COMMISSION IMPLEMENTING REGULATION (EU) 2019/1125

of 5 June 2019

concerning the authorisation of zinc chelate of methionine sulfate 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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of zinc chelate of methionine sulfate. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of zinc chelate of methionine sulfate as a feed additive for all animal species to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 18 May 2017 ([2]) and 4 October 2018 ([3]) that, under the proposed conditions of use, zinc chelate of methionine sulfate does not have an adverse effect on animal health and consumer safety. It also concluded that the additive is considered as a potential skin sensitizer and an eye and skin irritant and stated a risk for the users of the additive upon inhalation. 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 also concluded that that additive does not pose an additional risk for the environment compared to other compounds of zinc and that it is an efficacious source of zinc for all animal species. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are, subject to respective protective measures for the users of the additive, satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.

(6) 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 'compounds of trace elements', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2017;15(6):4859.
([3]) *EFSA Journal* 2018;16(10):5463.

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, 5 June 2019.

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
						Content of element (Zn) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b614	—	Zinc chelate of methionine sulfate	*Additive composition:* Zinc chelate of methionine sulfate as a powder with a zinc content between 2 % and 15 %. *Characterisation of the active substance:* Zinc, 2-amino-4 methylsulfanyl-butanoic acid, sulfate; zinc chelated with methionine in a molar ratio 1:1. Chemical formula: $C_5H_{11}NO_6S_2Zn$ CAS Number: 56329-42-1 *Analytical methods* (1): For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma – Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma – Atomic Emission Spectrometry (ICP-AES) after pressure digestion.	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Zinc chelate of methionine sulfate may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by those procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	22 July 2029

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
						Content of element (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of methionine content in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-UV/FD) – EN ISO 17180 or VDLUFA 4.11.6 and EN ISO 13903 For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma – Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma – Atomic Emission Spectrometry (ICP-AES) after pressure digestion.					

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/eurl/feed-additives/evaluation-reports