COMMISSION IMPLEMENTING REGULATION (EU) 2021/1425

of 31 August 2021

concerning the authorisation of manganese chelate of lysine and glutamic acid as 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 manganese chelate of lysine and glutamic acid. The 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 the preparation of manganese chelate of lysine and glutamic acid 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 opinions of 10 January 2020 ([2]) and 27 January 2021 ([3]) that, under the proposed conditions of use, manganese chelate of lysine and glutamic acid does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the handling of the additive poses a risk to users by inhalation and that it should be considered as an eye irritant, skin and respiratory 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 concluded that the additive 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 chelate of lysine and glutamic acid 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 preparation 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 preparation 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 2020;18(2):6001.
([3]) EFSA Journal 2021;19(3):6454.

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, 31 August 2021.

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: nutritional additives **Functional group: compounds of trace elements**									
3b509	-	Manganese chelate of lysine and glutamic acid	*Additive composition:* Preparation of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with a manganese content between 15 and 17 %, a lysine content between 20 and 21,5 %, a glutamic acid content between 22 and 24 %, a maximum of 3,5 % moisture and a maximum of 4 ppm nickel. *Characterisation of the active substances:* Chemical formulas: Manganese-2,6- diaminohexanoic acid, chloride and hydrogen sulfate salt: $C_6H_{19}ClN_2O_8SMn$ Manganese-2-aminopentanedioic acid, sodium and hydrogen sulfate salt:	All animal species	-	-	Fish: 100 (total) Other species: 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 by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. 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 eyes, skin and breathing.	21 September 2031

			$C_5H_{10}NNaO_9SMn$ *Analytical methods* (*): For the quantification of total manganese in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621). For the quantification of the lysine and glutamic acid content in the feed additive:						

			— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For proving the chelated structure of the feed additive: — mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the feed additive						

(*) 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