



2024/2184

4.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2184

of 3 September 2024

concerning the authorisation of a preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 as a feed additive for piglets and pigs for fattening of all Suidae 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 an 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 with *Komagataella phaffii* NCAIM (P) Y001485. 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 with *Komagataella phaffii* NCAIM (P) Y001485 as a feed additive for all pigs, requesting that additive to be classified in the category 'technological additives' and in the functional group 'substances for reduction of the contamination of feed by mycotoxins'.
- (4) The use of this additive, as indicated in Commission Regulation (EC) No 386/2009 ⁽²⁾ establishing the functional group 'substances for reduction of the contamination of feed by mycotoxins', should improve the quality of the feed for animal nutrition which is lawfully on the market, providing additional guarantees for the protection of animal and public health.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 January 2024 ⁽³⁾ that the preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 is safe up to 60 U/kg complete feed for weaned and suckling piglets, pigs for fattening and all minor growing porcine species and that its use in animal nutrition under the proposed conditions of use is safe for the consumers and environment. In the absence of adequate data, the Authority could not conclude on the safety of the additive at the maximum proposed use level (360 U/kg) nor on the safety for sows and minor reproductive porcine species. It also concluded that the preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 is considered to be a respiratory sensitiser, although the exposure through inhalation is unlikely, it is neither a skin nor an eye irritant, while no conclusions could be made on its skin sensitisation potential. The Authority further concluded that the substance is efficacious in reducing the fumonisins contamination in feed when added at the minimum use level of 60 U/kg feed for all Suidae. The Authority 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.
- (6) Subsequently, the applicant withdrew the application for sows and minor reproductive porcine species.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Commission Regulation (EC) No 386/2009 of 12 May 2009 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives (OJ L 118, 13.5.2009, p. 66, ELI: <http://data.europa.eu/eli/reg/2009/386/oj>).

⁽³⁾ EFSA Journal 2024, 22(3), e8614.

- (7) In view of the above, the Commission considers that the preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised for piglets and pigs for fattening of all Suidae species. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (8) 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

Authorisation

The substance 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.

Article 2

Entry into force

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, 3 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identifica- tion number of the feed 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 complete feedingstuff with 12 % moisture content			
Category: technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: fumonisins								
1m04	Fumonisin ester- ase EC 3.1.1.87	<i>Additive composition</i> Preparation of fumonisin esterase produced with <i>Komagataella phaffii</i> NCAIM (P) Y001485 containing a minimum of 1 200 U ⁽¹⁾ /g. <i>Solid form</i> <i>Characterisation of the active substance</i> Fumonisin esterase (EC 3.1.1.87) produced with <i>Komagataella phaffii</i> NCAIM (P) Y001485 <i>Analytical method ⁽²⁾</i> For the determination of fumonisin B1 esterase activity in the feed additive, premixtures and com- pound feed:	Piglets of all Suidae species Pigs for fattening of all Suidae species	—	60	60	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall only be used in feed which is already compliant with the rules established for mycotoxins in Union law on undesirable substances in animal feed. 3. 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 by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	24 September 2034

Identification number of the feed 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 complete feedingstuff with 12 % moisture content			
Category: technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: fumonisins								
		High Performance Liquid Chromatography coupled to fluorescence detection (HPLC-FLD) based on the quantification of hydrolysed fumonisin B1 released from the action of the enzyme on fumonisin B1 at pH 6,0 and 37 °C.						
(¹) One unit (U) is the amount of enzyme that releases one µmol of HFB1 per minute from 100 µM of FB1 in 50 mM phosphate buffer pH 6,0 at 37 °C. (²) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.								