Commission Implementing Regulation (EU) 2017/1492 of 21 August 2017 concerning the authorisation of cholecalciferol as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1492

of 21 August 2017

concerning the authorisation of cholecalciferol as a feed additive for all animal species

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

(2) Cholecalciferol was authorised without a time limit by Directive 70/524/EEC as a feed additive for all animal species. That additive was subsequently entered in the 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 thereof, three applications were submitted for the re-evaluation of cholecalciferol as a feed additive for all animal species and, in accordance with Article 7 of that Regulation, for the use in water for drinking. The applicants requested that additive to be classified in the additive category ‘nutritional additives’. Those applications were 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 opinions of 13 November 2012[(3)], 20 June 2013[(4)], 30 January 2014[(5)] and 25 January 2017[(6)] that, under the proposed conditions of use in feed, cholecalciferol does not have adverse effects on animal health, human health or the environment. The Authority further concluded that cholecalciferol is an effective source of vitamin D_3.

(5) The Authority concluded in its opinions that for some formulations of vitamin D_3 there is a potential for workers to be exposed to high levels of vitamin D_3 by inhalation. Inhaled vitamin D_3 is highly toxic and exposure to dust is harmful. Consequently,

appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of cholecalciferol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied except for water for drinking. Accordingly, the use of that substance should be authorised in feed as specified in the Annex to this Regulation. Maximum contents should be set for cholecalciferol. Cholecalciferol should not be administered directly via water for drinking because an additional route of administration would increase the risk for consumers and animals. Therefore, the authorisation of cholecalciferol as nutritional additive belonging to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' should be denied as regards their use in water. This prohibition does not apply to this substance when is used within compound feeds which are subsequently administered via water.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of cholecalciferol it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

Authorisation

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, provitamins and chemically well-defined substances having similar effect', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Denial

Authorisation of cholecalciferol, as an additive belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, provitamins and chemically well-defined substances having similar effect', is denied for its use in water for drinking.

Article 3

Transitional Measures

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 11 March 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 11 September 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3 Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 11 September 2019 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1492. (See end of Document for details)*

[F1ANNEX

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/849 of 24 May 2019 amending Implementing Regulation (EU) 2017/1492 as regards the maximum content of cholecalciferol (vitamin D3) in feed for salmonids (Text with EEA relevance).

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
						IU of cholecalciferol[a]/kg of complete feedingstuff with a moisture content of 12 %.			
Category of nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect.									
3a671	—	‘Cholecalciferol’ or ‘Vitamin D_3’	*Additive composition* Cholecalciferol. *Characterisation of the active substance* Cholecalciferol $C_{27}H_{44}O$ CAS number: 67-97-0 Cholecalciferol solid and resin form, produced by chemical synthesis. Purity criteria: Min. 80 % (cholecalciferol and	Pigs	—	—	2 000 IU	1. Vitamin D_3 may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the	11 September 2027
				Milk replacers for piglets	—	—	10 000 IU		
				Bovines	—	—	4 000 IU		
				Milk replacers for calves	—	—	10 000 IU		
				Ovines	—	—	4 000 IU		
				Chickens for fattening	—	—	5 000 IU		
				Turkeys	—	—	5 000 IU		
				Other poultry	—	—	3 200 IU		
				Equines	—	—	4 000 IU		

a 40 IU cholecalciferol = 0,001 mg cholecalciferol

b 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]