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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1070

of 12 April 2024

concerning the renewal of the authorisation of a preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs and the authorisation of that preparation for ruminants and repealing Commission Regulation (EC) No 887/2009

(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 and renewing such an authorisation.

(2) A preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 was authorised for a period of 10 years as a feed additive by Commission Regulation (EC) No 887/2009 ([2]) for chickens for fattening, turkeys for fattening, other poultry, and pigs.

(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 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of that preparation for ruminants. Those applications requested that additive to be classified in the category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' and were accompanied by the particulars and documents required respectively under Article 14(2) and Article 7(3) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 5 July 2023 ([3]) that under the conditions of use currently authorised the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 remains safe for chickens for fattening, turkeys for fattening, other poultry and pigs, and that it is safe for all ruminants. It concluded also that the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is safe for the consumers and the environment. It concluded that the preparation of 25- hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is an efficient source of vitamin D_3 for all ruminants and that, since the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority also concluded that 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is not irritant to the skin or eyes but no conclusion on its potential to be a skin sensitiser or on its effects on the respiratory system can be reached due to absence of data. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) Commission Regulation (EC) No 887/2009 of 25 September 2009 concerning the authorisation of a stabilised form of 25-hydroxycholecalciferol as a feed additive for chickens for fattening, turkeys for fattening, other poultry and pigs (OJ L 254, 26.9.2009, p. 68, ELI: http://data.europa.eu/eli/reg/2009/887/oj).
([3]) *EFSA Journal* 2023;21(8):8168 and *EFSA Journal* 2023;21(8):8169.

(5) The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003 for the application for renewal of the authorisation for chickens for fattening, turkeys for fattening, other poultry and pigs. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ([4]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive are valid and applicable for the current application for ruminants.

(6) In view of the above, the Commission considers that the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 ([5]) 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 for fattening, turkeys for fattening, other poultry and pigs and should be authorised for ruminants. As 25-hydroxycholecalciferol depresses the activity of 1α-hydroxylase in the kidney, the Commission considers that the simultaneous use of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract with that additive should not be allowed. The Commission further considers that the combination of the preparation of 25-hydroxycholecalciferol with cholecalciferol should be limited in order not to exceed the maximum daily intake level for vitamin D_3. The Commission considers that the restriction to use the additive via premixtures should be maintained. 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) As a consequence of the renewal of the authorisation of the preparation of 25-hydroxycholecalciferol, Regulation (EC) No 887/2009 should be repealed.

(8) 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 the authorisation

The authorisation of 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 renewed for chickens for fattening, turkeys for fattening, other poultry and pigs, subject to the conditions laid down in that Annex.

Article 2

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 for ruminants, subject to the conditions laid down in that Annex.

Article 3

Repeal

Regulation (EC) No 887/2009 is repealed.

([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 additive (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

([5]) *EFSA Journal* 2023;21(8):8168.

Article 4

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, 12 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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-Hydroxy cholecalciferol	*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-hydroxycholecalfciferol. $C_{27}H_{44}O_2.H_2O$ CAS number: 63283-36-3 Purity criteria — 25-hydroxycholecalciferol > 94 % — other sterol derivatives ≤ 1 % each — erythrosine < 5 mg/kg	Chickens for fattening			0,100	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: — ≤ 0,125 mg [2] (equivalent to 5 000 IU of cholecalciferol) for chickens for fattening and turkeys for fattening, — ≤ 0,080 mg (equivalent to 3 200 IU of cholecalciferol) for other poultry,	5 May 2034
			Turkeys for fattening			0,100		
			Other poultry			0,080		
			Pigs			0,050		
			Bovines and ovines			0,100		
			Ruminants other than bovines and ovines			0,050		

		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 (equivalent to 2 000 IU of cholecalciferol) for pigs, — ≤ 0,100 mg (equivalent to 4 000 IU of cholecalciferol) for milk replacers for calves, — ≤ 0,100 mg (equivalent to 4 000 IU of cholecalciferol) for bovines and ovines, — ≤ 0,050 mg (equivalent to 2 000 IU of cholecalciferol) for ruminants other than bovines and ovines. 4. The simultaneous use of the additive with glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophylum* extract shall not be permitted. 5. 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://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports.
([2]) 40 IU cholecalciferol (vitamin D_3) = 0,001 mg cholecalciferol (vitamin D_3).

ELI: http://data.europa.eu/eli/reg_impl/2024/1070/oj