Commission Implementing Regulation (EU) 2016/329 of 8 March 2016 concerning the authorisation of 6-phytase as a feed additive for all avian species and for weaned piglets, pigs for fattening, sows and minor porcine species (holder of the authorisation Kaesler Nutrition GmbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/329

of 8 March 2016

concerning the authorisation of 6-phytase as a feed additive for all avian species and for weaned piglets, pigs for fattening, sows and minor porcine species ([F1holder of the authorisation Kaesler Nutrition GmbH])

(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. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of 6-phytase as a feed additive for avian and porcine species to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 17 June 2015[(2)] that, under the proposed conditions of use, 6-phytase does not have an adverse effect on animal health, human health or the environment. It was also concluded that the additive has the potential to improve the phosphorus digestibility, phosphorus utilisation or the bone mineralisation of laying hens, chickens for fattening, all pig categories and turkeys for fattening. The Authority considered that these conclusions can be extended to chickens reared for laying and turkeys reared for breeding. Moreover, it determined that the conclusions can be extrapolated to all minor poultry species and other avian species up to point of lay and for laying. Similarly, the conclusions drawn in pigs can be extrapolated to minor porcine 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/329. (See end of Document for details)*

(5) The assessment of 6-phytase 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 additive 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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2017/2231 of 4 December 2017 amending Implementing Regulation (EU) 2016/329 as regards the name of the holder of the authorisation of 6-phytase (Text with EEA relevance).

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/329. (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									
4a23	[F1Kaesler Nutrition GmbH]	6-phytase EC 3.1.3.26	*Additive composition* Preparation of 6-phytase produced by *Komagataella pastoris* (DSM 25375) having a minimum activity of: 40 000 U[a]/g Liquid and solid form *Characterisation of the active substance* 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris*	Chickens for fattening and reared for laying, all avian species for fattening and reared for laying other than turkeys for fattening and reared for breeding	—	250 U	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to heating treatment. 2. For safety: breathing protection, safety glasses and gloves shall be used during handling.	29 March 2026
				All avian species for laying		125 U			
				Turkeys for fattening and		500 U			

a 1 U is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °C.

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