



Brussels, **XXX**
SANTE/10131078/2024 CIS
(POOL/G5/2024/10131078/10131078-
EN CIS.docx)
[...] (2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the renewal of the authorisation of a preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 as a feed additive for all poultry species, weaned piglets, pigs for fattening and sows (holder of authorisation: Adisseo France S.A.S.) and repealing Implementing Regulations (EU) No 290/2014 and (EU) No 1138/2014

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the renewal of the authorisation of a preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 as a feed additive for all poultry species, weaned piglets, pigs for fattening and sows (holder of authorisation: Adisseo France S.A.S.) and repealing Implementing Regulations (EU) No 290/2014 and (EU) No 1138/2014

(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 nutrition¹, 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-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536, was authorised for 10 years as a feed additive for poultry, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 290/2014², and for sows by Commission Implementing Regulation (EU) No 1138/2014³.
- (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-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 as a feed additive for all poultry species, weaned piglets, pigs for fattening and sows, requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>

² 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.) (OJ L 87, 22.3.2014, p. 84, ELI: http://data.europa.eu/eli/reg_impl/2014/290/oj).

³ Commission Implementing Regulation (EU) No 1138/2014 of 27 October 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 sows (holder of the authorisation Adisseo France S.A.S.) (OJ L 307, 28.10.2014, p. 30, ELI: http://data.europa.eu/eli/reg_impl/2014/1138/oj).

accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 November 2024⁴ that the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 in all its formulations remains safe for all poultry species, weaned piglets, pigs for fattening and sows, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536, in all its formulations, is non-irritant to the eyes and skin but should be considered a respiratory sensitiser, and all solid formulations should also be considered dermal sensitisers. It also indicated that there is no need for assessing the efficacy of the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536, as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisations which would have an impact on the efficacy of the additive. 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 the assessment carried out regarding the method of analysis of the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 as a feed additive in the context of the previous authorisations are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005⁵, 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-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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.
- (7) As a consequence of the renewal of the authorisation of the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced with *Talaromyces versatilis* IMI CC 378536 as a feed additive, Implementing Regulations (EU) No 290/2014 and (EU) No 1138/2014 should be repealed.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ EFSA Journal. 2025;23:e9131. <https://doi.org/10.2903/j.efsa.2025.9131>

⁵ 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 059 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of 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 subject to the conditions laid down in that Annex.

Article 2

Repeals

Implementing Regulations (EU) No 290/2014 and (EU) No 1138/2014 are repealed.

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,

For the Commission

The President

Ursula VON DER LEYEN