

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1703

of 7 September 2023

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), the authorisation of that preparation for suckling piglets and minor porcine species (suckling piglets) (holder of authorisation: Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) and repealing Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997

(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 authorisation.
- (2) The preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 (previously taxonomically identified as ATCC PTA-5588) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 (previously taxonomically identified as ATCC SD-2106) was authorised for 10 years as a feed additive for poultry, weaned piglets and pigs for fattening by Commission Regulation (EU) No 337/2011 ⁽²⁾, and for lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows) by Commission Implementing Regulation (EU) 2016/997 ⁽³⁾.
- (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 produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application included a proposal for amending the conditions of the original authorisation, consisting of a reduction of the minimum recommended level for turkeys. The application also included a request in accordance with Article 7 of Regulation (EC) No 1831/2003 for the authorisation of the same preparation as a feed additive for suckling piglets and minor porcine species (suckling piglets). The application was accompanied by the particulars and documents required respectively under Article 14(2) and 7(3) of that Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 337/2011 of 7 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as feed additive for poultry, weaned piglets and pigs for fattening (holder of the authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 94, 8.4.2011, p. 19).

⁽³⁾ Commission Implementing Regulation (EU) 2016/997 of 21 June 2016 concerning the authorisation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) as a feed additive for lactating sows and minor porcine species (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 164, 22.6.2016, p. 4).

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2022 ⁽⁴⁾ that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 remains safe for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), consumers and the environment under the conditions of use currently authorised. It added that those conclusions on safety apply also to the use of that preparation for suckling piglets and minor porcine species (suckling piglets). It further stated that the preparation should be considered a potential eye irritant and a respiratory sensitiser, while no conclusions could be drawn on the skin irritancy and sensitisation potential of the preparation. The Authority also concluded that there was no need for an assessment of the efficacy of the preparation for poultry species other than turkeys, for weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), and that the preparation was considered efficacious in turkeys, suckling piglets and minor porcine species (suckling piglets) at the newly proposed intended level of 610 Units of activity of endo-1,4-beta-xylanase per kilogramme of complete feedingstuff and 76 Units of activity of endo-1,3(4)-beta-glucanase per kilogramme of complete feedingstuff. However, the Authority also highlighted that the actual effective level used in the studies supporting the conclusions on efficacy for all target species, except lactating sows and minor porcine species (lactating sows), was approximately 50 % higher than the newly proposed intended level. Finally, the Authority concluded that there was no need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), first subparagraph, points (a) and (c), of Commission Regulation (EC) No 378/2005 ⁽⁵⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment of 28 June 2010 ⁽⁶⁾ are valid and applicable to the current application.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that preparation should be renewed for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows) and the use of that preparation should be authorised for suckling piglets and minor porcine species (suckling piglets). However, it is appropriate to set the minimum content applicable to poultry species, suckling piglets, weaned piglets, pigs for fattening and minor porcine species (suckling piglets, weaned piglets and pigs for fattening) 50 % higher than the intended level in order to ensure the efficacy of that preparation when fed to those target species and categories.
- (7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (8) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive, Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997 should be repealed.
- (9) 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 produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 for use for poultry species, weaned piglets, pigs for fattening and minor porcine species (weaned piglets and pigs for fattening), it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements.

⁽⁴⁾ EFSA Journal 2022;20(11):7615.

⁽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 59, 5.3.2005, p. 8).

⁽⁶⁾ Report of the European Union Reference Laboratory available at <https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-FAD-2010-0007.pdf>.

- (10) 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 poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), 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 for suckling piglets and minor porcine species (suckling piglets) as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 3

Repeals

Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997 are repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for poultry species, weaned piglets, pigs for fattening and minor porcine species (weaned piglets and pigs for fattening) and are produced and labelled before 28 March 2024 in accordance with the rules applicable before 28 September 2023, may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are intended for poultry species, weaned piglets, pigs for fattening and minor porcine species (weaned piglets and pigs for fattening) and are produced and labelled before 28 September 2024 in accordance with the rules applicable before 28 September 2023, may continue to be placed on the market and used until the existing stocks 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 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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.									
4a15	Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.	Endo-1,4-beta-xylanase (EC 3.2.1.8) Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	<p><i>Additive composition</i> Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> CBS 143953 and endo-1,3(4)-beta-glucanase produced by <i>Trichoderma reesei</i> CBS 143945 having a minimum activity of:</p> <p>— 12 200 U ⁽¹⁾/g endo-1,4-beta-xylanase — 1 520 U ⁽²⁾/g endo-1,3(4)-beta-glucanase</p> <p>Solid and liquid form</p> <p><i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> CBS 143953 and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Trichoderma reesei</i> CBS 143945</p> <p><i>Analytical method</i> ⁽³⁾ For quantification of the active substances in the additive, premixtures and compound feeds:</p> <p>— colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrates; — colorimetric method measuring water soluble dye released by action of endo-1,3(4)-beta-glucanase from azurine cross-linked barley beta-glucan substrates.</p>	Laying hens	—	Endo-1,4-beta-xylanase 1 830 U Endo-1,3(4)-beta-glucanase 228 U	—	1. In the directions for use of the additive and premixture, 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, skin and eye protective equipment.	28 September 2033
				Lactating sows Minor porcine species (lactating sows)	—	Endo-1,4-beta-xylanase 1 220 U Endo-1,3(4)-beta-glucanase 152 U	—		
				Other poultry Suckling piglets Weaned piglets Pigs for fattening Minor porcine species (suckling piglets, weaned piglets and pigs for fattening)	—	Endo-1,4-beta-xylanase 915 U Endo-1,3(4)-beta-glucanase 114 U	—		

⁽¹⁾ One U of endo-1,4-beta-xylanase is the amount of enzyme that liberates 0,48 µmol of reducing sugar (xylose equivalents) per minute from a wheat arabinoxylan at pH 4,2 and 50 °C.

⁽²⁾ One U of endo-1,4-beta-glucanase is the amount of enzyme that liberates 2,4 µmol of reducing sugar (glucose equivalents) per minute from a barley glucan at pH 5,0 and 50 °C.

⁽³⁾ 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.