



2026/2115

24.9.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/2115

of 23 September 2026

concerning the renewal of the authorisation of menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃) as feed additives for all animal species and repealing Implementing Regulation (EU) 2015/2307

(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 and renewing such an authorisation.
- (2) Menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃) were authorised for 10 years as feed additives for cats and dogs by Commission Implementing Regulation (EU) 2015/2307 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃) for all animal species, requesting the additives to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having a similar effect'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 November 2025 ⁽³⁾ that, the applicant has provided evidence that menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃) remain safe for all animal species as well as for the consumers, the users and the environment under the conditions currently authorised. The Authority further concluded that the exposure of users to menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃) by any route is considered as risk and should be minimised. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additives. Therefore, it concluded that there is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation. The Authority considered that there is no need for specific requirements of post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the methods of analysis of menadione sodium bisulphite and menadione nicotinamide bisulphite as a feed additives in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the evaluation report of the Reference Laboratory is therefore not required.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ 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. (OJ L 326, 11.12.2015, p. 49, ELI: http://data.europa.eu/eli/reg_impl/2015/2307/oj).

⁽³⁾ EFSA Journal 2025;23(12):e9792 <https://doi.org/10.2903/j.efsa.2025.9792>.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additive (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

- (6) In view of the above, the Commission considers that menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃) satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of menadione sodium bisulphite (vitamin K₃) and menadione nicotinamide bisulphite (vitamin K₃), Implementing Regulation (EU) 2015/2307 should be repealed.
- (8) Since the specifications of the additives have been modified, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of 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

Renewal of the Authorisation

The authorisation of 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', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Implementing Regulation (EU) 2015/2307 is repealed.

Article 3

Transitional measures

1. The feed additives menadione sodium bisulphite (Vitamin K₃) and menadione nicotinamide bisulphite (Vitamin K₃) as authorised by Implementing Regulation (EU) 2015/2307 and premixtures containing those substances, which are produced and labelled before 14 April 2027 in accordance with the rules applicable before 14 October 2026 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 additives referred to in paragraph 1, which are produced and labelled before 14 October 2027 in accordance with the rules applicable before 14 October 2026 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 additives referred to in paragraph 1, which are produced and labelled before 14 October 2028 in accordance with the rules applicable before 14 October 2026 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 4***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, 23 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the 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 feed with a moisture content of 12 %			
Category: Nutritional additives. Functional group: Vitamins, pro-vitamins and chemically well-defined substances having a similar effect								
3a710	'Menadione sodium bisulphite' or 'Vitamin K ₃ '	<i>Additive composition</i> Menadione sodium bisulphite (MSB) Chromium III and IV ≤ 45 mg/kg Solid form <i>Characterisation of the active substance</i> Menadione sodium bisulphite Produced by chemical synthesis C₁₁H₉NaO₅S·3H₂O CAS number: 6147-37-1 Purity: minimum 96 % MSB complex which corresponds to minimum 50 % of menadione. <i>Analytical method</i> ⁽¹⁾ 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). — For the determination of menadione sodium bisulphite in premixtures and compound feed: Normal Phase High-Performance Liquid Chromatograph coupled to UV detector – Decreto 29/4/2010, Gazzetta Ufficiale della Repubblica Italiana No 120, 25.5.2010. — For the determination of total chromium: atomic absorption spectrometry (AAS) – GB/T 13088	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions, and the stability to heat treatment shall be indicated. 2. The additive shall be incorporated into feed in the form of a premixture. 3. 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. 4. 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. In particular, the exposure to chromium by inhalation or dermal route. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	14 October 2036

⁽¹⁾ Details of the analytical methods for the additives 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.

Identification number of the additive	Name of the 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 feed with a moisture content of 12 %			
Category: Nutritional additives. Functional group: Vitamins, pro-vitamins and chemically well-defined substances having a similar effect								
3a711	'Menadione nicotinamide bisulphite' or 'Vitamin K ₃ '	<i>Additive composition</i> Menadione nicotinamide bisulphite Chromium III and IV≤ 142 mg/kg Solid form <i>Characterisation of the active substance</i> Menadione nicotinamide bisulphite C₁₁H₉O₅S·C₆H₇N₂O CAS number: 73581-79-0 Produced by chemical synthesis Purity: min. 96 % menadione nicotinamide bisulphite complex which corresponds to minimum 43,9 % menadione and minimum 31,2 % nicotinamide <i>Analytical method ⁽¹⁾</i> — 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). — For the determination of menadione nicotinamide bisulphite in premixtures and compound feed: Normal Phase High-Performance Liquid Chromatograph – Decreto 29/4/2010, Gazzetta Ufficiale della Repubblica Italiana No 120, 25.5.2010 — For the determination of total chromium: atomic absorption spectrometry (AAS) – GB/T 13088	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions, and the stability to heat treatment shall be indicated. 2. The additive shall be incorporated into feed in the form of a premixture. 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 4. 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. In particular, the exposure to chromium by inhalation or dermal route. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	14 October 2036

⁽¹⁾ Details of the analytical methods for the additives 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.