

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1334**of 29 June 2023****concerning the renewal of the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species and repealing Regulation (EU) No 349/2010****(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 and renewing such authorisation.
- (2) The preparation of copper chelate of hydroxy analogue of methionine was authorised for a period of 10 years as a feed additive for all animal species by Commission Regulation (EU) No 349/2010 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species, requesting the additive to be classified in the additive category 'nutritional additives' and in the functional group 'compounds of trace elements'. The application included a proposal for amending the conditions of the current authorisation, consisting of the removal of the mineral oil from the additive, which is therefore to be considered as a substance and no longer a preparation. In addition, the minimum content of copper in the additive has been slightly modified. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 ⁽³⁾ that the applicant has provided evidence that the additive, in its new composition, remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is considered as a skin and eye irritant and a skin sensitiser, while the risk of respiratory sensitisation is considered low. The Authority stated that the proposed modification of the conditions of the original authorisation does not have an impact on the efficacy of the additive. Finally, it did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 349/2010 of 23 April 2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species (OJ L 104, 24.4.2010, p. 31).

⁽³⁾ EFSA Journal 2021;19(5):6618.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (6) The assessment of copper chelate of hydroxy analogue of methionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive, Regulation (EU) No 349/2010 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of copper chelate of hydroxy analogue of methionine, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation, with regard to the composition of the additive, which now consists of a substance, and the derived modification of the identification number of the additive.
- (9) 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

Renewal of the authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Regulation (EU) No 349/2010 is repealed.

Article 3

Transitional measures

1. The additive specified in the Annex and premixtures containing that additive, which are produced and labelled before 20 January 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the additive specified in the Annex, which are produced and labelled before 20 July 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the additive specified in the Annex, which are produced and labelled before 20 July 2025 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 4

Entry into force

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, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 the element (Cu) in mg/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: compounds of trace elements

3b410i	Copper chelate of hydroxy analogue of methionine	<i>Additive composition</i> Copper chelate of hydroxy analogue of methionine containing a minimum of 16 % copper and a minimum of 78 % (2-hydroxy-4-methylthio) butanoic acid Maximum content of nickel: 20 ppm. Solid form	All animal species	-	-	Bovines: — 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. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment. 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.' — of 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.'	20 July 2033
		<i>Characterisation of the active substances</i> Chemical formula: copper bis (-2-hydroxy-4-methylthio)butanoate: $\text{Cu}(\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{OH})\text{-COO})_2$ CAS: 292140-30-8						
		<i>Analytical methods ⁽¹⁾</i> For the quantification of the hydroxy analogue of methionine content in the feed additive: titrimetry, potentiometric titration after oxidation reduction reaction. 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 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).						
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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>