EUROPEAN
COMMISSION

Brussels, XXX
SANTE/6173510/2025 CIS
(POOL/G5/2025/6173510/6173510-EN CIS.docx)
[…](2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of 25-hydroxycholecalciferol (vitamin D) produced with Saccharomyces cerevisiae CBS 146008 as a feed additive for all animal species except poultry, pigs and ruminants

(Text with EEA relevance)

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(Text with EEA relevance)**This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.**

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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of 25-hydroxycholecalciferol (vitamin D) produced with Saccharomyces cerevisiae CBS 146008. The 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 a preparation of 25-hydroxycholecalciferol (vitamin D) produced with Saccharomyces cerevisiae CBS 146008 as a feed additive for all animal species except poultry, pigs and ruminants, requesting that additive to be classified in the additive category ‘nutritional additives’ and in the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 20 May 2025[2] that, under the proposed conditions of use, the preparation of 25-hydroxycholecalciferol produced with Saccharomyces cerevisiae CBS 146008 is safe for all animal species except poultry, pigs and ruminants as well as for consumers and the environment. The Authority also concluded that the additive is not irritant to the skin or eyes. However, due to lack of information, no conclusion on its potential to be a skin sensitiser or on its effects on the respiratory system could be reached The Authority further concluded that the additive is efficacious in covering the animal’s

[1] OJ L 268, 18.10.2003, p. 29.
[2] EFSA Journal. 2025;23:e9479. https://doi.org/10.2903/j.efsa.2025.9479

nutritional requirements. It did not considered that there is a need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 5 of July 2023[3] are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory was therefore not required

(6) In view of the above, the Commission considers that a preparation of 25-hydroxycholecalciferol produced with Saccharomyces cerevisiae CBS 146008 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of the preparation should be authorised for all animal species except poultry, pigs and ruminants. 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 ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, 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

[3] EFSA Journal 2023;21(8):8168.https://doi.org/10.2903/j.efsa.2023.8168.

[4] 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).