COMMISSION IMPLEMENTING REGULATION (EU) No 669/2014

of 18 June 2014

concerning the authorisation of calcium D-pantothenate and D-panthenol 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) Calcium D-pantothenate and D-panthenol were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for use on all animal species as part of the group 'Vitamins, pro-vitamins and chemically well-defined substances having similar effect'. Those feed additives were subsequently entered in the Community 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 calcium D-pantothenate and D-panthenol as feed additives for all animal species and, in accordance with Article 7 of that Regulation, for a change in the terms of the authorisation as regards their use via drinking water. The applicants requested those additives 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 11 October 2011 ([3]) that, under the proposed conditions of use in feed, calcium D-pantothenate and D-panthenol do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that calcium D-pantothenate and D-panthenol are regarded as effective sources of pantothenic acid and that no safety concerns would arise for users provided that appropriate protective measures are 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.

(5) The assessment of calcium D-pantothenate and D-panthenol 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.

(6) 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 the disposal of existing stocks of the additives, premixtures and compound feed containing them, as authorised by Directive 70/524/EEC.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) *EFSA Journal* 2011; 9(11):2409 and *EFSA Journal* 2011; 9(11):2410.

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

The substances specified in the Annex and feed containing those substances, which are produced and labelled before 9 January 2015 in accordance with the rules applicable before 9 July 2014 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 18 June 2014.

For the Commission
The President
José Manuel BARROSO

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/kg of complete feedingstuff with a moisture content of 12 % or mg/l of water			
Category: Nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect									
3a841	—	Calcium D-pantothenate	*Additive composition* Calcium D-pantothenate. *Characterisation of the active substance* Calcium D-pantothenate $Ca[C_9H_{16}NO_5]_2$ CAS No: 137-08-6 Calcium D-pantothenate, solid form, produced by chemical synthesis. Purity criteria: 1. Min. 98 % (on dry basis) 2. Max. 0,5 % 3-aminopropionic acid. *Method of Analysis* (1) — For the determination of Calcium D-pantothenate in the feed additive: potentiometric titration with perchloric acid and identification by specific optical rotation (European Pharmacopoeia monograph 0470). — For the determination of Calcium D-pantothenate in premixtures and feedingstuffs: Reverse Phase High-Performance Liquid Chromatography coupled to a single-quadrupole mass selective detector (RP-HPLC-MS).	All animal species.	—	—	—	1. May be used also via water for drinking. 2. In the directions for use of the additive and premixture, indicate the storage and stability conditions. 3. For safety: breathing protection, safety glasses and gloves should be worn during handling.	19 June 2024

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/kg of complete feedingstuff with a moisture content of 12 % or mg/l of water			
3a842	—	D-Panthenol	*Additive composition* D-Panthenol *Characterisation of the active substance.* D-Panthenol $C_9H_{19}NO_4$ CAS No: 81-13-0 D-Panthenol, liquid form, produced by chemical synthesis Purity criteria: 1. Min. 98 % on anhydrous basis (water < 1 %) 2. Max. 0,5 % 3-aminopropanol. *Method of Analysis* (1) — For the determination of D-panthenol in the feed additive: titration with perchloric acid and potassium hydrogen phthalate and identification by specific optical rotation and infrared spectroscopy (European Pharmacopoeia monograph 0761). — For the determination of D-panthenol in water: Reverse Phase High-Performance Liquid Chromatography, coupled to UV detector (RP-HPLC).	All animal species	—	—		1. To be used only via water for drinking. 2. In the directions for use of the additive indicate the storage conditions. 3. For safety: breathing protection, safety glasses and gloves should be worn during handling.	19 June 2024

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx