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.) (Text with EEA relevance)

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.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a 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 by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of the 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 by *Talaromyces versatilis* IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for all major and minor poultry species for fattening, reared for laying and breeding, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that preparation was authorised for 10 years 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)].

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 April 2015[(3)] that, under the proposed conditions of use, the 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 by *Talaromyces versatilis* IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702

does not have an adverse effect on animal health, human health or the environment, and that it has a significant improvement in the feed-to-gain ratio of turkeys for fattening. This conclusion is extended to turkeys reared for breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It 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.

(6) The assessment of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(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

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, subject to the conditions laid down in that Annex.

Article 2

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, 10 December 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

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									
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 by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 having a minimum activity of: *Characterisation of the active substance* 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 *Analytical method* [b] For the determination of endo-1,4-beta-xylanase activity: Viscosimetry For the determination of endo-1,3(4)-beta-glucanase activity: Viscosimetry	Turkeys for fattening Turkeys reared for breading	—	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 premixture, indicate the storage conditions and stability to pelleting. 2. For safety: breathing protection, glasses and gloves shall be used during handling.	31 December 2025

a 1 VU (viscosimetry unit) is the amount of enzyme which hydrolyses the substrate (barley betaglucan and wheat arabinoxylan, 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.

b Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

			— solid form: endo-1,4-beta-xylanase 22 000 VU[a]/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-						

a 1 VU (viscosimetry unit) is the amount of enzyme which hydrolyses the substrate (barley betaglucan and wheat arabinoxylan, 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.

b Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

			glucanase (EC 3.2.1.6) produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702. *Analytical method*[b] For the quantification 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 quantification						

a 1 VU (viscosimetry unit) is the amount of enzyme which hydrolyses the substrate (barley betaglucan and wheat arabinoxylan, 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.

b Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

				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 substrate barley betaglucan at pH = 5,5 and 30 °C.					

a 1 VU (viscosimetry unit) is the amount of enzyme which hydrolyses the substrate (barley betaglucan and wheat arabinoxylan, 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.

b Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

(**1**) OJ L 268, 18.10.2003, p. 29.

(**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).

(**3**) *EFSA Journal 2014*; 13(5):4106.

Status:
Point in time view as at 10/12/2015.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/2304.