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)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/2307

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(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 K_3 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,

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/2307. (See end of Document for details)*

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’	*Additive composition* Menadione sodium bisulphite Chromium ≤ 45 mg/kg *Characterisation of the active substance* Menadione sodium bisulphite $C_{11}H_9NaO_5S \cdot 3H_2O$ CAS No: 6147-37-1 Produced by chemical synthesis Purity: min. 96 % MSB complex which corresponds to min. 50 % menadione. *Method of Analysis*[a] — For the	All animal species	—	—	—	1. The additive shall be incorporated into feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 3. The following equivalency shall be used if the amount of the additive is labelled: 1 mg	31 December 2025

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/2307. (See end of Document for details)*

							vitamin K_3=1mg of menadione = 2 mg of menadione sodium bisulphite.
							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
			—	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 feedingstuffs: Normal Phase High-Performance Liquid Chromatograph coupled to UV detector- decree 29/04/2010, Official Italian Journal No 120 25/5/2010.			