phytase produced by *Komagataella pastoris* (DSM 23036) as a feed additive under the conditions laid down in the Annex to this Regulation, Implementing Regulation (EU) No 98/2012 should be repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 98/2012 of 7 February 2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows (holder of authorisation Huvepharma AD) (OJ L 35, 8.2.2012, p. 6).

⁽³⁾ EFSA Journal 2022;20(5):7238

- (7) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the 6-phytase produced by *Komagataella pastoris* (DSM 23036) may continue to be placed on the market and used until they are exhausted.
- (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 additive 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

Implementing Regulation (EU) No 98/2012 is repealed.

Article 3

The additive, 6-phytase, produced by *Komagataella pastoris* (DSM 23036), premixtures and compound feed containing that substance, which are produced and labelled before 22 September 2022 in accordance with the rules applicable before 22 September 2022 may continue to be placed on the market and used until the existing stock are exhausted.

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, 1 September 2022.

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.

4a16	Huvepharma EOOD	6-phytase (EC 3.1.3.26)	<i>Additive composition</i> Preparation 6-phytase (EC 3.1.3.26) produced by <i>Komagataella pastoris</i> (DSM 23036) with a minimum activity of: 4 000 OTU ⁽¹⁾ /g in solid form 8 000 OTU/g in liquid form	All avian species other than turkeys All porcine species other than piglets	-	125 OTU		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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	22.9.2032
			<i>Characterisation of the active substance</i> 6-phytase (EC 3.1.3.26) produced by <i>Komagataella pastoris</i> (DSM 23036) <i>Analytical method ⁽²⁾</i> Colorimetric method based on the quantification of the inorganic phosphate released by the enzyme from the sodium phytate.			250 OTU			

⁽¹⁾ 1 OTU is the amount of enzyme that catalyses the release of one micromole of inorganic phosphate per minute from 5,1 mM sodium phytate in pH 5,5 citrate buffer at 37 °C, measured as the blue phosphorus-molybdate complex colour at 820 nm.

⁽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