

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1445**of 31 August 2022****amending Implementing Regulation (EU) 2018/1039 as regards the terms of authorisation of copper
(II) chelate of amino acids hydrate 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 13(3) 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 an authorisation.
- (2) The use of copper (II) chelate of amino acids hydrate as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2018/1039 ⁽²⁾.
- (3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of copper (II) chelate of amino acids hydrate as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, if modified as proposed by the applicant. That modification consists in the extension of the protein sources for the amino acids and in the introduction of a minimum specification for free amino acids and of a tighter specification of the copper content. The request was accompanied by the relevant supporting data.
- (4) The Authority concluded in its opinion of 29 September 2021 ⁽³⁾ that the modifications of the terms of authorisation applied for do not modify the conclusions reached in the previous assessments on the safety for the target species, consumers, environment and efficacy of the additive above. The Authority concluded that the additive should be considered a skin and eye irritant and a skin sensitiser and stated a potential risk due to exposure by 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 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 the proposed modifications to the authorisation shows that the conditions for authorisation as provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (6) For reasons of clarity, the composition of the additive should be modified to include the indication that the additive consists of a preparation.
- (7) Implementing Regulation (EU) 2018/1039 should therefore be amended accordingly.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ 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 (OJ L 186, 24.7.2018, p. 3).

⁽³⁾ EFSA Journal 2021;19(10):6896.

- (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

In the Annex to Implementing Regulation (EU) 2018/1039, the entry of copper (II) chelate of amino acids hydrate is amended in accordance with the Annex to this Regulation.

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 2022.

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 (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
‘3b406	-	Copper (II) chelate of amino acids hydrate	Additive composition Preparation of copper(II) amino acid complex where the copper and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 10 % copper	All animal species	-	-	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 weaning up to 8 weeks after weaning: 100 (total). Crustaceans: 50 (total). Other animals: 25 (total).	1. The additive shall be incorporated into feed in the form of a premixture. 2. The following words shall be included in the labelling: — For feed for ovines, 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.’ 3. 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. Where	13 August 2028
			Characterisation of the active substance Chemical formula: Cu(x) ₁₋₃ · nH ₂ O, x = anion of any amino acid from soya protein hydrolysate. Maximum 10 % of molecules exceeding 1 500 Da.						
			Analytical methods ⁽¹⁾ For the quantification of amino acid content in the feed additive: — ion exchange chromatography with post-column derivatisation and optical detection (IEC-VIS/FLD)						

			For the quantification of total copper in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total copper in premixtures: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of total copper in feed materials and compound feed: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)					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.	
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3b406i	-	Copper (II) chelate of amino acids hydrate	<i>Additive composition</i> Preparation of copper (II) amino acid complex, where the copper and the amino acids are chelated via coordinate covalent bonds, as a powder with a content of 10-11 % copper and a minimum of 18 % free amino acids. <i>Characterisation of the active substance</i> Chemical formula: $\text{Cu}(\text{x})_{1-3} \cdot \text{nH}_2\text{O}$, where x is equal to any amino acid coming from hydrolysed protein sources from feathers or plants; Maximum 10 % of molecules exceeding 1 500 Da. <i>Analytical methods</i> ⁽¹⁾ For the quantification of amino acid content in the feed additive: — ion exchange chromatography with post-column derivatisation and optical detection (IEC-VIS/FLD), Commission Regulation 152/2009 (Annex III,F) and EN ISO 17180 For the quantification of total copper in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869)	All animal species	-	-	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 5th week after weaning up to 8 weeks after weaning: 100 (total). Crustaceans: 50 (total). Other animals: 25 (total).	- The additive shall be incorporated into feed in the form of a premixture. - The following words shall be included in the labelling: - For feed for ovines, 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.' - 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. 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 skin, eye and breathing protection.	13 August 2028'
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			For the quantification of total copper in premixtures: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of total copper in feed materials and compound feed: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)				4. For additives produced from hydrolysis of animal protein, the animal origin (<i>avian species</i>) shall be indicated on the label of the additive and premixtures.'	
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(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>