Commission Implementing Regulation (EU) 2016/348 of 10 March 2016 amending Implementing Regulation (EU) No 98/2012 as regards the minimum content of the preparation of 6-phytase (EC 3.1.3.26) produced by Komagataella pastoris (DSM 23036) as a feed additive for pigs for fattening (holder of authorisation Huvepharma EOOD) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/348

of 10 March 2016

amending Implementing Regulation (EU) No 98/2012 as regards the minimum content of the preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) as a feed additive for pigs for fattening (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 13(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 modifying such authorisation.

(2) The use of the preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036), formerly known as *Pichia pastoris*, was authorised until 28 February 2022 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 Implementing Regulation (EU) No 98/2012[(2)], following an application to that effect in accordance with Article 7 of Regulation (EC) No 1831/2003.

(3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of that preparation as a feed additive for pigs for fattening by reducing its minimum recommended content from 250 OTU/kg to 125 OTU/kg. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'The Authority').

(4) The Authority concluded in its opinion of 9 July 2015[(3)] that, under the new proposed conditions of use, the preparation 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) has the potential to be efficacious at the requested minimum recommended dose of 125 OTU/kg of complete feedingstuff as regards pigs for

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/348. (See end of Document for details)*

fattening. The Authority does not consider that there is a need for specific requirements for a post-market monitoring plan. 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.

(5) The assessment of the preparation of 6-phytase (EC 3.1.3.26) 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.

(6) Implementing Regulation (EU) No 98/2012 should therefore be amended accordingly.

(7) 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 Annex to Implementing Regulation (EU) No 98/2012 is replaced by the text set out in the Annex to this Regulation.

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, 10 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/348. (See end of Document for details)*

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 Units of activity/kg of complete feedingstuff with a moisture content of 12 %	Maximum content	Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a16	Huvepharma EOOD	6-phytase (EC 3.1.3.26)	*Additive composition* Preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) with a minimum activity of: *Characterisation of the active substance*	Chickens for fattening, chickens reared for laying, laying hens, other avian species other than turkeys for fattening and turkeys reared for breeding, in solid form	—	125 OTU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended maximum dose for all authorised species: 500 OTU/Kg of complete feedingstuff. 3. For use in feed containing more	28 February 2022
			4 000 OTU/g 8 000 OTU/g	Turkeys for fattening, turkeys reared for breeding, piglets (weaned) in liquid form		250 OUT			

a 1 OTU is the amount of enzyme that catalyzes the release of 1 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 P-molybdate complex color at 820 nm.

b Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx