COMMISSION IMPLEMENTING REGULATION (EU) 2020/992

of 9 July 2020

concerning the authorisation of a preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) as feed additive for all avian species for laying (holder of the authorisation BASF SE)

(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, produced by *Aspergillus niger* (DSM 25770). 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 a preparation of 6-phytase produced by *Aspergillus niger* (DSM 25770) as a feed additive for laying hens and minor poultry and other avian species for laying to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 July 2019 ([2]) that, under the proposed conditions of use, the preparation of 6-phytase produced by *Aspergillus niger* (DSM 25770) 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 dermal sensitiser and 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 has the potential to be efficacious showing improvements of the zootechnical performance and/or phosphorus utilisation in laying hens. This conclusion can be extrapolated to all minor poultry species and other avian species for laying. 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 *Aspergillus niger* (DSM 25770) 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*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal 2019*;17(7):5789.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 July 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.									
4a27	BASF SE	6-Phytase (EC 3.1.3.26)	**Additive composition** Preparation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus niger* (DSM 25770) with a minimum content of: Solid form: 5 000 FTU (1)/g Liquid form: 5 000 FTU/g **Characterisation of active substance** 6-phytase produced by *Aspergillus niger* (DSM 25770) **Analytical method** (2) For quantification of phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate. For the quantification of phytase activity in premixtures: — colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.3. For the quantification of phytase activity in feedingstuffs: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024.	All avian species for laying	-	200 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 operational procedures and organisational measures to address potential risks resulting from their 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 personal protective equipment, including skin and breathing protection.	30.7.2030

(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37 °C.
(2) 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