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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)

(OJ L 331, 18.11.2014, p. 18)

Corrected by:

►**C1** Corrigendum, OJ L 134, 30.5.2015, p. 32 (1230/2014)

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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)

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2014; 12(7):3796.

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(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:

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.

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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 ►**C1** lysine-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* ([1]): For the quantification of Lysine content in the feed additive: — Ion-exchange chromatography combined with post-column derivatisation and colorimetric or fluorescence detection — EN ISO 17180.	All animal species	—	—	Bovines: — bovines before the start of rumination: 15 (total), — other bovines: 35 (total). Ovines: 15 (total). Piglets up to 12 weeks: 170 (total). Crustaceans: 50 (total). Other animals: 25 (total).	1. The 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 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 feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: ‘The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.’	8 December 2024.

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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 %			
			For the quantification of total copper content in the feed additive and premixtures: — 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 copper in the feed materials and compound feed: — Atomic absorption spectrometry (AAS) — Commission Regulation (EC) No 152/2009, 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.					— 'The lysine content of the additive should be considered when formulating feed.'	

([1]) 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