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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 as a feed additive for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species, turkeys for fattening, the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 as a feed additive for suckling piglets (holder of authorisation: AVEVE BV) and repealing Implementing Regulations (EU) No 1088/2011, (EU) No 989/2012 and (EU) No 1040/2013

(Text with EEA relevance)

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(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 and renewing such an authorisation.

(2) A preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 was authorised for a period of 10 years as a feed additive for weaned piglets by Commission Implementing Regulation (EU) No 1088/2011[2], for laying hens and minor poultry species for laying and fattening by Commission Implementing Regulation (EU) No 989/2012[3], for pigs for fattening, minor porcine species for fattening other than *Sus scrofa domesticus* and turkeys for fattening by Commission Implementing Regulation (EU) No 1040/2013[4].

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

2 Commission Implementing Regulation (EU) No 1088/2011 of 27 October 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) as a feed additive for weaned piglets (holder of authorisation Aveve NV) (OJ L 281, 28.10.2011, p. 14, ELI: http://data.europa.eu/eli/reg_impl/2011/1088/oj).

3 Commission Implementing Regulation (EU) No 989/2012 of 25 October 2012 concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) as a feed additive for laying hens and minor poultry species for fattening and laying (holder of authorisation Aveve NV) (OJ L 297, 26.10.2012, p. 11, ELI: http://data.europa.eu/eli/reg_impl/2012/989/oj).

4 Commission Implementing Regulation (EU) No 1040/2013 of 24 October 2013 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 as a feed additive for weaned piglets, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application also concerned the authorisation of a new use of the same preparation as a feed additive for suckling piglets, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.

(4) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, another application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced with Trichoderma reesei MUCL 49755 and endo-1,3(4)-beta-glucanase produced with Trichoderma reesei MUCL 49754 as a feed additive for laying hens and minor poultry species for laying and fattening, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(5) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, another application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 as a feed additive for pigs for fattening, minor porcine species for fattening other than *Sus scrofa domesticus* and turkeys for fattening, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(6) The European Food Safety Authority ('the Authority') concluded in its opinions of 5 June 2024[5] and 3 July 2024[6] that, under the current authorised conditions of use and considering the fact that the composition and manufacturing of the additive have not been substantially modified, both formulations (powder and liquid) of the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 remain safe for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening, minor porcine species for fattening and turkeys for fattening, the consumers and the environment. It also concluded that the extension of use to suckling piglets would not affect these conclusions. The Authority further concluded that the preparation in its powder formulation, containing calcium carbonate and sepiolite, and the liquid form of the preparation are not irritant to skin and eyes. Due to the lack of data, no conclusions on the irritation potential of the powder formulation of the

49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) as a feed additive for pigs for fattening and minor porcine species for fattening other than *Sus scrofa domesticus* and turkeys for fattening (holder of authorisation Aveve NV) (OJ L 283, 25.10.2013, p. 46, ELI: http://data.europa.eu/eli/reg_impl/2013/1040/oj).

5 *EFSA Journal*. 2024;22:e8852. *EFSA Journal*. 2024;22:e8853.

6 *EFSA Journal.* 2024;22:e8951.

preparation formulated with calcium carbonate and wheat flour could be drawn. The additive, in all its formulations, is considered a respiratory and skin sensitiser. The Authority considered that there is no need to assess the efficacy of the additive in the context of the renewal of the authorisation as the application does not include a proposal for amending or supplementing the conditions of use that would have an impact on the efficacy of the additive for those species/categories for which there is an authorisation. It considered that the conclusions reached for those species can be extended to other species and therefore concluded that the additive has the potential to be efficacious in suckling piglets at 4000 XU and 900 BGU/kg complete feed. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

(7) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 as a feed additive in the context of the previous authorisations are valid and applicable for the current applications. In accordance with Article 5(4), points (a) and (c), of Commission Regulation (EC) No 378/2005[7], an evaluation report of the Reference Laboratory is therefore not required.

(8) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species (which corresponds to both pigs for fattening and minor porcine species for fattening) and turkeys for fattening. Furthermore, the use of that preparation should be authorised for suckling piglets. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(9) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 as a feed additive for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species and turkeys for fattening, Implementing Regulations (EU) No 1088/2011, (EU) No 989/2012 and (EU) No 1040/2013 should be repealed.

(10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species and turkeys for fattening, it is appropriate to provide for a transitional period for interested parties to

[7] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8). ELI: http://data.europa.eu/eli/reg/2005/378/oj.

prepare themselves to meet the new requirements resulting from the renewal of the authorisations concerned.

(11) 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
Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species and turkeys for fattening, subject to the conditions laid down in that Annex.

Article 2
Authorisation

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 for suckling piglets, subject to the conditions laid down in that Annex.

Article 3
Repeal

Implementing Regulations (EU) No 1088/2011, (EU) No 989/2012 and (EU) No 1040/2013 are repealed.

Article 4
Transitional measures

1. The feed additive endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754, as authorised by Implementing Regulations (EU) No 1088/2011, (EU) No 989/2012 and (EU) No 1040/2013, and premixtures containing that additive, which are intended for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species and turkeys for fattening and which are produced and labelled before [*6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for weaned piglets, laying hens and minor poultry species for laying and fattening, pigs for fattening of all Suidae species and turkeys for fattening, and which are produced and labelled before [*12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the*

publication] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 5
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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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: zootechnical additives. Functional group: digestibility enhancers.									
4a9	AVEVE BV	Endo-1,4-beta-xylanase (EC 3.2.1.8) Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	***Additive composition*** Preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 having a minimum activity of: 40 000 XU ([1]) and 9 000 BGU ([2])/g. Solid and liquid forms. ***Characterisation of the active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced with *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase (EC	Piglets (weaned and suckling) Pigs for fattening of all Suidae species Turkeys for fattening Laying hens and minor poultry species for laying	-	4 000 XU 900 BGU	-	1. In 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 address the potential risks resulting from their use. Where those risks cannot be eliminated by such	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

([1]) 1 XU is the amount of enzyme which releases 1 μmol of reducing sugar per minute from xylan of oat spelt at pH 4,8 and 50°C.
([2]) 1 BGU is the amount of enzyme which releases 1 μmol of reducing sugar per minute from β-glucan of barley at pH 5,0 and 50°C.

			3.2.1.6) produced with *Trichoderma reesei* MUCL 49754 ***Analytical method (3)*** For the determination of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase in the feed additive: — Colorimetric methods based on the formation of reducing sugars reacted with dinitrosalicilic acid (DNS). For the determination of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase in compound feed: — Colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from dye cross-linked wheat arabinoxylan substrate; — Colorimetric method measuring water soluble dye released by action of endo-1,3(4)-beta-glucanase from dye cross-linked barley betaglucan substrate.	Minor poultry species for fattening		3 000 XU 675 BGU		procedures and measures, the additive and premixtures shall be used with personal eye (only for the powder formulation of the preparation formulated with calcium carbonate and wheat flour), breathing and skin protective equipment.	

(3) 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