Commission Implementing Regulation (EU) 2018/338 of 7 March 2018 concerning the authorisation of a preparation of 6-phytase, produced by Aspergillus niger (DSM 25770) as feed additive for chickens for fattening, chickens reared for laying, pigs for fattening, sows, minor porcine species for fattening or for reproduction, turkeys for fattening, turkeys reared for breeding, all other avian species (excluding laying birds) and weaned piglets (holder of the authorisation BASF SE) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/338

of 7 March 2018

concerning the authorisation of a preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) as feed additive for chickens for fattening, chickens reared for laying, pigs for fattening, sows, minor porcine species for fattening or for reproduction, turkeys for fattening, turkeys reared for breeding, all other avian species (excluding laying birds) and weaned piglets (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 the preparation of 6-phytase produced by *Aspergillus niger* (DSM 25770) as a feed additive for chickens for fattening, chickens reared for laying, pigs for fattening, sows, minor porcine species for fattening or for reproduction, turkeys for fattening, turkeys reared for breeding, all avian species for fattening or growing or reared for laying and weaned piglets to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 September 2017[(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, human health or the environment, and that it improves the zootechnical performance and/or phosphorus utilisation in the target species. The Authority does not

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/338. (See end of Document for details)*

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*.

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) 2018/338. (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									
4a27	BASF SE	6-phytase EC 3.1.3.26	*Additive composition* Preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) with a minimum content of: Solid form: 5 000 FTU[a]/g Liquid form: 5 000 FTU/g *Characterisation of the active substance* 6-phytase produced by *Aspergillus niger* (DSM 25770)	Pigs for fattening Sows Minor porcine species for fattening or for reproduction	—	100 FTU		1. 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 to	28.3.2028 In
				Weaned piglets		125 FTU			
				Chickens for fattening Chickens reared for laying		[F1 125 FTU]			
				Turkeys for fattening Turkeys reared for breeding All other avian species (excluding laying birds)		125 FTU			

a 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

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