Commission Implementing Regulation (EU) 2020/1376 of 1 October 2020 concerning the authorisation of a preparation of 6-phytase, produced by Komagataella phaffii (CGMCC 12056) as feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species (holder of the authorisation Andrés Pintaluba S.A) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1376

of 1 October 2020

concerning the authorisation of a preparation of 6-phytase, produced by *Komagataella phaffii* (CGMCC 12056) as feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species (holder of the authorisation Andrés Pintaluba S.A)

(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 6-phytase, produced by *Komagataella phaffii* (CGMCC 12056). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) Those applications concern the authorisation of the preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) as a feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 7 October 2019[(2)] that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive should be regarded as a 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 showed improvements on the phosphorus utilisation and content. This conclusion can be extended to turkeys 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 preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) 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, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1376. (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**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a31	Andrés Pintaluba S.A.	6-phytase EC 3.1.3.26	*Additive composition:* Preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella phaffii* (CGMCC 12056) having a minimum activity of: Solid form: 20 000 U[a]/g Liquid form: 20 000 U/ml *Characterisation of the active substance:* 6-phytase (EC 3.1.3.26)	Turkeys for fattening Turkeys reared for breeding		250 U		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	*22 October 2030*
				Piglets (suckling and weaned) Minor porcine species (suckling and weaned)		1000 U			

a One unit is the amount of enzyme which releases one micromole of inorganic phosphate from phytate per minute at 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