

COMMISSION IMPLEMENTING REGULATION (EU) 2015/2307**of 10 December 2015****concerning the authorisation of menadione sodium bisulphite and menadione nicotinamide bisulphite 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) Vitamin K was authorised without a time limit in accordance with Directive 70/524/EEC as feed additive for all animal species. That product was subsequently entered in the Register of feed additives as an 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 the use of vitamin K₃ in the form of menadione sodium bisulphite and menadione nicotinamide bisulphite as feed additives for all animal species. The applicant requested that these additives be classified in the additive category 'nutritional additives'. This 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 16 January 2014 ⁽³⁾ that, under the proposed conditions of use in feed, menadione sodium bisulphite and menadione nicotinamide bisulphite do not have adverse effects on animal health, human health or the environment.
- (5) The Authority further concluded that menadione sodium bisulphite and menadione nicotinamide bisulphite are effective sources of vitamin K 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.
- (6) The assessment of menadione sodium bisulphite and menadione nicotinamide bisulphite shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of menadione sodium bisulphite and menadione nicotinamide bisulphite should be authorised as specified in the Annex to this Regulation.
- (7) Although the applicant withdrew the application for the use of menadione sodium bisulphite in water for drinking, this additive can be used within a compound feed subsequently administered via water.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for menadione sodium bisulphite and menadione nicotinamide bisulphite, 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,

⁽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 2014;12(1):3532.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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 feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 30 June 2016 in accordance with the rules applicable before 31 December 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 31 December 2016 in accordance with the rules applicable before 31 December 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 specified in the Annex which are produced and labelled before 31 December 2017 in accordance with the rules applicable before 31 December 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

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, 10 December 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 %			

Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect

3a710	—	'Menadione sodium bisulphite' or 'Vitamin K ₃ '	<p><i>Additive composition</i></p> <p>Menadione sodium bisulphite</p> <p>Chromium ≤ 45 mg/kg</p> <p><i>Characterisation of the active substance</i></p> <p>Menadione sodium bisulphite</p> <p>C₁₁H₉NaO₅S·3H₂O</p> <p>CAS No: 6147-37-1</p> <p>Produced by chemical synthesis</p> <p>Purity: min. 96 % MSB complex which corresponds to min. 50 % menadione.</p> <p><i>Method of Analysis</i> ⁽¹⁾</p> <p>— For the determination of menadione sodium bisulphite in the feed additive: a spectrophotometric method using a visible detector at 635 nm (VDLUFA -Bd. III 13.7.1).</p> <p>— For the determination of menadione sodium bisulphite in premixtures and feedingstuffs: Normal Phase High-Performance Liquid Chromatograph coupled to UV detector-decree 29/04/2010, Official Italian Journal No 120 25/5/2010.</p>	All animal species	—	—	—	<ol style="list-style-type: none"> The additive shall be incorporated into feed in the form of a premixture. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. The following equivalency shall be used if the amount of the additive is labelled: 1 mg vitamin K₃ = 1 mg of menadione = 2 mg of menadione sodium bisulphite. Appropriate measures shall be taken to avoid the chromium emission in the air and prevent the exposure by inhalation or by dermal route. If such measures are technically not feasible or not sufficient, protective measures shall be taken according to national regulations implementing Union legislation on health and safety at work including Council Directives 89/391/EEC ⁽²⁾, 89/656/EEC ⁽³⁾, 92/85/EEC ⁽⁴⁾ and 98/24/EC ⁽⁵⁾ and Directive 2004/37/EC of the European Parliament and of the Council ⁽⁶⁾. 	31 December 2025
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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 %			
								5. Appropriate protective gloves, respiratory and eye protection according to Council Directive 89/686/EEC (?) shall be worn during handling.	
3a711	—	'Menadione nicotinamide bisulphite' or 'Vitamin K ₃ '	<p><i>Additive composition</i></p> <p>Menadione nicotinamide bisulphite</p> <p>Chromium ≤ 142 mg/kg</p> <p><i>Characterisation of the active substance</i></p> <p>Menadione nicotinamide bisulphite</p> <p>C₁₁H₉O₅S·C₆H₇N₂O</p> <p>CAS No: 73581-79-0</p> <p>Produced by chemical synthesis</p> <p>Purity: min. 96 % menadione nicotinamide bisulphite complex which corresponds to min. 43,9 % menadione and min. 31,2 % nicotinamide</p> <p><i>Method of Analysis</i> (1)</p> <p>— For the determination menadione nicotinamide bisulphite in the feed additive: a spectrophotometric method using a visible detector at 635 nm (VDLUFA — Bd.III 13.7.1).</p>	All animal species	—	—	—	<p>1. The additive shall be incorporated into feed in the form of a premixture.</p> <p>2. In the directions for use of the additive and premixtures, indicate the storage and stability conditions.</p> <p>3. The following equivalency shall be used if the amount of the additive is labelled: 1 mg vitamin K₃ = 1 mg of menadione = 2,27 mg of menadione nicotinamide bisulphite.</p> <p>4. Appropriate measures shall be taken to avoid the chromium emission in the air and prevent the exposure by inhalation or by dermal route. If such measures are technically not feasible or not sufficient, protective measures shall be taken according to national regulations implementing Union legislation on health and safety at work including Directives 89/391/EEC, 89/656/EEC, 92/85/EEC, 98/24/EC and 2004/37/EC.</p>	31 December 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 determination of menadione nicotinamide bisulphite in premixtures and feedingstuffs: Normal Phase High-Performance Liquid Chromatograph-decree 29/04/2010, Official Italian Journal No 120 25/5/2010.					5. Appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC shall be worn during handling.	

(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) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

(3) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (OJ L 393, 30.12.1989, p. 18).

(4) Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (OJ L 348, 28.11.1992, p. 1).

(5) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p. 11).

(6) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 158, 30.4.2004, p. 50).

(7) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).