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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2491

of 10 December 2025

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

(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 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 produced with *Saccharomyces cerevisiae* CBS 146008. That 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 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 target animals' nutritional requirements. It did not consider 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 is therefore not required.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal*. 2025;23:e9479. https://doi.org/10.2903/j.efsa.2025.9479.
([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, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

(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 that 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, 10 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed additive	Name of the 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
					mg active substance/kg of complete feed with a moisture content of 12 %			
Category: Nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect								
Sub classification: vitamin D								
3a670a	25-Hydroxycholecalciferol	*Additive composition* Preparation with a maximum content of 1,25 % of 25-hydroxycholecalciferol Solid form *Characterisation of the active substance* 25-Hydroxycholecalciferol. Its precursor compound,5,7,24-cholestatrienol, is produced with *Saccharomyces cerevisiae* CBS 146008. After extraction, the precursor is converted chemically to 25-hydroxy-pro-vitamin D_3, which is further transformed photochemically to 25-hydroxycholecalciferol. Chemical formula: $C_{27}H_{44}O_2 \bullet H_2O$ CAS number: 63283-36-3 Purity criteria: — 25-hydroxycholecalciferol > 94 %; — other sterol derivatives ≤ 1 % each; — erythrosine < 5 mg/kg.	Salmonids			0,800	1. The additive shall be incorporated in feedingstuffs via the use of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 3. Maximum content of the combination of 25-hydroxycholecalciferol with cholecalciferol (vitamin D_3) per kg of complete feedingstuff: — ≤ 1,500 mg [2] (equivalent to 60 000 IU of cholecalciferol) for salmonids, — ≤ 0,075 mg [2] (equivalent to 3 000 IU of cholecalciferol) for fish species other than salmonids and for ornamental fish,	31 December 2035
			Finfish species other than salmonids			0,075		
			Ornamental fish			0,075		
			Other species and categories of animals except pigs, poultry and ruminants			0,050		

Identification number of the feed additive	Name of the 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
					mg active substance/kg of complete feed with a moisture content of 12 %			
		Analytical method (1) For the determination of 25-hydroxycholecalciferol in the feed additive: Ultra Performance Liquid Chromatography coupled to spectrophotometric detection (UPLC-UV). For the determination of 25-hydroxycholecalciferol in premixtures: High Performance Liquid Chromatography coupled to spectrophotometric detection (HPLC-UV). For the determination of 25-hydroxycholecalciferol in compound feed and in low concentrated premixtures: High Performance Liquid Chromatography coupled to tandem mass spectrometry (HPLC-MS/MS).					— ≤ 0,050 mg (2) (equivalent to 2 000 IU of cholecalciferol) for other categories of animals except poultry, pigs and ruminants. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 and skin protective equipment.	

(1) 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.

(2) 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).

ELI: http://data.europa.eu/eli/reg_impl/2025/2491/oj