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►**B** **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)

(OJ L 216, 22.8.2017, p. 19)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2019/849 of 24 May 2019	L 139	4	27.5.2019

▼B

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)

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.

▼M1

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
						IU of cholecalciferol ([1])/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 precholecalciferol) and max. 7 % tachysterol. *Method of analysis* ([2]) — For the determination of Vitamin D_3 in the feed additive: High Performance Liquid Chromatography coupled to UV detection (HPLC-UV, 254 nm) - European Pharmacopoeia method 01/2008:0574,0575,0598.	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 directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 4. Maximum content of the combination of 25-hydroxycholecalciferol with cholecalciferol per kg of complete feedingstuff: — ≤ 5 000 IU of vitamin D_3 for chickens for fattening and turkeys for fattening, — ≤ 3 200 IU for other poultry, — ≤ 2 000 IU for pigs. 5. Simultaneous use with Vitamin D_2 is not allowed.	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		
				Salmonids	—	—	60 000 IU		
				Other fish species	—	—	3 000 IU		
				Other animal species	—	—	2 000 IU		

▼M1

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 (1)/kg of complete feedingstuff with a moisture content of 12 %.			
			— For the determination of Vitamin D_3 in premixtures: High Performance Liquid Chromatography coupled to UV detection at 265 nm (HPLC-UV) - VDLUFA 1997, Methodenbuch, Method 13.8.1. — For the determination of vitamin D_3 in feedingstuffs: — High Performance Liquid Chromatography coupled to UV detection at 265 nm (HPLC-UV)- VDLUFA 1997, Methodenbuch, Method 13.8.1; or — Reverse-Phase High Performance Liquid Chromatography coupled to UV detection at 265 nm (RP-HPLC-UV), EN 12821. — For the determination of vitamin D_3 in water: Reverse-Phase High Performance Liquid Chromatography coupled to UV detection at 265 nm (RP-HPLC-UV), EN 12821.					6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the very hazardous effects of vitamin D_3 by inhalation. Where the risks associated to those very hazardous effects cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	

(1) 40 IU cholecalciferol = 0,001 mg cholecalciferol
(2) 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