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

of **XXX**

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 as a feed additive for chickens and turkeys for fattening, ducks, and laying hens, and the authorisation of new uses of that preparation as a feed additive for all other poultry species and categories (holder of authorisation: Genencor International B.V.) and repealing Commission Regulation (EC) No 1087/2009 and Implementing Regulation (EU) No 389/2011

(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 nutrition¹, 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 with *Trichoderma reesei* CBS 143953 (formerly deposited at the American Type Culture Collection (ATCC) PTA 5588), subtilisin produced with *Bacillus subtilis* CBS 143946 (formerly ATCC 2107) and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 (formerly ATCC 3978) was authorised for a period of 10 years as a feed additive for chickens for fattening, for ducks and for turkeys for fattening by Commission Regulation (EC) No 1087/2009² and for laying hens by Commission Implementing Regulation (EU) No 389/2011³.
- (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-

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

² Commission Regulation (EC) No 1087/2009 of 12 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) as a feed additive for chickens for fattening, for ducks and for turkeys for fattening (holder of authorisation Danisco Animal Nutrition, legal entity Finnfeeds International Limited) (OJ L 297, 13.11.2009, p. 4, ELI: <http://data.europa.eu/eli/reg/2009/1087/oj>).

³ Commission Implementing Regulation (EU) No 389/2011 of 19 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase as feed additive for laying hens (holder of authorisation Danisco Animal Nutrition) (OJ L 104, 20.4.2011, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2011/389/oj).

xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 as a feed additive for chickens and turkeys for fattening, ducks and laying hens, requesting that additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’. The application included a proposal for amending the conditions of the original authorisation of the preparation consisting in the reduction of the minimum recommended level in turkeys for fattening (from 300 U endo-1,4-betaxylanase, 4,000 U subtilisin and 400 U alpha-amylase/kg feed to 187.5 U endo-1,4-beta-xylanase, 2,500 U subtilisin and 250 U alpha-amylase/kg feed). 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 of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954. The application concerns the authorisation of that preparation as a feed additive for all poultry species (except ducks) for laying other than laying hens, for fattening other than chickens and turkeys, reared for breeding and reared for laying 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 18 April 2024⁴ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 is safe for chickens for fattening, ducks, turkeys for fattening and laying hens. The conclusion can be extended to all poultry species for fattening, reared for breeding, reared for laying and all poultry species for laying. It further stated that the preparation is safe for consumers and the environment. The Authority also concluded that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 is a mild irritant to skin and eyes, it is not a dermal sensitiser but should be considered a respiratory sensitiser. The Authority further concluded that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 has the potential to be efficacious in ducks at 75 U xylanase, 1000 U subtilisin and 100 U amylase/kg of complete feed, in turkeys for fattening, all poultry species for fattening, reared for breeding and reared for laying (except for ducks) at 187.5 U xylanase, 2500 U subtilisin and 250 U amylase per kg of complete feed and at 300 U xylanase, 4000 U subtilisin and 400 U amylase per kg of complete feed for all poultry species for laying (except for ducks). It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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.

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EFSA Journal. 2024;22:e8797.

- (6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for chickens and turkeys for fattening, ducks and laying hens, and the use of that preparation should be authorised for all poultry species (except ducks) for laying other than laying hens, for fattening other than chickens and turkeys, reared for breeding and reared for laying. 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 with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 as a feed additive for chickens and turkeys for fattening, ducks and laying hens, Regulation (EC) No 1087/2009 and Implementing Regulation (EU) No 389/2011 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 with *Trichoderma reesei* CBS 143953, subtilisin produced with *Bacillus subtilis* CBS 143946 and alpha-amylase produced with *Bacillus amyloliquefaciens* CBS 143954 as a feed additive for chickens and turkeys for fattening, ducks 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.
- (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', is renewed for chickens and turkeys for fattening, ducks 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 (except ducks) for laying other than laying hens, for fattening other than chickens and turkeys, reared for breeding and reared for laying, subject to the conditions laid down in that Annex.

Article 3

Repeals

Regulation (EC) No 1087/2009 and Implementing Regulation (EU) No 389/2011 are repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for chickens and turkeys for fattening, ducks 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 chickens and turkeys for fattening, ducks 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