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COMMISSION IMPLEMENTING REGULATION (EU) 2025/281

of 12 February 2025

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

(2) Propyl gallate was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) 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 propyl gallate as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'technological additives' and in the functional group 'antioxidants'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The applicant requested the additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of technological additives for use in water for drinking. Therefore, the use of the additive in water for drinking should not be allowed.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 March 2020 ([3]) and 31 January 2024 ([4]) (as readopted on 26 June 2024) that propyl gallate is safe for all animal species and for consumers at certain maximum concentrations further specified in the opinions and for the environment. The Authority also concluded that propyl gallate is irritant to skin and eyes, it is a dermal sensitiser and that exposure via inhalation is possible and it is considered a hazard. The Authority further concluded that the additive has the potential to act as an antioxidant in feedingstuffs for all animal species. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) In view of the above, the Commission considers that propyl gallate satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. 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.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: http://data.europa.eu/eli/dir/1970/524/oj).
([3]) *EFSA Journal* 2020;18(4):6069.
([4]) *EFSA Journal*. 2024;22:e8638.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to provide for 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 'technological additives' and to the functional group 'antioxidants', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additive propyl gallate, as authorised pursuant to Directive 70/524/EEC and premixtures containing this additive, which are produced and labelled before 5 September 2025 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 March 2026 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 March 2027 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 3

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 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

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 complete feedingstuff with 12 % moisture content			
Category: technological additives. Functional group: antioxidants								
1b310	Propyl gallate	*Additive composition* Propyl gallate ≥ 97 % Solid form Sulphated ash < 0,1 % Gallic acid < 0,5 % Chlorinated organic compounds < 100 mg/kg *Characterisation of the active substance* Propyl gallate Produced by esterification of gallic acid from gallnuts Chemical formula: $C_{10}H_{12}0_5$ CAS No: 121-79-9	Bovines Sheep Goats Cervids Camelids Sows of all Suidae species Equines Salmonids and minor fin fish	-	-	40	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 skin, eye and breathing protective equipment.	
			Ornamental fish			100		

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 complete feedingstuff with 12 % moisture content			
Category: technological additives. Functional group: antioxidants								
		Analytical method (1) For the quantification of propyl gallate in the feed additive: — Spectrophotometry at 275 nm (European Pharmacopoeia monograph 1039) For the quantification of propyl gallate in premixtures and compound feed: — Reversed Phase High Performance Liquid Chromatography coupled to UltraViolet-Diode-Array Detection (RP-HPLC-UV(DAD), 285 nm)	Chickens for fattening Minor poultry for fattening and reared for laying or reared for reproduction Ornamental birds			15		
			Turkeys for fattening Laying hens Minor poultry species for laying or for reproduction Leporids			20		

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 complete feedingstuff with 12 % moisture content			
Category: technological additives. Functional group: antioxidants								
			Piglets of all Suidae species All Suidae species for fattening and reared for reproduction			27		
			Dogs Cats			71		
			All other animal species			15		

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.