



2024/262

18.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/262

of 17 January 2024

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, the authorisation of that preparation as a feed additive for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets (holder of the authorisation: Huvepharma NV) and amending Implementing Regulation (EU) 2015/2305

(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-glucanase produced by *Trichoderma citrinoviride* IMI 360748 (previously taxonomically identified as *Trichoderma citrinoviride* Bisset (IM SD142)) was authorised for a period of 10 years as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets by Commission Implementing Regulation (EU) 2015/2305 ⁽²⁾.
- (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-glucanase produced by *Trichoderma citrinoviride* IMI 360748 for chickens for fattening, minor poultry species for fattening and weaned piglets, 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 turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 March 2023 ⁽³⁾, that the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 remains safe for chickens for fattening, minor poultry species for fattening and weaned piglets, as well as for the consumers and the environment under the conditions of use currently authorised, and indicated that this conclusion on safety also applies to turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. The Authority further concluded that the preparation is not considered skin corrosive or eye irritant. It stated that the preparation should be considered a skin sensitiser and a respiratory sensitiser, while no conclusion could be drawn on the potential of the additive to be a skin irritant. The Authority indicated that there was no need

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2015/2305 of 10 December 2015 concerning the authorisation of a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma Citrinoviride* Bisset (IM SD142) as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, and amending Regulations (EC) No 2148/2004 and (EC) No 1520/2007 (holder of authorisation Huvepharma NV) (OJ L 326, 11.12.2015, p. 43).

⁽³⁾ EFSA Journal 2023;21(4):7954.

for assessing the efficacy of the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 in the context of the renewal of the authorisation for chickens for fattening, minor poultry species for fattening and weaned piglets, and considered that the conclusions on efficacy reached in chickens for fattening and weaned piglets can be extended to turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. 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-glucanase 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 ⁽⁴⁾, 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-glucanase produced by *Trichoderma citrinoviride* IMI 360748 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that preparation should be renewed for chickens for fattening, minor poultry species for fattening and weaned piglets, and the use of that preparation should be authorised for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. 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.
- (7) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, Implementing Regulation (EU) 2015/2305 should be amended.
- (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-glucanase produced by *Trichoderma citrinoviride* IMI 360748 for chickens for fattening, minor poultry species for fattening and weaned piglets, 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,

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', for chickens for fattening, minor poultry species for fattening and weaned piglets, is renewed subject to the conditions laid down in that Annex.

⁽⁴⁾ 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).

*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 turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets, subject to the conditions laid down in that Annex.

*Article 3***Amendments to Implementing Regulation (EU) 2015/2305**

Implementing Regulation (EU) 2015/2305 is amended as follows:

- (1) Article 1 is deleted;
- (2) the Annex is deleted.

*Article 4***Transitional measures**

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for chickens for fattening, minor poultry species for fattening and weaned piglets, and which are produced and labelled before 7 August 2024 in accordance with the rules applicable before 7 February 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, minor poultry species for fattening and weaned piglets, and which are produced and labelled before 7 February 2025 in accordance with the rules applicable before 7 February 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, 17 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

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.

4a1616	Huvepharma NV	Endo-1,4-beta-glucanase (EC 3.2.1.4)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Trichoderma citrinoviride</i> IMI 360748 having a minimum activity of 2000 CU ⁽¹⁾/g.</p> <p>Solid or liquid form.</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Trichoderma citrinoviride</i> IMI 360748.</p> <p><i>Analytical method ⁽²⁾</i></p> <p>For the determination of endo-1,4-beta-glucanase in feed additive, premixtures and compound feeds: colorimetric method based on the quantification of water soluble dyed fragments (azurine) produced by the action of endo-1,4-beta-glucanase on azurine-crosslinked cellulose.</p>	All poultry species for fattening	—	500 CU	—	<p>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.</p>	7 February 2034
				All poultry species reared for laying or breeding					
				Ornamental birds					
				Suckling piglets	—	350 CU	—		
				Weaned piglets					

⁽¹⁾ One CU is the amount of enzyme that liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °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