Commission Implementing Regulation (EU) No 290/2014 of 21 March 2014 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 as a feed additive for poultry, weaned piglets and pigs for fattening and amending Regulations (EC) No 1259/2004, (EC) No 943/2005, (EC) No 1206/2005 and (EC) No 322/2009 (holder of the authorisation Adisseo France S.A.S.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 290/2014

of 21 March 2014

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 as a feed additive for poultry, weaned piglets and pigs for fattening and amending Regulations (EC) No 1259/2004, (EC) No 943/2005, (EC) No 1206/2005 and (EC) No 322/2009 (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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) 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 *Penicillium funiculosum* IMI SD 101 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1259/2004[(3)]; for laying hens and turkeys for fattening by Commission Regulation (EC) No 943/2005[(4)]; for pigs for fattening by Commission Regulation (EC) No 1206/2005[(5)]; and for ducks for fattening and weaned piglets by Commission Regulation (EC) No 322/2009[(6)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that 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 (formerly

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 290/2014. (See end of Document for details)*

Penicillium funiculosum IMI SD 101), as a feed additive for chickens, turkeys and ducks for fattening, laying hens, weaned piglets, pigs for fattening, and, in accordance with Article 7 of that Regulation, for a new use for all major and minor poultry species, requesting that additive to be classified in the additive category 'zootechnical additives'. That 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 opinion of 10 July 2013[7] 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* sp. nov. IMI CC 378536 does not have an adverse effect on animal health, human health or the environment, and that it has a potential to favourably affect animal performance in chickens and turkeys for fattening, laying hens, weaned piglets and pigs for fattening. Since the mode of action can be considered to be similar in all poultry species, this conclusion can be extrapolated to ducks, guinea fowls, quails, geese, pheasant and pigeons. 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.

(5) 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 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.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC) No 1259/2004, (EC) No 943/2005, (EC) No 1206/2005 and (EC) No 322/2009 should be amended accordingly.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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, subject to the conditions laid down in that Annex.

Article 2

Amendments to Regulation (EC) No 1259/2004

Regulation (EC) No 1259/2004 is amended as follows:

(1) Article 2 is replaced by the following:

Article 2

The preparations belonging to the group "enzymes", as set out in Annexes III, V and VI are authorised for use without a time limit as additive in animal nutrition under the conditions laid down in those Annexes.;

(2) Annex IV is deleted.

Article 3

Amendment to Regulation (EC) No 943/2005

In Annex II to Regulation (EC) No 943/2005 the entry on E 1604, endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase EC 3.2.1.6, is deleted.

Article 4

Amendment to Regulation (EC) No 1206/2005

In Annex to Regulation (EC) No 1206/2005 the entry on E 1604, endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase EC 3.2.1.6, is deleted.

Article 5

Amendment to Regulation (EC) No 322/2009

In Regulation (EC) No 322/2009, Article 3 and Annex III are deleted.

Article 6

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 11 October 2014 in accordance with the rules applicable before 11 April 2014 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 7

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 290/2014. (See end of Document for details)*

Done at Brussels, 21 March 2014.

For the Commission

The President

José Manuel BARROSO

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									
4a1604i	Adisseo France S.A.S.	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition* Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 having a minimum activity of: —	*Pigs for fattening* Piglets (weaned) — solid form: endo-1,3(4)-beta-glucanase 30 000 VU[a]/g and	—	endo-1,3(4)-beta-glucanase 1 500 VU endo-1,4-beta-xylanase 1 100 VU		1. In the instructions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For use in (weaned) piglets up to approximately 35 kg. 3. For safety: breathing protection, glasses and gloves	1 April 2024

a VU (viscosimetry unit) is the amount of enzyme which hydrolyzes 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: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx