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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of 6-phytase produced with *Trichoderma reesei* CBS 126897 as a feed additive for fin fish (holder of authorisation: AB Enzymes Finland Oy)

(Text with EEA relevance)

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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 6-phytase produced with *Trichoderma reesei* CBS 126897. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of 6-phytase produced with *Trichoderma reesei* CBS 126897 as a feed additive for fin fish, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 March 2024[2] that, under the proposed conditions of use, the preparation of 6-phytase produced with *Trichoderma reesei* CBS 126897 is safe for fin fish. It further stated that the preparation is safe for consumers and the environment. The Authority also concluded that the preparation of 6-phytase produced with *Trichoderma reesei* CBS 126897, in all formulations of the additive, is neither considered a skin or eye irritant nor a skin sensitiser but is considered a respiratory sensitiser. The Authority further concluded that the preparation of 6-phytase produced with *Trichoderma reesei* CBS 126897 has the potential to be efficacious for salmonids and ornamental fish at 500 FTU/kg complete feed and for other fin fish at 2500 FTU/kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring.

(5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005[3], the Reference Laboratory set up by Regulation (EC) No 1831/2003

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

[2] *EFSA Journal*. 2024;22:e8709.

[3] 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

considered that the conclusions and recommendations reached in a previous assessment concerning the same additive are valid and applicable for the current application.

(6) In view of the above, the Commission considers that the preparation of 6-phytase produced with *Trichoderma reesei* CBS 126897 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for fin fish. 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,

For the Commission
The President
Ursula VON DER LEYEN

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).