



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/6950632/2024 CIS
(POOL/G5/2024/6950632/6950632-EN
CIS.docx)
[...](2024) **XXX** draft

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, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 as a feed additive for weaned piglets and the authorisation of that preparation as a feed additive for suckling piglets (holder of authorisation: AVEVE BV) and repealing Implementing Regulation (EU) No 527/2011

(Text with EEA relevance)

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, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 as a feed additive for weaned piglets and the authorisation of that preparation as a feed additive for suckling piglets (holder of authorisation: AVEVE BV) and repealing Implementing Regulation (EU) No 527/2011

(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 nutrition¹, 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, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* (originally identified as *Aspergillus aculeatus*) CBS 589.94 was authorised for a period of 10 years as a feed additive for weaned piglets by Commission Implementing Regulation (EU) No 527/2011².
- (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, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 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 new uses of the same preparation as a feed additive for suckling

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 527/2011 of 30 May 2011 concerning the authorisation of a preparation of endo-1,4-β-xylanase produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)-β-glucanase produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) as feed additive for weaned piglets (holder of the authorisation Aveve NV) (OJ L 143, 31.5.2011, p. 6), ELI: http://data.europa.eu/eli/reg_impl/2011/527/oj.

piglets. 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) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 June 2024³ that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 remains safe for weaned piglets, consumers and the environment under the authorised conditions of use, and that this conclusion also applies to the extension of its use to suckling piglets. The Authority further concluded that the preparation in both formulations (powder and liquid) is not irritant to the skin or eyes but due to its proteinaceous nature should be considered a dermal and respiratory 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 for weaned piglets for which there is an authorisation. It also considered that the conclusions reached for weaned piglets can be extended and extrapolated to other species and therefore concluded that the additive has the potential to be efficacious in suckling piglets. The Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (5) 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, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), points (a) and (c), of Commission Regulation (EC) No 378/2005⁴, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 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, and 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.
- (7) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* MUCL 49755, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 as a feed additive for weaned piglets, Implementing Regulation (EU) No 527/2011 should be repealed.

³ EFSA Journal. 2024,22(7),e8854.

⁴ 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>.

- (8) 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, endo-1,3(4)-beta-glucanase produced with *Trichoderma reesei* MUCL 49754 and polygalacturonase produced with *Aspergillus fijiensis* CBS 589.94 for weaned piglets, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) 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, 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 Regulation (EU) No 527/2011 is repealed.

Article 4

Transitional measures

1. The feed additive endo-1,4- β -xylanase produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)- β -glucanase produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94), as authorised by Regulation (EU) No 527/2011, and premixtures containing that additive, which are intended for weaned piglets 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 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