COMMISSION IMPLEMENTING REGULATION (EU) 2015/724

of 5 May 2015

concerning the authorisation of retinyl acetate, retinyl palmitate and retinyl propionate as feed additives 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]), 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) Vitamin A was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That product was subsequently entered in the Register of feed additives as 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, an application was submitted for the re-evaluation of vitamin A in the form of retinyl acetate, retinyl palmitate and retinyl propionate as feed additives and their preparations for all animal species and, in accordance with Article 7 of that Regulation, for a new use in water for drinking. The applicant requested these additives 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 12 December 2012 ([3]) that, under the proposed conditions of use in feed, retinyl acetate, retinyl palmitate and retinyl propionate do not have an adverse effects on animal health, human health or the environment.

(5) The Authority further concluded that retinyl acetate, retinyl palmitate and retinyl propionate are effective sources of vitamin A and that no safety concerns would arise for users. 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 retinyl acetate, retinyl palmitate and retinyl propionate 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 these substances should be authorised in feed as specified in the Annex to this Regulation. Maximum contents should be set for vitamin A irrespective of its form. Vitamin A should not be administered directly via water for drinking because an additional route of administration would increase the risk for consumers. Therefore, the authorisation of retinyl acetate, retinyl palmitate and retinyl propionate as nutritional additives 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 those additives within a compound feed subsequently administered via water.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, 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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) *EFSA Journal 2013;11(1):3037*.

HAS ADOPTED THIS REGULATION:

Article 1

The substances 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', are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Authorisation of retinyl acetate, retinyl palmitate and retinyl propionate, as additives belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is denied for use in water.

Article 3

The substances specified in the Annex and premixtures containing these substances, which are produced and labelled 26 November 2015 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 26 May 2016 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 26 May 2017 in accordance with the rules applicable before 26 May 2015 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

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, 5 May 2015.

For the Commission
The President
Jean-Claude JUNCKER

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 vitamin 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 a similar effect									
3a672a	—	'Retinyl acetate', or 'Vitamin A'	*Additive composition* Retinyl acetate Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg *Characterisation of the active substance* Retinyl acetate $C_{22}H_{32}O_2$ CAS No: 127-47-9 Retinyl acetate, solid form, produced by chemical synthesis. Purity criteria: min. 95 % (min. 2,76 MIU/g). *Methods of analysis* (1) For the determination of Vitamin A in the feed additive: thin Layer Chromatography and UV detection (TLC-UV) (Ph. Eur. 6th edition, monograph 0217). For the determination of Vitamin A in premixtures and feedingstuffs: Reversed Phase High Performance Liquid Chromatography (RP-HPLC) with UV or fluorescence detection — Commission Regulation (EC) No 152/2009 (2).	Piglets (suckling and weaned)	—	—	16 000	1. The additive shall be incorporated into the feed via a premixture. 2. Retinyl acetate may be placed on the market and used as an additive consisting of a preparation. 3. For the content, as set out on the label the following equivalency shall be used: 1IU = 0,344 µg retinyl acetate. 4. The mixture of retinyl acetate, retinyl palmitate or retinyl propionate shall not exceed the maximum content for the relevant species and categories. 5. In the directions for use of the additive and premixtures indicate storage and stability conditions. 6. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	26 May 2025
				Pigs for fattening	—	—	6 500		
				Sows	—	—	12 000		
				Other pigs	—	—	—		
				Chickens and minor poultry species	≤ 14 days	—	20 000		
					> 14 days	—	10 000		
				Turkeys	≤ 28 days	—	20 000		
					> 28 days	—	10 000		
				Other poultry	—	—	10 000		
				Dairy cows and cows for reproduction		—	9 000		
				Calves for rearing	4 months	—	16 000		
				Other calves and cows	—	—	25 000		

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 vitamin A/kg of complete feedingstuff with a moisture content of 12 %			
				Lambs and kids for rearing	≤ 2 months	—	16 000		
					> 2 months	—	—		
				Cattle, sheep and goats for fattening	—	—	10 000		
				Other bovines, sheep and goats	—	—	—		
				Mammals	—	—	Milk replacers only: 25 000		
				Other animal species	—	—	—		
3a672b		'Retinyl palmitate' or 'Vitamin A'	*Additive composition* Retinyl palmitate Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg of the additive *Characterisation of the active substance* Retinyl palmitate $C_{36}H_{60}O_2$ Cas No:79-81-2 Retinyl palmitate, solid and liquid forms, produced by chemical synthesis: min. 90 % or 1,64 MIU/g.	Piglets (suckling and weaned)	—	—	16 000	1. The additive shall be incorporated into the feed via a premixture. 2. Retinyl palmitate may be placed on the market and used as an additive consisting of a preparation. 3. For the content, as set out on the label, the following equivalency shall be used: 1IU = 0,5458 µg retinyl palmitate.	26 May 2025
				Pigs for fattening	—	—	6 500		
				Sows	—	—	12 000		
				Other pigs	—	—	—		
				Chickens and minor poultry species	≤ 14 days	—	20 000		
					> 14 days	—	10 000		

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 vitamin A/kg of complete feedingstuff with a moisture content of 12 %			
			Methods of analysis ([1]) For the determination of Vitamin A in the feed additive: thin Layer Chromatography and UV detection (TLC-UV) (Ph. Eur. 6th edition, monograph 0217). For the determination of Vitamin A in premixtures and feedingstuffs: Reversed Phase High Performance Liquid Chromatography (RP-HPLC) with UV or fluorescence detection — Regulation (EC) No 152/2009.	Turkeys	≤ 28 days	—	20 000	4. The mixture of retinyl acetate, retinyl palmitate or retinyl propionate shall not exceed the maximum content for the relevant species and categories. 5. In the directions for use of the additive and premixtures indicate storage and stability conditions. 6. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	
					> 28 days	—	10 000		
				Other poultry	—	—	10 000		
				Dairy cows and cows for reproduction	—	—	9 000		
				Calves for rearing	4 months	—	16 000		
				Other calves and cows	—	—	25 000		
				Lambs and kids for rearing	≤ 2 months	—	16 000		
					> 2 months	—	—		
				Cattle, sheep and goats for fattening	—	—	10 000		
				Other bovines, sheep and goats	—	—	—		
				Mammals	—	—	Milk replacers only: 25 000		
				Other animal species	—	—	—		

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 vitamin A/kg of complete feedingstuff with a moisture content of 12 %			
3a672c		'Retinyl propionate' or 'Vitamin A'	*Additive composition* Retinyl propionate Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg of the additive *Characterisation of the active substance* Retinyl propionate $C_{23}H_{34}O_2$ Cas No.:7069-42-3 Retinyl propionate, liquid form, produced by chemical synthesis: min. 95 % or 2,64 MIU/g *Methods of analysis* (1) For the determination of Vitamin A in the feed additive: thin Layer Chromatography and UV detection (TLC-UV) (Ph. Eur. 6th edition, monograph 0217). For the determination of Vitamin A in premixtures and feedingstuffs: Reversed Phase High Performance Liquid Chromatography (RP-HPLC) with UV or fluorescence detection — Regulation (EC) No 152/2009.	Piglets (suckling and weaned)	—	—	16 000	1. The additive shall be incorporated into the feed via a premixture. 2. Retinyl propionate may be placed on the market and used as an additive consisting of a preparation. 3. For the content, as set out on the label, the following equivalency shall be used: 1IU = 0,3585 µg retinyl propionate. 4. The mixture of retinyl acetate, retinyl palmitate or retinyl propionate shall not exceed the maximum content for the relevant species and categories. 5. In the directions for use of the additive and premixtures indicate storage and stability conditions 6. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	26 May 2025
				Pigs for fattening	—	—	6 500		
				Sows	—	—	12 000		
				Other pigs	—	—	—		
				Chickens and minor poultry species	≤ 14 days	—	20 000		
					> 14 days	—	10 000		
				Turkeys	≤ 28 days	—	20 000		
					> 28 days	—	10 000		
				Other poultry	—	—	10 000		
				Dairy cows and cows for reproduction	—	—	9 000		
				Calves for rearing	4 months	—	16 000		
				Other calves or cows	—	—	25 000		
				Lambs and kids for rearing	≤ 2 months	—	16 000		
					> 2 months	—	—		

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 vitamin A/kg of complete feedingstuff with a moisture content of 12 %			
				Cattle, sheep and goats for fattening	—	—	10 000		
				Other bovines, sheep and goats	—	—	—		
				Mammals	—	—	Milk replacers only: 25 000		
				Other animal species	—	—	—		

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
(2) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).