Commission Implementing Regulation (EU) 2020/1799 of 30 November 2020 concerning the authorisation of a preparation of 6-phytase produced by Komagataella phaffii CGMCC 12056 as a feed additive for laying hens and other laying birds (holder of authorisation: Andrés Pintaluba S.A.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1799

of 30 November 2020

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(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 a preparation of 6-phytase. That 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 a preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 as a feed additive for laying hens and other laying birds 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 opinion of 7 May 2020[(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 the health of laying hens and other laying birds, consumer safety or the environment. It was also concluded that the additive should be considered as a potential 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 laying hens and other laying birds. 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, 30 November 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) 2020/1799. (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)	laying hens and other laying birds		300 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	21.12.2030

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