Commission Implementing Regulation (EU) 2020/2121 of 16 December 2020 concerning the authorisation of a preparation of 6-phytase produced by Komagataella phaffii DSM 32854 as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction (holder of authorisation: Huvepharma EOOD) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2121

of 16 December 2020

concerning the authorisation of a preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction (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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 three applications were submitted for the authorisation of a preparation of 6-phytase. 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 authorisation of the preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction 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 7 May 2020[(2)], 25 May 2020[(3)] and 1 July 2020[(4)] that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 does not have an adverse effect on the health of all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction, consumer safety or the environment. It was also concluded that the additive should be considered as an eye irritant and a potential dermal and 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 concluded that the additive is efficacious as a zootechnical additive in improving the digestibility of the diets in all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction. 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 preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 shows that the conditions for authorisation, 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,

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, 16 December 2020.

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.									
4a32	Huvepharma EOOD	6-phytase (EC 3.1.3.26)	**Additive composition** Preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella phaffii (DSM 32854)* with a minimum activity of 5 000 FTU[a]/g in granular form 5 000 FTU/g in coated form 5 000 FTU/g in liquid form **Characterisation of the**	—	all poultry species ornamental birds piglets pigs for fattening sows minor porcine species for fattening or reproduction	250 FTU		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	6.1.2031

a 1 FTU is the amount of enzyme that releases 1 micromole of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5,5 and 37 °C

b 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

			active substance 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii DSM 32854*					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 protective equipment, including breathing, eye and skin protections.
			Analytical method[b] For the quantification of phytase activity in the feed additive:					
			—	colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4				
			—	For the quantification of phytase activity in premixtures:				

a 1 FTU is the amount of enzyme that releases 1 micromole of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5,5 and 37 °C

b 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

			— colorimetric method based on the enzymatic reaction of phytase on the phytate - VDLUFA 27.1.3 — For the quantification of phytase activity in feed materials and compound feed: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024						

a 1 FTU is the amount of enzyme that releases 1 micromole of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5,5 and 37 °C

b 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

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) *EFSA Journal* 2020;18(5): 6141.

(**3**) *EFSA Journal* 2020;18(6): 6161.

(**4**) *EFSA Journal* 2020;18(7): 6204.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/2121.