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) (Text with EEA relevance)

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)

(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, an application was submitted for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036). The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns 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, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 11 October 2011[(2)] that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus digestibility in all target species and performance parameters in avian species. 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 6-phytase (EC 3.1.3.26) produced by *Pichia 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 use of this 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 the Food Chain and Animal Health,

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 20th day following 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 98/2012. (See end of Document for details)*

[F1ANNEX

Textual Amendments

F1 Substituted by 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).

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)	*Additive composition* Preparation 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) with a minimum activity of: 4 000 OTU/g in solid form 8 000 OTU/l in liquid form *Characterisation of active substance* 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) *Analytical method*[b] For the determination of 6-phytase in feed additives and premixtures: spectrophotometric method based on the release of inorganic phosphate from sodium phytate at pH 5,5 and 37 °C, measured as the blue P-molybdate complex color at 820 nm.	Chickens for fattening, chickens reared for laying, laying hens, other avian species other than turkeys for fattening and turkeys reared for breeding, pigs for fattening, sows.	—	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/	28 February 2022

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]