



2024/780

6.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/780

of 5 March 2024

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma citrinoviride* DSM 34663 as a feed additive for all poultry species for fattening, all poultry species for laying and reared for laying, weaned piglets, pigs for fattening and carp, the authorisation of that preparation as a feed additive for all poultry species for breeding, turkeys reared for breeding, minor poultry species reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening (holder of authorisation: Huvepharma NV) and repealing Implementing Regulations (EU) 2015/1043, (EU) 2017/1906 and (EU) 2018/327

(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 an authorisation.
- (2) A preparation of endo-1,4-beta-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (previously taxonomically identified as *Trichoderma citrinoviride* Bisset (IMI SD135)) was authorised for a period of 10 years as a feed additive for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) 2015/1043 ⁽²⁾, for chickens reared for laying and minor poultry species reared for laying by Commission Implementing Regulation (EU) 2017/1906 ⁽³⁾ and for carp by Commission Implementing Regulation (EU) 2018/327 ⁽⁴⁾.
- (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 citrinoviride* DSM 34663 as a feed additive for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application also concerned the authorisation of new uses of the same preparation as a feed additive for breeding hens, turkeys reared for breeding, turkeys for breeding, ornamental birds, suckling piglets, minor porcine species for fattening, minor poultry species reared for breeding and minor poultry species for breeding. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.

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

⁽²⁾ Commission Implementing Regulation (EU) 2015/1043 of 30 June 2015 concerning the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, pigs for fattening and minor poultry species for fattening and for laying, and amending Regulations (EC) No 2148/2004, (EC) No 828/2007 and (EC) No 322/2009 (holder of authorisation Huvepharma NV) (OJ L 167, 1.7.2015, p. 63, ELI: http://data.europa.eu/eli/reg_impl/2015/1043/oj).

⁽³⁾ Commission Implementing Regulation (EU) 2017/1906 of 18 October 2017 concerning the authorisation of a preparation of endo-1,4-b-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) as a feed additive for chickens reared for laying and minor poultry species reared for laying (holder of authorisation Huvepharma NV) (OJ L 269, 19.10.2017, p. 33, ELI: http://data.europa.eu/eli/reg_impl/2017/1906/oj).

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/327 of 5 March 2018 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) as a feed additive for carp (holder of authorisation Huvepharma NV) (OJ L 63, 6.3.2018, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2018/327/oj).

- (4) The European Food Safety Authority ('the Authority') stated in its opinion of 5 July 2023 ⁽⁵⁾, that there is no new evidence that would lead to reconsider previous conclusions that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma citrinoviride* DSM 34663 is safe for the target species, including species for which it is currently authorised, namely all poultry species for fattening, for laying and reared for laying, weaned piglets, pigs for fattening and carp, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is safe for all poultry species for breeding, turkeys reared for breeding, minor poultry species reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening, the consumers and the environment, under the recommended conditions of use. The Authority further stated that the preparation is not a skin corrosive or a skin sensitiser. It stated that the preparation is an eye irritant and is considered a respiratory sensitiser, while no conclusion could be drawn on the potential of the additive to be a skin irritant. The Authority considered that there is no need to assess the efficacy of the additive in the context of the renewal of the authorisation as the application does not include a proposal for amending or supplementing the conditions of use for those species/categories for which there is an authorisation. It considered that the conclusions reached for those species can be extended and extrapolated to other species and therefore concluded that the additive has the potential to be efficacious in minor poultry species reared for breeding, all poultry species for breeding, ornamental birds, turkeys reared for breeding, suckling piglets and minor porcine species for fattening. 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 endo-1,4-beta-xylanase produced by *Trichoderma citrinoviride* DSM 34663 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), points (a) and (c), of Commission Regulation (EC) No 378/2005 ⁽⁶⁾, 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-1,4-beta-xylanase produced by *Trichoderma citrinoviride* DSM 34663 satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, and the use of that preparation should be authorised for breeding hens, turkeys reared for breeding, turkeys for breeding, ornamental birds, suckling piglets, minor porcine species for fattening, minor poultry species reared for breeding and minor poultry species for breeding. 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-1,4-beta-xylanase produced by *Trichoderma citrinoviride* DSM 34663 as a feed additive for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, Implementing Regulations (EU) 2015/1043, (EU) 2017/1906 and (EU) 2018/327 should be repealed.
- (8) 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 citrinoviride* DSM 34663 for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁵⁾ EFSA Journal 2023;21(8):8171.

⁽⁶⁾ 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, 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 for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, 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 as an additive in animal nutrition for breeding hens, turkeys reared for breeding, turkeys for breeding, ornamental birds, suckling piglets, minor porcine species for fattening, minor poultry species reared for breeding and minor poultry species for breeding, subject to the conditions laid down in that Annex.

Article 3

Repeals

Implementing Regulations (EU) 2015/1043, (EU) 2017/1906 and (EU) 2018/327 are repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, and which are produced and labelled before 26 September 2024 in accordance with the rules applicable before 26 March 2024 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 chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and for laying, weaned piglets, pigs for fattening, chickens reared for laying, minor poultry species reared for laying, and carp, and which are produced and labelled before 26 March 2025 in accordance with the rules applicable before 26 March 2024 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, 5 March 2024.

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.									
4a1617	Huvepharma NV	Endo– 1,4-beta-xylanase (EC 3.2.1.8)	<i>Additive composition</i> Preparation of endo– 1,4-beta-xylanase produced by <i>Trichoderma citrinoviride</i> DSM 34663 having a minimum activity of 6 000 EPU (¹)/g. Solid or liquid form.	Turkeys for fattening Turkeys reared for breeding Minor poultry species for fattening Carp	—	1 050 EPU	—	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, eye and skin protective equipment.	26 March 2034
			<i>Characterisation of the active substance</i> Endo– 1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma citrinoviride</i> DSM 34663. <i>Analytical method (²)</i> For characterisation of endo– 1,4-beta-xylanase activity in the feed additive, premixtures and compound feed: colorimetric method measuring water-soluble dye released by action of endo– 1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrates.	Chickens for fattening Chickens reared for laying Minor poultry species reared for laying or reared for breeding All poultry species for breeding Laying hens Minor poultry species for laying Ornamental birds		1 500 EPU			

				Suckling piglets Weaned piglets Pigs for fattening Minor porcine species for fattening					
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(¹) One EPU is the amount of enzyme which releases 0,008 3 micromol of reducing sugars (xylose equivalent) per minute from oat spelt xylan at pH 4,5 and 50 °C.

(²) 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