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.) (Text with EEA relevance)

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.)

(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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for 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* 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 Regulation (EC) No 1831/2003.

(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* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for laying hens 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)] and for turkeys for fattening and for breeding by Commission Implementing Regulation (EU) 2015/2304[(3)].

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 25 May 2016[(4)] that, under the proposed conditions of use, the preparation of endo-1,4-

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/210. (See end of Document for details)*

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 does not have an adverse effect on animal health, human health or the environment, and that it improved the performance in laying hens. 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 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 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, 7 February 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/210. (See end of Document for details)*

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** **Units of activity/kg of complete feedingstuff with a moisture content of 12 %**	**Maximum content**	**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 by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 having a minimum activity of:	Laying hens	—	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 users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to	28 February 2027

a 1 VU (viscosimetric 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/210. (See end of Document for details)*

			— solid form: endo-1,4-beta-xylanase 22 000 VU/g and endo-1,3(4)-beta-glucanase 15 200 VU[a]/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-				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 breathing, and skin protections.

a 1 VU (viscosimetric 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