Commission Implementing Regulation (EU) 2016/2261 of 15 December 2016 concerning the authorisation of copper(I) oxide as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/2261

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concerning the authorisation of copper(I) oxide as a feed additive for all animal species

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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 dicopper oxide accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of dicopper oxide 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 25 May 2016[(2)] that, under the proposed conditions of use, dicopper oxide does not have an adverse effect on animal or consumer health and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(5) The Authority furthermore concluded that dicopper oxide does not pose additional risks to the environment than the other copper sources 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 Article 21 of Regulation (EC) No 1831/2003.

(6) The name of the additive in the application is dicopper oxide. However, the International Union of Pure and Applied Chemistry (IUPAC) name of the additive is copper(I) oxide. In line with the Authority`s recommendation in its opinion on cupric oxide[(3)] the additive should be named copper(I) oxide.

(7) The assessment of copper(I) oxide 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.

(8) 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.

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive**	**Composition, chemical formula, description, analytical method**	**Species or animal category**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						Content of Cu in mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b412	—	Copper(I) oxide	*Characterisation of the additive* Preparation of copper(I) oxide with — a minimum copper content of 73 %, — Sodium lignosulfonates between 12 % and 17 %, — 1 % Bentonite. Granulated form with particles < 50 µm: below 10 % *Characterisation of the*	All animal species	—	—	[F1Bovines: — — Ovines: 15 (total). Caprines: 35 (total) Piglets: — —]	[Bovines before the start of rumination: 15 (total); Other bovines: 30 (total). 2. suckling and weaned up to 4 weeks after weaning: 150 (total); from 5-th week after weaning	5 January 2027 The additive shall be incorporated into feed in the form of a premixture. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation,

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

			active substance Copper(I) oxide Chemical formula: Cu_2O CAS number: 1317-39-1 *Analytical methods*[a] For the identification of Cu_2O in the additive: —	X-Ray diffraction (XRD).			Crustaceans: 50 (total). Other animals: 25 (total).]	up to 8 weeks after weaning: 100 (total).	dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.
			For the quantification of the total copper content in the additive: — —	Titrimetry; or Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) — EN 15510.				3.	The following words shall be included in the labelling:
			For the quantification of total copper content in premixtures: —	Inductively Coupled Plasma					

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				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 content in feed materials and compound feed: — Atomic Absorption Spectrometry (AAS) — Commission Regulation (EC) No 152/2009; or — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) —			—	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

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			—	EN 15510; or Inductively Coupled Plasma Atomic Emission Spectrometry after pressure digestion (ICP-AES) — EN 15621.						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.

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Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2018/1039 of 23 July 2018 concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006 and (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261 (Text with EEA relevance).

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) EFSA Journal 2016;14(6):4509.

(**3**) EFSA Journal 2015;13(4):4057.

Status:
Point in time view as at 13/08/2018.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/2261.