

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1409
of 27 August 2021
concerning the authorisation of phytomenadione as a feed additive for horses
(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of phytomenadione. ⁽²⁾ That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of phytomenadione as a feed additive for horses. The applicant requested this additive to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ⁽³⁾ that, under the proposed conditions of use, phytomenadione does not have adverse effects on animal health, consumer safety or the environment. The Authority concluded that users will not be exposed by inhalation when the additive is presented in solid form or viscous liquid. Data from the Scientific Committee on Consumer Safety indicates that vitamin K₁ can be categorised as a dermal sensitiser. For preparations, the Authority could not conclude on their potential to be toxic by inhalation or on their potential as skin/eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive and its preparations. The Authority concluded that phytomenadione is considered as an efficacious source of vitamin K₁ for horses, when added to feed. 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 phytomenadione shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of phytomenadione should be authorised. 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

The substance 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 a similar effect', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Also known as vitamin K₁.

⁽³⁾ EFSA Journal 2021;19(4):6538

Article 2

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a712	'Phytomenadione' or 'Vitamin K ₁ '	<p>Additive composition Preparation containing ≥ 4,2 % of phytomenadione. Solid form</p> <p>Characterisation of active substance 2-methyl-3-[(E,7R,11R)-3,7,11,15-tetramethylhexadec-2-enyl] naphthalene-1,4-dione Chemical formula: C₃₁H₄₆O₂ CAS number: 84-80-0 Purity: ≥ 97 % for the sum of E-phytomenadione, E-epoxyphytomenadione and Z-phytomenadione isomers Purity criteria: — ≥ 75 % E-phytomenadione; — ≤ 4 % E-epoxyphytomenadione Produced by chemical synthesis</p> <p>Analytical method ⁽¹⁾ For the determination of phytomenadione in the feed additive: – High Performance Liquid Chromatography – European Pharmacopoeia (8.0, 01/2014:1036). For the determination of phytomenadione in the additive preparation and in complementary feed: – High Performance Liquid Chromatography with Fluorescence detection (HPLC-FLD)</p>	Horses	-	-	-	<ol style="list-style-type: none"> 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 by inhalation, skin and eye irritation and dermal sensitization, resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin, eyes and breathing protection. 	19.9.2031

⁽¹⁾ 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>