

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/329****of 24 February 2021****concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase for chickens for fattening (holder of the authorisation: AVEVE NV), and repealing Regulation (EC) No 1091/2009****(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 <sup>(1)</sup>, 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 authorisation.
- (2) A preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1091/2009 <sup>(2)</sup>.
- (3) In accordance with Article 14 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 by *Trichoderma reesei* MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* MUCL 49754 as feed additive for chickens for fattening in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The microorganism *Trichoderma reesei* has meanwhile been renamed to *Trichoderma longibrachiatum*. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2020 <sup>(3)</sup> that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* MUCL 49754 does not have an adverse effect on animal health, consumer health or the environment. It also stated that the additive should be considered a dermal and respiratory 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 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 endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* MUCL 49754 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 1091/2009 of 13 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) as a feed additive for chickens for fattening (holder of authorisation Aveve NV) (OJ L 299, 14.11.2009, p. 6).

<sup>(3)</sup> EFSA Journal 2020;18(4):6062.

- (6) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49754 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1091/2009 should be repealed.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49754, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (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

The authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49754, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers' is renewed subject to the conditions laid down in the Annex.

#### Article 2

1. The preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49755 and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (formerly identified as *Trichoderma reesei*) MUCL 49754 and premixtures containing it, which are produced and labelled before 17 September 2021 in accordance with the rules applicable before 17 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the preparation referred to in point 1, which are produced and labelled before 17 March 2022 in accordance with the rules applicable before 17 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted where they are intended for food-producing animals.

#### Article 3

Regulation (EC) No 1091/2009 is repealed.

#### Article 4

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, 24 February 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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| 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 % |                 |                  |                                |

Category of zootechnical additives. Functional group: digestibility enhancers.

|     |          |   |  |                        |   |                     |   |   |           |
|-----|----------|---|--|------------------------|---|---------------------|---|---|-----------|
| 4a9 | Aveve NV | Endo-1,4-beta-xylanase (EC 3.2.1.8) and Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) | <p><b>Additive composition:</b><br/>Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) having a minimum activity of 40 000 XU <sup>(1)</sup>/g and 9 000 BGU <sup>(2)</sup>/g in solid and liquid form</p> <p><b>Characterisation of the active substances:</b><br/>Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma longibrachiatum</i> MUCL 49755 and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Trichoderma longibrachiatum</i> MUCL 49754</p> <p><b>Analytical method <sup>(3)</sup></b><br/>Characterisation of the active substance in the additive:<br/>— colorimetric method based on reaction of dinitrosalicylic acid on reducing sugar produced by action of endo-1,4-beta-xylanase on a xylan containing substrate;<br/>— colorimetric method based on reaction of dinitrosalicylic acid on reducing sugar produced by action of endo-1,3(4)-beta-glucanase on a <math>\beta</math>-glucan containing substrate.</p> | Chickens for fattening | - | 3 000 XU<br>675 BGU | - | <ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to heat treatment.</li> <li>2. For use in feed rich in starch and non-starch polysaccharides (mainly beta-glucans and arabinoxylans).</li> <li>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation and dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and</li> </ol> | 17.3.2031 |
|-----|----------|---|--|------------------------|---|---------------------|---|---|-----------|

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|--|--|--|--|--|--|--|--|--|--|
|  |  |  | <p>Characterisation of the active substances in the feed</p> <ul style="list-style-type: none"> <li>— colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from dye cross-linked wheat arabinoxylan substrate;</li> <li>— colorimetric method measuring water soluble dye released by action of endo-1,3(4)-beta-glucanase from dye cross-linked barley betaglucan substrate.</li> </ul> |  |  |  |  | <p>measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection and gloves.</p> |  |
|--|--|--|--|--|--|--|--|--|--|

(<sup>1</sup>) 1 XU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) per minute from xylan of oat spelt at pH 4,8 and 50 °C.

(<sup>2</sup>) 1 BGU is the amount of enzyme which liberates 1 micromole of reducing sugars (cellobiose equivalents) per minute from  $\beta$ -glucan of barley at pH 5,0 and 50 °C.

(<sup>3</sup>) Details of the analytical methods are available at the following address of the Reference Laboratory: [http://irmm.jrc.ec.europa.eu/EURLs/EURL\\_feed\\_additives/Pages/index.aspx](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)