



2025/2513

12.12.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2513
of 11 December 2025
concerning the authorisation of copper(II)-betaine complex 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(II)-betaine complex. The 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(II)-betaine complex as a feed additive for all animal species, requesting that additive to be classified in the additive category 'nutritional additives' and in the functional group 'compounds of trace elements'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 January 2023 ⁽²⁾ that, under the proposed conditions of use, copper(II)-betaine complex is safe for all animal species as well as for the consumers. In regard to the environment, the Authority concluded that at the proposed use levels the substance is considered safe for the terrestrial species and the land-based aquaculture systems. The data available did not allow the conclusion to be made on the safety of the additive for marine sediment, when it is used in sea cages. The Authority also concluded that the additive exposure by inhalation is likely. The additive is irritant to eyes and non-irritant to skin. The additive is considered to be a skin and respiratory sensitiser, due to the presence of nickel. The Authority further concluded that based on the data available, the efficacy of the additive cannot be demonstrated. In its second opinion of 15 November 2023 ⁽³⁾, the Authority concluded that the use of the additive at the proposed conditions of use in marine aquaculture does not pose a risk to the marine sediment compartment. The Authority reiterated its previous conclusion that, based on the data available, the efficacy of the additive cannot be demonstrated. In its third opinion of 6 May 2025 ⁽⁴⁾, the Authority concluded that the additive is efficacious as a source of copper for all animal species. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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) In view of the above, the Commission considers that copper(II)-betaine complex satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised for all animal species. 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.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <https://eur-lex.europa.eu/eli/reg/2003/1831/oj/eng>.

⁽²⁾ EFSA Journal, 2023;21(2):7817, <https://doi.org/10.2903/j.efsa.2023.7817>.

⁽³⁾ EFSA Journal, 2023;21:e8460, <https://doi.org/10.2903/j.efsa.2023.8460>.

⁽⁴⁾ EFSA Journal, 2025;23:e9469, <https://doi.org/10.2903/j.efsa.2025.9469>.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

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, 11 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the 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: nutritional additives. Functional group: compounds of trace elements								
3b416	Copper (II)–betaine complex	<i>Additive composition</i> Copper betaine complex with a minimum content of 19 % of copper and a minimum content of 36 % of betaine; Nickel: maximum 77 mg/kg; Solid form	Bovines	Before start of rumination		15	1. The additive shall be incorporated into feed in the form of a premixture. 2. The following information 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.’	1 January 2036
			Other bovines			30		
			Ovines			15		
			Caprines			35		
		<i>Characterisation of the active substances</i> Name: catena-[diaqua-sulphato-μ2-(trimethylammonio)acetato-copper(II)]; Chemical formula: [Cu(H ₂ O) ₂ ((CH ₃) ₃ NCH ₂ COO)(SO ₄)] _n Specifications: Copper: minimum of 19 %; Betaine: minimum 36 %; Sulphur: 9 %–12 %; Moisture: maximum 5 %	Piglets suckling and weaned	Up to 4 weeks after weaning		150		
			Piglets	From 5-th week after weaning up to 8 weeks after weaning		100		
			Crustaceans			50		
			Other animal species and categories			25		

Identification number of the additive	Name of the 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: nutritional additives. Functional group: compounds of trace elements								
		For the quantification of total <i>copper</i> in the <i>premixtures</i>: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or — Atomic absorption spectrometry, AAS (ISO 6869) or — Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053). For the quantification of total <i>copper</i> in the <i>compound feed</i>: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) 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). For the quantification of <i>betaine</i> in the <i>feed additive</i>: — High performance liquid chromatography with refraction index detection (HPLC-RI). For the quantification of <i>sulphur</i> and <i>sulphate</i> in the <i>feed additive</i>: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621).					3. Users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks of exposure by inhalation, dermal contact or eyes contact, in particular due to the content of nickel. Where such risks cannot be eliminated by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	

Identification number of the additive	Name of the 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: nutritional additives. Functional group: compounds of trace elements								
		For proving the formation of copper (II) betaine complex: — Powder X-ray diffraction (XRD).						
(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.								