COMMISSION IMPLEMENTING REGULATION (EU) 2015/1061

of 2 July 2015

concerning the authorisation of ascorbic acid, sodium ascorbyl phosphate, sodium calcium ascorbyl phosphate, sodium ascorbate, calcium ascorbate and ascorbyl palmitate 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]), 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) Ascorbic acid, sodium ascorbyl phosphate, sodium calcium ascorbyl phosphate, sodium ascorbate, calcium ascorbate and ascorbyl palmitate were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, 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, two applications were submitted for the re-evaluation of ascorbic acid, sodium ascorbyl phosphate and sodium calcium ascorbyl phosphate as feed additives for all animal species and, in accordance with Article 7 of that Regulation, for a new use in water for drinking for ascorbic acid. The applicants requested these additives to be classified in the additive category 'nutritional additives'. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) 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 ascorbic acid, sodium ascorbate, calcium ascorbate and ascorbyl palmitate as feed additives for all animal species. The applicant requested these additives to be classified in the additive category 'technological additives'. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 30 January 2013 ([3]) that, under the proposed conditions of use in feed, ascorbic acid, sodium ascorbyl phosphate, sodium calcium ascorbyl phosphate, sodium ascorbate, calcium ascorbate and ascorbyl palmitate do not have adverse effects on animal health, human health or the environment. The Authority also concluded that ascorbic acid, sodium ascorbyl phosphate and sodium calcium ascorbyl phosphate are regarded as effective sources of vitamin C and that since ascorbic acid, sodium ascorbate, calcium ascorbate and ascorbyl palmitate are authorised for use as antioxidants in food and their function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

(6) The Authority further concluded 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 and in water for ascorbic acid, submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

([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(2):3103 and EFSA Journal 2013; 11(2):3104.

(7) The assessment of ascorbic acid, sodium ascorbyl phosphate, sodium calcium ascorbyl phosphate, sodium ascorbate, calcium ascorbate and ascorbyl palmitate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(8) 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.

(9) 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

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.

2. The substances specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'antioxidants', are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 23 January 2016 in accordance with the rules applicable before 23 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 23 July 2016 in accordance with the rules applicable before 23 July 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.

3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 July 2017 in accordance with the rules applicable before 23 July 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 3

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, 2 July 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
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 % or mg of active substance/l of water			
Category of nutritional additives. Functional group: vitamins, provitamins and chemically well-defined substances having a similar effect									
3a300	—	'Ascorbic acid' or 'Vitamin C'	*Additive composition* Ascorbic acid. *Characterisation of the active substance* L-ascorbic acid $C_6H_8O_6$ CAS No: 50-81-7 L-ascorbic acid, solid form, produced by chemical synthesis. Purity criteria: min 99 %. *Analytical methods* (1) For the determination of L-ascorbic acid in the feed additive: titrimetry — European Pharmacopoeia monograph (Ph.Eur. 01/2011:0253). For the quantification of L-ascorbic acid in premixtures and feedingstuffs: titrimetry. For the quantification of L-ascorbic acid in water: — Titrimetry (AOAC 967.21); or — High Performance Liquid Chromatography coupled to UV detection at 265 nm (EN 14130:2003)	All animal species	—	—	—	1. Ascorbic acid may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 3. For safety: breathing protection, safety glasses and gloves shall be worn during handling. 4. The additive may be used in water for drinking.	23 July 2025

(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

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 of active substance/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									
3a311		'Sodium ascorbyl phosphate' or 'Vitamin C'.	*Additive composition* Sodium ascorbyl phosphate. *Characterisation of the active substance* Sodium ascorbyl phosphate $C_6H_6O_9Na_3P \cdot 2H_2O$ CAS No: 66170-10-3 Sodium ascorbyl phosphate, solid form, produced by chemical synthesis. Purity criteria: min. 95 % with a min. content of 45 % ascorbic acid. *Analytical methods* (1) For the determination of the purity of sodium ascorbyl phosphate and the ascorbic acid equivalent in the feed additive: High Performance Liquid Chromatography coupled to Variable Wavelength Detector (VWD). For the quantification of total sodium in the feed additive: — Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or — Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN15510:2007). For the quantification of ascorbyl monophosphate in premixtures and feedingstuffs: High Performance Liquid Chromatography coupled to UV detection at 254 nm (HPLC-UV).	All animal species	—	—	—	1. Sodium ascorbyl phosphate may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 3. For safety: breathing protection, shall be used during handling.	23 July 2025

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
3a312		'Sodium calcium ascorbyl phosphate' or 'Vitamin C'.	*Additive composition* Sodium calcium ascorbyl phosphate. *Characterisation of the active substance* Sodium calcium ascorbyl phosphate $C_6H_6O_9P \cdot CaNa$. Sodium- calcium-L-ascorbyl phosphate, solid form, produced by chemical synthesis. Purity criteria: min. 95 % with a min. content of 35 % ascorbic acid. *Analytical methods* (1) For the determination of the purity of sodium calcium ascorbyl phosphate and the ascorbic acid equivalent in the feed additive: High- Performance Liquid Chromatography coupled to Variable Wavelength Detector (VWD). For the quantification of total calcium and total sodium in the feed additive: — Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or — Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN15510:2007). For the quantification of ascorbyl monophosphate in premixtures and feedingstuffs: High- Performance Liquid Chromatography coupled to UV detection at 254 nm (HPLC-UV).	All animal species				1. Sodium calcium ascorbyl phosphate may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 3. For user safety: breathing protection, shall be used during handling.	23 July 2025

(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

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional Group antioxidants									
3a300	—	Ascorbic acid	*Additive composition* Ascorbic acid. *Characterisation of the active substance* L-ascorbic acid $C_6H_8O_6$ CAS No: 50-81-7 L-ascorbic acid, solid form, produced by chemical synthesis. Purity criteria: min 99 %. *Analytical methods* (1) For the determination of L-ascorbic acid in the feed additive: titrimetry — European Pharmacopoeia monograph (Ph.Eur. 01/2011:0253). For the quantification of L-ascorbic acid in premixtures and feedingstuffs: titrimetry.	All animal species	—	—	—	1. Ascorbic acid may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive indicate the stability and storage conditions and for the premixtures the storage conditions. 3. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	23 July 2025
1b301		Sodium ascorbate	*Additive composition* Sodium ascorbate. *Characterisation of the active substance* Sodium L ascorbate. $C_6H_7O_6Na$ CAS No: 134-03-2 Sodium L-ascorbate, solid form, produced by chemical synthesis. Purity criteria: min. 99 %.	All animal species	—	—	—	1. In the directions for use of the additive indicate the stability and storage conditions and for the premixtures the storage conditions. 2. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	23 July 2025

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			Analytical methods (1) For the determination of Sodium L-ascorbate in the feed additive: titrimetry — European Pharmacopoeia monograph (Ph.Eur. 01/2011:1791). For the quantification of total sodium in the feed additive: — Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or — Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN15510:2007). For the quantification of Sodium L-ascorbate in premixtures and feedingstuffs: titrimetry.						
1b302		Calcium ascorbate	*Additive composition* Calcium ascorbate. *Characterisation of the active substance* Calcium L-(+)-ascorbate dehydrate $C_{12}H_{14}O_{12}Ca \cdot 2H_2O$ CAS No: 5743-28-2 Calcium L-(+)-ascorbate dehydrate, solid form, produced by chemical synthesis. Purity criteria: min. 99 %. *Analytical methods* (1) For the determination of Calcium L-ascorbate in the feed additive: Titrimetry — European Pharmacopoeia monograph (Ph.Eur. 01/2008:1182).	All animal species	—	—	—	1. In the directions for use of the additive indicate the stability and storage conditions and for the premixtures the storage conditions. 2. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	23 July 2025

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			For the quantification of total calcium in the feed additive: — Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or — Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN15510:2007). For the quantification of Calcium L-ascorbate in premixtures and feedingstuffs: titrimetry.						
1b304		Ascorbyl palmitate	*Additive composition* Ascorbyl palmitate. *Characterisation of the active substance* L-ascorbyl-6-palmitate $C_{22}H_{38}O_7$ CAS No: 137-66-6 L-ascorbyl-6- palmitate, solid form, produced by chemical synthesis. Purity criteria: min. 98 %. *Analytical method* (1) For the determination of L-ascorbyl-6-palmitate in the feed additive: — Titrimetry — European Pharmacopoeia monograph (Ph.Eur. 01/2008:0807).	All animal species	—	—	—	1. In the directions for use of the additive indicate the stability and storage conditions and for the premixtures the storage conditions. 2. For safety breathing protection, safety glasses and gloves shall be worn during handling.	23 July 2025

(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