Commission Implementing Regulation (EU) 2020/1378 of 1 October 2020 concerning the authorisation of copper chelate of lysine and glutamic acid as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1378

of 1 October 2020

concerning the authorisation of copper chelate of lysine and glutamic acid 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 copper chelate of lysine and glutamic acid. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of copper chelate of lysine and glutamic acid 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 opinion of 15 May 2019[(2)] that, under the proposed conditions of use, copper chelate of lysine and glutamic acid does not have an adverse effect on animal health and consumer safety. It also concluded that the additive is an eye irritant, skin and respiratory sensitizer, 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 copper and that it is an efficacious source of copper 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 the relevant 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.

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, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1378. (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**
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b415	—	Copper chelate of lysine and glutamic acid	*Additive composition* Mixture of chelate of copper with lysine and chelate of copper with glutamic acid in a ratio of 1:1 as a powder with a copper content between 17 and 19 %, a lysine content between 19 and 21 %, a glutamic acid content between	All animal species	—	—	Bovines: — — — Caprines: 35 (total) Piglets: — —	1. Bovines before the start of rumination: 15 (total); Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total). Piglets: 4 weeks after weaning: 150 (total). 5. Other uses of the additive and premixtures, feed	22 October 2030 The additive shall be incorporated into feed in the form of a premixture. Copper chelate of lysine and glutamic acid may be placed on the market and used as an additive consisting of a preparation. For users of the additive and premixtures, feed

a 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

			19 and 21 % and a maximum of 3 % moisture					
			Characterisation of the active substances Chemical formulas: Copper-2,6-diaminohexanoic acid, chloride and hydrogen sulfate salt: $C_6H_{15}ClCuN_2O_6S$ Copper-2-aminopentanedioic acid, sodium and hydrogen sulfate salt: $C_5H_9CuNNaO_{8.5}S$					
			Analytical methods[a] For the quantification of the lysine and glutamic acid content in the feed additive: —	ion exchange chromatography coupled with post-			Crustaceans: 50 (total). Other animals: 25 (total).	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

a 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