COMMISSION IMPLEMENTING REGULATION (EU) 2021/363

of 26 February 2021

concerning the authorisation of a preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 as a feed additive for all animal 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 all animal species, to be classified in the additive category 'technological additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 July 2020 ([2]) that, under the proposed conditions of use, the preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is not toxic by inhalation and the respiratory exposure is likely to be low but a risk of sensitisation via the respiratory route could not be excluded. The additive is non-irritant to skin and eyes and is not considered a as a dermal 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 also concluded that the preparation concerned has the capability to degrade fumonisins in fermenting feed (with a fumonisin content within the limits operating in the Union) but only in silages, not in other fermenting feeds. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods 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.

(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 reduction of the contamination of feed by mycotoxins', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2020;18(7):6207

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, 26 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 fresh material			
Category of technological additives. Functional group: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 (1) *Characterisation of the active substance* Preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159. *Analytical method* (2) — For the determination of fumonisin esterase activity: High Performance Liquid Chromatography coupled with a tandem mass spectrometry. (HPLC-MS/MS) method based on the quantification of the tricarballylic acid released from the action of the enzyme on fumonisin B1 at pH 8,0 and 30 °C.	All animal species	-	40	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The use of the additive is only allowed in maize based silages. 3. Recommended maximum dose: 300 U/kg of fresh material. 4. The use of the additive is allowed in feedingstuffs complying with European Union legislation on undesirable substances in animal feed (3) 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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 breathing protection.	21.3.2031

(1) 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.
(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
(3) 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).