Commission Implementing Regulation (EU) No 1230/2014 of 17 November 2014 concerning the authorisation of copper bilysinate as a feed additive for all animal species (Text with EEA relevance)

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concerning the authorisation of copper bilysinate 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 bilysinate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of copper bilysinate 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 3 July 2014[(2)] that, under the proposed conditions of use, copper bilysinate does not have an adverse effect on animal health, human health or the environment and that it may be considered as 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 copper bilysinate 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1230/2014. (See end of Document for details)*

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1230/2014. (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 feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b411	—	Copper bilysinate	*Characterisation of the additive* Powder or granulate with a content of copper ≥ 14,5 % and [X1lysine-HCl] ≥ 84,0 %. *Characterisation of the active substance* Copper chelate of L-lysinate-HCl Chemical formula: $Cu(C_6H_{13}N_2O_2)_2 \times 2HCl$ CAS number: 53383-24-7 *Analytical methods*[a]: For the quantification	All animal species	—	—	[F1Bovines: — Bovines before the start of rumination: 15 (total), — Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total) Piglets: — suckling and weaned up to 4 weeks after weaning: 150 (total), — from 5-th week after	1. Bovines additive shall be incorporated into feed in the form of a premixture. 2. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 3. The following words shall be included in the labelling: For feed for sheep	8 December 2024.

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

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			of Lysine content in the feed additive: —	Ion-exchange chromatography combined with post-column derivatisation and colorimetric or fluorescence detection — EN ISO 17180.			Crustaceans: 50 (total). Other animals: 25 (total).]	weaning up to 8 weeks after weaning: 100 (total).	if the level of copper in the feed exceeds 10 mg/kg: ‘The level of copper in this feed may cause poisoning in certain breeds of sheep.’
			For the quantification of total copper content in the feed additive and premixtures: —	Inductively coupled plasma atomic emission spectrometry (ICP-AES) — EN 15510, or				—	For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg:
			—	Inductively coupled plasma atomic emission spectrometry after pressure					

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