Commission Implementing Regulation (EU) 2018/1568 of 18 October 2018 concerning the authorisation of a preparation of fumonisin esterase produced by Komagataella phaffii (DSM 32159) as a feed additive for all pigs and all poultry species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1568

of 18 October 2018

concerning the authorisation of a preparation of fumonisin esterase produced by *Komagataella phaffii* (DSM 32159) as a feed additive for all pigs and all poultry species

(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 fumonisin esterase produced by *Komagataella phaffii* (DSM 32159). 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 fumonisin esterase produced by *Komagataella phaffii* (DSM 32159) as a feed additive for pigs and poultry, to be classified in the additive category ‘technological additives’.

(4) The European Food Safety Authority (‘the Authority’) in its opinion of 17 April 2018[(2)] concluded that, under the proposed conditions of use, the preparation of fumonisin esterase produced by *Komagataella phaffii* (DSM 32159) does not have adverse effect on animal health, human health or the environment. It also concluded that it has the capability to degrade fumonisins in feed. 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 fumonisin esterase produced by *Komagataella phaffii* (DSM 32159) 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 ‘technological additives’ and to the functional group ‘substances for the reduction of the contamination of feed by mycotoxins’, is authorised as an additive in animal nutrition subject to the conditions laid down in the 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, 18 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1568. (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**
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Technological additives: substances for reduction of the contamination of feed by mycotoxins: fumonisins									
1m03i	—	Fumonisin esterase EC 3.1.1.87	*Additive composition* Preparation of fumonisin esterase produced by *Komagataella phaffii* (DSM 32159) containing a minimum of 3 000 U/g[a]. *Characterisation of the active substance* Preparation of fumonisin esterase produced by *Komagataella phaffii* (DSM 32159)	All pigs All poultry species	—	10		1. In the directions for use of the additive and premixtures, the storage conditions and stability to pelleting shall be indicated. 2. Recommended maximum dose: 300 U/kg of complete feedingstuff. 3. The use of the additive is allowed	8 November 2028

a 1 U is the enzymatic activity that releases 1 µmol tricarballylic acid per minute from 100 µM fumonisin B1 in 20 mM Tris-Cl buffer pH 8,0 with 0,1 mg/ml bovine serum albumin at 30 °C.

b Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

c Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).