COMMISSION IMPLEMENTING REGULATION (EU) 2023/1333

of 29 June 2023

concerning the authorisation of a preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 as a feed additive for chickens for fattening and weaned piglets (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.), amending Regulation (EC) No 1811/2005 and repealing Regulation (EC) No 1259/2004

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 (previously taxonomically identified as *Aspergillus aculeatus*) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1259/2004 ([3]) and for piglets (weaned) by Commission Regulation (EC) No 1811/2005 ([4]). That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of the preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 as a feed additive for chickens for fattening and weaned piglets. The applicant requested the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 November 2022 ([5]) that, under the proposed conditions of use, the preparation does not have adverse effects on animal health, consumer safety or the environment. As regards safety for the users when handling the preparation, owning to the lack of data with the final formulations, the Authority could not conclude on the potential of the additive to be irritant to skin and eyes or on its potential as a dermal sensitiser, but considered that the additive is a respiratory sensitiser due to the proteinaceous nature of the active substance. The Authority concluded that the additive is efficacious as a zootechnical additive in chickens for fattening and weaned piglets at the minimum recommended level of 10 FBG/kg feed. It also verified the report on the methods of analysis of the feed additives 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]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1259/2004 of 8 July 2004 concerning the permanent authorisation of certain additives already authorised in feedingstuffs (OJ L 239, 9.7.2004, p. 8).
([4]) Commission Regulation (EC) No 1811/2005 of 4 November 2005 concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 291, 5.11.2005, p. 12).
([5]) *EFSA Journal* 2023;21(1):7703.

(5) The assessment of the additive 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 additive should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) As a consequence of the authorisation of the preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 as a feed additive, Regulation (EC) No 1811/2005 should be amended and Regulation (EC) No 1259/2004 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,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment of Regulation (EC) No 1811/2005

Article 1 and Annex I to Regulation (EC) No 1811/2005 are deleted.

Article 3

Repeal of Regulation (EC) No 1259/2004

Regulation (EC) No 1259/2004 is repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 20 January 2024 in accordance with the rules applicable before 20 July 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 produced and labelled before 20 July 2024 in accordance with the rules applicable before 20 July 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, 29 June 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									
4a1603	DSM Nutritional Products Ltd., represented by DSM Nutritional Products Sp. z o.o.	Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	***Additive composition*** Preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by *Aspergillus fijiensis* CBS 589.94 with a minimum activity of: Coated form: 50 FBG ([1])/g. Liquid form: 120 FBG/mL ***Characterisation of the active substance*** Endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 ***Analytical method*** ([2]) For the quantification of 1,3(4)-beta-glucanase activity in the feed additive: colorimetric method measuring coloured compound produced by the dinitro salicylic acid (DNSA) based on the enzymatic hydrolysis of beta-glucan at pH 5,0 and 50 °C. For the quantification of 1,3(4)-beta-glucanase activity in premixtures and compound feed: colorimetric method measuring water soluble dyed fragments based on the enzymatic hydrolysis of cross-linked azo-barley-glucan at pH 4,5 and 50 °C.	Chickens for fattening Weaned piglets	-	10 FBG	-	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 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.	20 July 2033

(1) One glucanase unit (FBG) corresponds to the amount of enzyme which under standard conditions (pH 5,0 and 30 °C) liberates glucose or other reducing carbohydrates at a rate corresponding to 1 µmol glucose per minute.

(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