COMMISSION IMPLEMENTING REGULATION (EU) 2022/1472

of 5 September 2022

concerning the authorisation of manganese lysinate sulphate 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of manganese lysinate sulphate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of manganese lysinate sulphate as a feed additive for all animal species, to be classified in the additive category 'nutritional additives' and the functional group 'compounds of trace elements'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2022 ([2]) that, under the proposed conditions of use, manganese lysinate sulphate does not have an adverse effect on animal health, consumer safety or the environment. The Authority further concluded that the handling of the substance poses a risk to users by inhalation and that it is irritant to eyes and skin and should be considered a dermal sensitiser. 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 the substance is efficacious in chickens for fattening; this conclusion can be extended to all other 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 manganese lysinate sulphate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance 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* 2022;20(3):7165.

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 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 (Mn) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements.									
3b511	-	Manganese lysinate sulphate	*Additive composition* Manganese and amino acid L-lysine: ratio of 1:1 (monohydrate) having a content of: — manganese 16 % – 18 %; — lysine 44 % – 47 %; — sulphate 27 % – 31 % (calculated from sulphur), Solid form (≤ 10 % moisture)	All animal species other than fish	-	-	150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection.	26.9.2032
			Characterisation of the active substances Chemical formulas: $C_6H_{16}MnN_2O_7S$ IUPAC: monoaquamonolysinatomanganese (II) sulphate	Fish			100 (total)		
			Analytical methods [1] For the quantification of total manganese in the feed additive, premixtures and feedingstuffs: — Atomic Absorption Spectrometry (AAS) – ISO 6869; or — Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) – EN 15621; or						

			— Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES) – EN 15510; or — Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) – EN 17053 (for premixtures and feedingstuffs only); or — Atomic Absorption Spectrometry (AAS) – Commission Regulation (EC) No 152/2009 (for feedingstuffs only) For the quantification of lysine in the feed additive: — ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: — European Pharmacopoeia monograph 20301						

(1) Details of the analytical methods 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