

## COMMISSION IMPLEMENTING REGULATION (EU) 2023/61

of 5 January 2023

**concerning the authorisation of a preparation of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, a preparation of endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, a preparation of endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and a preparation of endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 as feed additives 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 <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 such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC <sup>(2)</sup>. Article 10(7) of Regulation (EC) No 1831/2003 sets out specific provisions for the placing on the market and use of products used in the Union as silage additives.
- (2) The preparations of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 were entered in the Register of feed additives as existing products <sup>(3)</sup> for all animal species belonging to the functional group of silage additives, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(2) and Article 7 thereof, an application was submitted for the authorisation of the preparations of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 as feed additives for all animal species. The applicant requested the preparations to be classified in the additive category 'technological additives' and the functional group 'silage additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 7 March 2018 <sup>(4)</sup> and 29 June 2022 <sup>(5)</sup>, that, under the proposed conditions of use, the preparations concerned do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that in the absence of data, no conclusion could be drawn on the skin and eye irritancy of the additives and on their skin sensitisation potential. Owing to the proteinaceous nature of the active substances, these preparations should be considered to be potential

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

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> In the Register of feed additives: endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604 was identified as cellulase from *Aspergillus niger* CBS 120604; endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199 was identified as beta-glucanase from *Aspergillus niger* MUCL 39199 or *Aspergillus tubingensis* MUCL 39199; endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 was identified as xylanase from *Trichoderma longibrachiatum* MUCL 39203 or *Trichoderma koningii* MUCL 39203; endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 was identified as xylanase from *Trichoderma longibrachiatum* CBS 614.94.

<sup>(4)</sup> EFSA Journal 2018;16(4):5224.

<sup>(5)</sup> EFSA Journal 2022;20(7):7425.

respiratory sensitisers. The Authority further concluded in its opinion of 29 June 2022 that the preparations concerned have the potential to improve the production of silage from easy, moderate and difficult to ensile forage materials. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of the preparations of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised. 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.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparations concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) 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 preparations specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

#### *Article 2*

### **Transitional measures**

1. The preparations specified in the Annex and premixtures containing these preparations, which are produced and labelled before 26 July 2023 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparations specified in the Annex which are produced and labelled before 26 January 2024 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the preparations specified in the Annex which are produced and labelled before 26 January 2025 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

#### *Article 3*

### **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, 5 January 2023.

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

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## 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 of additive/kg of fresh material			
<b>Category: technological additives. Functional group: silage additives.</b>								
1k105	Endo-1,4-beta-glucanase (EC 3.2.1.4)	<p><i>Additive composition</i> Preparation of endo-1,4-beta-glucanase produced by: <i>Aspergillus niger</i> CBS 120604, having a minimum activity of 25 650 DNS <sup>(1)</sup>/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Aspergillus niger</i> CBS 120604</p> <p><i>Analytical method</i> <sup>(2)</sup></p> <p>For the determination of endo-1,4-beta-glucanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxymethyl cellulose (CMC) at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 3 DNS/kg of fresh material.</li> <li>3. 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 skin, eye, and breathing protection.</li> </ol>	26 January 2033

<sup>(1)</sup> 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as glucose equivalents in µmol per g per min at pH 4,5 and 37 °C from starch.

<sup>(2)</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)

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 of additive/kg of fresh material			
<b>Category: technological additives. Functional group: silage additives.</b>								
1k106	Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,3(4)-β-glucanase produced by:</p> <p><i>Aspergillus neoniger</i> MUCL 39199, having a minimum activity of 10 000 DNS <sup>(1)</sup>/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Aspergillus neoniger</i> MUCL 39199</p> <p><i>Analytical method <sup>(2)</sup></i></p> <p>For the determination of endo-1,3(4)-beta-glucanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxymethyl cellulose (CMC) at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 3,4 DNS/kg of fresh material.</li> <li>3. 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 skin, eye and breathing protection.</li> </ol>	26 January 2033

<sup>(1)</sup> 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as glucose equivalents in μmol per g per min at pH 4,5 and 37 °C from starch.

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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 of additive/kg of fresh material			
<b>Category: technological additives. Functional group: silage additives.</b>								
1k107	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by:</p> <p><i>Trichoderma citrinoviride</i> MUCL 39203, having a minimum activity of 51 600 DNS <sup>(1)</sup>/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma citrinoviride</i> MUCL 39203</p> <p><i>Analytical method <sup>(2)</sup></i></p> <p>For the determination of endo-1,4-beta-xylanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the xylan at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 3,2 DNS/kg of fresh material.</li> <li>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 skin, eye and breathing protection.</li> </ol>	26 January 2033

<sup>(1)</sup> 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as xylose equivalents in µmol per g per min at pH 4,5 and 37 °C from birchwood xylan.

<sup>(2)</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)

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 of additive/kg of fresh material			

**Category: technological additives. Functional group: silage additives.**

1k108	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by:</p> <p><i>Trichoderma citrinoviride</i> CBS 614.94, having a minimum activity of 70 000 DNS <sup>(1)</sup>/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma citrinoviride</i> CBS 614.94</p> <p><i>Analytical method</i> <sup>(2)</sup></p> <p>For the determination of endo-1,4-beta-xylanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the xylan at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 15 DNS/kg of fresh material.</li> <li>3. 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 skin, eye and breathing protection.</li> </ol>	26 January 2033
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<sup>(1)</sup> 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as xylose equivalents in µmol per g per min at pH 4,5 and 37 °C from birchwood xylan.

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