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COMMISSION IMPLEMENTING REGULATION (EU) 2026/1016

of 7 May 2026

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying, the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 as a feed additive for chickens reared for breeding, chickens for breeding, turkeys for breeding, minor poultry species reared for breeding, and minor poultry species for laying and breeding (holder of authorisation: Adisseo France S.A.S.), and repealing Implementing Regulations (EU) 2015/661, (EU) 2015/2304 and (EU) 2017/210

(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 and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 was authorised for a period of 10 years as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying by Commission Implementing Regulation (EU) 2015/661 ([2]), for turkeys for fattening and for breeding by Commission Implementing Regulation (EU) 2015/2304 ([3]) and for laying hens by Commission Implementing Regulation (EU) 2017/210 ([4]).

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

([2]) Commission Implementing Regulation (EU) 2015/661 of 28 April 2015 concerning the authorisation of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying (holder of the authorisation Adisseo France S.A.S.) (OJ L 110, 29.4.2015, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2015/661/oj).

([3]) Commission Implementing Regulation (EU) 2015/2304 of 10 December 2015 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov DSM 26702 as a feed additive for turkeys for fattening and for breeding (holder of the authorisation Adisseo France S.A.S.) (OJ L 326, 11.12.2015, p. 39, ELI: http://data.europa.eu/eli/reg_impl/2015/2304/oj).

([4]) Commission Implementing Regulation (EU) 2017/210 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for laying hens (holder of the authorisation Adisseo France S.A.S.) (OJ L 33, 8.2.2017, p. 19, ELI: http://data.europa.eu/eli/reg_impl/2017/210/oj).

(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 and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying, 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 chickens reared for breeding, chickens for breeding, turkeys for breeding, minor poultry species reared for breeding, and minor poultry species for laying and breeding, 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) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 June 2025 ([5]) that, under the current authorised conditions of use and considering the fact that the manufacturing and composition of the additive have not been substantially modified, the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 remains safe for the target species, consumers and the environment. In addition, the Authority concluded that, regarding the extension of use to all poultry species, the additive is safe for the target species, consumers, and the environment. It further concluded that the preparation is not an irritant to the skin or eyes, but should be considered a potential skin and respiratory sensitiser and any exposure by inhalation is considered a risk. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, it concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. It also considered that the conclusions reached in the original authorisation can be extended to other species and therefore concluded that the additive has the potential to be efficacious in all poultry species at a minimum inclusion level of 1100 VU endo-1,4-beta-xylanase and 760 VU endo-1,3(4)-beta-glucanase/kg complete feed. 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 a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 2 July 2014 ([6]) are valid and applicable for the current application. 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.

(6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying. Furthermore, the use of that preparation should be authorised for chickens reared for breeding, chickens for breeding, turkeys for breeding, minor poultry species reared for breeding, and minor poultry species for laying and breeding. 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.

([5]) *EFSA Journal*. 2025;23:e9547. https://doi.org/10.2903/j.efsa.2025.9547.
([6]) *EFSA Journal* 2014;12(7):3793. https://doi.org/10.2903/j.efsa.2014.3793.
([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).

(7) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying, Implementing Regulations (EU) 2015/661, (EU) 2015/2304 and (EU) 2017/210 should be repealed.

(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 and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying, 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 the 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 chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying, 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 chickens reared for breeding, chickens for breeding, turkeys for breeding, minor poultry species reared for breeding, and minor poultry species for laying and breeding, subject to the conditions laid down in that Annex.

Article 3

Repeal

Implementing Regulations (EU) 2015/661, (EU) 2015/2304 and (EU) 2017/210 are repealed.

Article 4

Transitional measures

1. The feed additive endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702, as authorised by Implementing Regulations (EU) 2015/661, (EU) 2015/2304 and (EU) 2017/210, and premixtures containing that additive, which are intended for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying and which are produced and labelled before 28 November 2026 in accordance with the rules applicable before 28 May 2026 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 chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, and minor poultry species for fattening and reared for laying, and which are produced and labelled before 28 May 2027 in accordance with the rules applicable before 28 May 2026 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, 7 May 2026.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content / Maximum content (Units of activity/kg of complete feed with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a22	Adisseo France S.A.S.	Endo-1,4-beta-xylanase (EC 3.2.1.8) and Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	*Additive composition* Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702 having a minimum activity of: — solid form: endo-1,4-beta-xylanase 22 000 VU (1)/g and endo-1,3(4)-beta-glucanase 15 200 VU/g; — liquid form: endo-1,4-beta-xylanase activity of 5 500 VU/ml and endo-1,3(4)-beta-glucanase 3 800 VU/ml. *Characterisation of the active substance* Endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3 (4)-beta-glucanase (EC 3.2.1.6) produced with *Talaromyces versatilis* IMI 378536 and *Talaromyces versatilis* DSM 26702.	Poultry	-	Endo-1,4-beta-xylanase 1 100 VU Endo-1,3(4)-beta-glucanase 760 VU	-	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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing and skin protections.	28 May 2036

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %			
			Analytical method (2) For the determination of endo-1,4-beta-xylanase activity: — viscosimetric method based on decrease in viscosity produced by action of endo-1,4- beta-xylanase on the xylan containing substrate (wheat arabinoxylan). For the determination of endo-1,3(4)-beta-glucanase activity: — viscosimetric method based on decrease in viscosity produced by action of endo-1,3 (4)-beta-glucanase on the glucan containing substrate (barley beta-glucan).						

(1) 1 VU (viscosimetric unit) of the xylanase or glucanase activity is the amount of the enzyme which hydrolyses the substrate (wheat arabinoxylan or barley betaglucan, respectively), reducing the viscosity of the solution, to give a change in relative fluidity of 1 (dimensionless unit)/min at 30 °C and pH 5,5.

(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

ELI: http://data.europa.eu/eli/reg_impl/2026/1016/oj