COMMISSION IMPLEMENTING REGULATION (EU) 2021/506

of 23 March 2021

concerning the authorisation of methanethiol as a feed additive 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(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Methanethiol was authorised without a time limit, in accordance with Directive 70/524/EEC, as a feed additive for all animal species. This additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) 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 methanethiol as a feed additive for all animal species.

(4) The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 April 2013 ([3]) and 30 September 2020 ([4]) that, under the proposed conditions of use, methanethiol does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive should be considered as irritant to skin and eyes and to the respiratory tract and no conclusions could be drawn on skin sensitisation. 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. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods 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 methanethiol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of methanethiol should be authorised as specified in the Annex to this Regulation.

(7) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, a recommended content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(8) The fact that the use of the substance concerned in water for drinking is not authorised does not preclude its use in compound feed which is administered via water.

([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* 2013;11(5):3208.
([4]) *EFSA Journal* 2020;18(11):6288.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of methanethiol, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(10) 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 substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional Measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 13 October 2021, in accordance with the rules applicable before 13 April 2021, may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance as specified in the Annex, which are produced and labelled before 13 April 2022, in accordance with the rules applicable before 13 April 2021, 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 substance as specified in the Annex, which are produced and labelled before 13 April 2023, in accordance with the rules applicable before 13 April 2021, 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, 23 March 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: sensory additives. Functional group: flavouring compounds.								
2b12003	Methanethiol	*Additive composition* Methanethiol *Characterisation of active substance* Methanethiol Produced by chemical synthesis Purity: min. 98 % Chemical formula: CH_4S CAS number: 74-93-1 FLAVIS No 12.003 *Analytical method* (1) For the identification of methanethiol in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg.' 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: 0,05 mg/kg	13.4.2031

							5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protection.	

([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