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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC [2].

(2) A stabilised form of 25-hydroxycholecalciferol, CAS number 63283-36-3, was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening, laying hens and turkeys by Commission Regulation (EC) No 1443/2006 [3]. That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that additive and, in accordance with Article 7 of that Regulation, for a new use on other poultry and pigs, requesting that additive to be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 5 February 2009 that that additive does not have an adverse effect on animal health, consumer health or the environment and that its use is efficacious as a substitute for vitamin D_3 [4]. The Authority recommends appropriate measures for user safety. It does 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on that preparation in Regulation (EC) No 1443/2006 should be deleted.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 270, 14.12.1970, p. 1.
[3] OJ L 271, 30.9.2006, p. 12.
[4] *The EFSA Journal* (2009) 969, pp. 1-32.

Article 2

In Regulation (EC) No 1443/2006, Article 3 and Annex III are deleted.

Article 3

This Regulation shall enter into force on the 20th day following 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, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Identification number of the additive	Name of the holder of authorisation	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/kg of complete feedingstuff with a moisture content of 12 %			
Category: nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect									
Sub classification: vitamin D									
3a670a	—	25-hydroxy cholecalciferol	Additive composition: Stabilised form of 25-hydroxycholecalciferol Characterisation of the active substance: 25-hydroxycholecalciferol, $C_{27}H_{44}O_2.H_2O$ CAS number: 63283-36-3 Purity criteria: 25-hydroxycholecalciferol > 94 % other related sterols < 1 % each erythrosine < 5 mg/kg Analytical method (1) Determination of 25-hydroxycholecalciferol: high performance liquid chromatography coupled to a mass spectrometer (HPLC-MS) Determination of vitamin D_3 in complete feedingstuff: reverse phase HPLC method with ultraviolet (UV) detection at 265 nm [EN 12821:2000]	Chickens for fattening	—		0,100	1. The additive shall be incorporated in feedingstuffs via the use of a premixture. 2. Maximum content of the combination of 25-hydroxycholecalciferol with vitamin D_3 (cholecalciferol) per kg of complete feedingstuff: — ≤ 0,125 mg (2) (equivalent to 5 000 IU of vitamin D_3) for chickens for fattening and turkeys for fattening, — ≤ 0,080 mg for other poultry, — ≤ 0,050 mg for pigs. 3. Simultaneous use of vitamin D_2 is not allowed. 4. The content of ethoxyquin shall be indicated in the label. 5. For safety: breathing protection shall be used.	16 October 2019
				Turkeys for fattening	—		0,100		
				Other poultry	—		0,080		
				Pigs	—		0,050		

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives
(2) 40 IU cholecalciferol (vitamin D_3)= 0,001 mg cholecalciferol (vitamin D_3).