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[...] (2024) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of XXX**

**concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 33700 as a feed additive for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, the change of the terms of the authorisation and authorisation of new uses of that preparation as a feed additive for all poultry species and all *Suidae* (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.) and repealing Implementing Regulations (EU) No 1206/2012, (EU) 2020/995 and (EU) 2020/1034**

(Text with EEA relevance)

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(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<sup>1</sup>, and in particular Article 9(2) and Article 13(3) 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, modifying and renewing such an authorisation.
- (2) A preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 26372 was authorised for a period of 10 years as a feed additive for poultry for fattening, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 1206/2012<sup>2</sup>, for lactating sows by Commission Implementing Regulation (EU) 2020/995<sup>3</sup> and for laying hens by Commission Implementing Regulation (EU) 2020/1034<sup>4</sup>.

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

<sup>2</sup> Commission Implementing Regulation (EU) No 1206/2012 of 14 December 2012 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) as a feed additive for poultry for fattening, weaned piglets and pigs for fattening and amending Regulations (EC) No 1332/2004 and (EC) No 2036/2005 (holder of the authorisation DSM Nutritional Products) (OJ L 347, 15.12.2012, p. 12, ELI: [http://data.europa.eu/eli/reg\\_impl/2012/1206/oj](http://data.europa.eu/eli/reg_impl/2012/1206/oj)).

<sup>3</sup> Commission Implementing Regulation (EU) 2020/995 of 9 July 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) as a feed additive for lactating sows (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o.o) (OJ L 221, 10.7.2020, p. 84, ELI: [http://data.europa.eu/eli/reg\\_impl/2020/995/oj](http://data.europa.eu/eli/reg_impl/2020/995/oj)).

<sup>4</sup> Commission Implementing Regulation (EU) 2020/1034 of 15 July 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 26372) as a feed additive for laying hens (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o.o) (OJ L 227, 16.7.2020, p. 34, ELI: [http://data.europa.eu/eli/reg\\_impl/2020/1034/oj](http://data.europa.eu/eli/reg_impl/2020/1034/oj)).

- (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 endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 26372 as a feed additive for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, requesting that additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’. In the context of that application, the holder of the authorisation also proposed changing the terms of the authorisation of the preparation concerned by requesting for a change in the production strain, from *Aspergillus oryzae* DSM 26372 to *Aspergillus oryzae* DSM 33700 in accordance with Article 13(3) of Regulation (EC) No 1831/2003. The application was accompanied by the particulars and documents required under Article 14(2) and by the relevant data supporting the request for the change.
- (4) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of new uses of the preparation endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 33700. The application concerns the authorisation of that preparation as a feed additive for all poultry species and all *Suidae*, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 26 September 2023<sup>5</sup> that the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 33700 remains safe for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is safe for all poultry and all *Suidae*, the consumers and the environment, under the recommended conditions of use. The Authority further stated that both formulations of the additive (liquid and solid) were not irritant to skin. Liquid formulation is not an eye irritant, however, no conclusions can be drawn on the potential of solid formulation to be an eye irritant. Due to the lack of data, the Authority was not able to conclude on the potential of both formulations of the additive to be dermal sensitisers. Due to the proteinaceous nature of the active substance (xylanase), the additive is considered a respiratory sensitiser. As regards the proposed new uses for the additional target species, the Authority concluded that the additive has the potential to be efficacious in all poultry species and in all *Suidae* at the proposed conditions of use. The Authority further concluded that the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 33700 remains efficacious for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens. The Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (6) 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 *Aspergillus oryzae* DSM 33700 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), point (c), of

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<sup>5</sup> EFSA Journal 2023;21(10):8339.

Commission Regulation (EC) No 378/2005<sup>6</sup>, an evaluation report of the Reference Laboratory is therefore not required.

- (7) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 33700 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, and the use of that preparation should be authorised for all poultry species other than poultry for fattening and laying hens, and all *Suidae* other than weaned piglets, pigs for fattening and lactating sows. 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.
- (8) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* DSM 33700 as a feed additive for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, Implementing Regulations (EU) No 1206/2012, (EU) 2020/995 and (EU) 2020/1034 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 *Aspergillus oryzae* DSM 33700 for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, 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.
- (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 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 for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, 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 all poultry species other than poultry for fattening and laying hens, and all

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<sup>6</sup> 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>).

*Suidae* other than weaned piglets, pigs for fattening and lactating sows, subject to the conditions laid down in that Annex.

### *Article 3*

#### **Repeals**

Implementing Regulations (EU) 1206/2012, (EU) 2020/995 and (EU) 2020/1034 are repealed.

### *Article 4*

#### **Transitional measures**

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for poultry for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, and which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 for fattening, weaned piglets, pigs for fattening, lactating sows and laying hens, and which are produced and labelled before [12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*