COMMISSION IMPLEMENTING REGULATION (EU) 2023/1713

of 7 September 2023

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 for chickens for fattening, chickens reared for laying and minor poultry species (holder of authorisation: Danisco (UK) Ltd represented in the Union by Genencor international B.V.)

(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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease (also known as 'subtilisin') produced by *Bacillus subtilis* ATCC SD-2107 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* ATCC SD-2107 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 as a feed additive for chickens for fattening, chickens reared for laying, laying hens and minor poultry species, to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') could not conclude, in its opinion of 25 May 2020 ([2]), on the safety of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* ATCC SD-2107 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 for the target species, consumers, users and the environment. However, in its subsequent opinion of 6 January 2023 ([3]), the Authority reported that the applicant submitted new information to address some of the limitations identified in the opinion of 25 May 2020 and declared a change in the production strain of the protease, substituting *Bacillus subtilis* ATCC SD-2107 for *Bacillus subtilis* CBS 148232, and concluded that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that that preparation is considered a respiratory sensitiser and, in the absence of data, could not conclude on its irritancy potential to skin and eyes nor on its skin sensitising properties. The Authority also concluded in its opinion of 6 January 2023 with reference to its opinion of 25 May 2020 that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 is efficacious in chickens for fattening, chickens reared for laying and minor poultry species up to the point of lay, but could not conclude on its efficacy for laying hens. It did 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2020;18(6):6165.
([3]) *EFSA Journal* 2023;21(2):7816.

(5) The applicant withdrew the application, on 14 April 2023, for the authorisation of the preparation for laying hens.

(6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 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. 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) 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

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

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									
4a40	Danisco (UK) Ltd represented in the Union by Genencor International B.V.	Endo- 1,4-beta-xylanase (EC 3.2.1.8), protease (EC 3.4.21.62) and alpha-amylase (EC 3.2.1.1)	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 with a minimum activity of: Endo-1,4-beta-xylanase: 20 000 U_X (1)/g Protease: 40 000 U_P (2)/g Alpha-amylase: 2 000 U_A (3)/g Solid form *Characterisation of the active substance* Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* ATCC PTA-5588, protease (EC 3.4.21.62, also known as 'subtilisin') produced by *Bacillus subtilis* CBS 148232 and alpha-amylase (EC 3.2.1.1) produced by *Bacillus licheniformis* ATCC SD-6525	Chickens for fattening Chickens reared for laying Minor poultry species for fattening and reared for laying	—	Endo-1,4-beta-xylanase 2 000 U_X Protease 4 000 U_P Alpha-amylase 200 U_A	—	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 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, eye and skin protective equipment.	28 September 2033

			Analytical method (4) For the quantification of endo-1,4-beta-xylanase in the feed additive, premixtures and compound feeds: colorimetric method, based on the enzymatic hydrolysis by xylanase of an azurine cross-linked wheat arabinoxylan substrate at pH 4,2 and 50 °C; For the quantification of protease in feed additive and premixtures and compound feeds: colorimetric method based on the enzymatic hydrolysis by protease of a dyed cross-linked casein substrate at pH 10,0 and 50 °C; For the quantification of alpha-amylase in feed additive, premixtures and compound feeds: colorimetric method based on the enzymatic hydrolysis by amylase of an azurine cross-linked starch polymer substrate at pH 8,0 and 40 °C.						

(1) One unit of endo-1,4-beta-xylanase activity (U_X) is the amount of enzyme, which liberates 0,48 micromoles per minute of reducing sugars, expressed as xylose equivalents, from a wheat arabinoxylan substrate at pH 4,2 and 50 °C.

(2) One unit of protease activity (U_P) is defined as the amount of enzyme which liberates 2,3 micrograms per minute of phenolic compounds, expressed as tyrosine equivalents from a casein substrate at pH 10,0 and 50 °C.

(3) One unit of alpha-amylase activity (U_A) is the amount of enzyme required to release, in the presence of an excess of alpha-glucosidase, 0,20 micromoles per minute of glucosidic linkages, expressed as p-nitrophenol equivalents, from a maltoheptasoide substrate at pH 8,0 and 40 °C.

(4) 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.