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COMMISSION

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[...] (2025) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**concerning the authorisation of copper(II)-betaine complex as a feed additive for all animal species**

(Text with EEA relevance)

**EN**

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# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

## concerning the authorisation of copper(II)-betaine complex as a feed additive for all animal species

(Text with EEA relevance) **This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.**

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<sup>1</sup>, 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<sup>2</sup> that, under the proposed conditions of use, copper(II)-betaine complex is safe for all animal species as well as for the consumers. For the environment the Authority concluded that at the proposed use levels for the terrestrial species and land-based aquaculture systems is considered safe for the environment. 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 sensitisier, 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 the second opinion of 15

<sup>1</sup> OJ L 268, 18.10.2003, p. 29.

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

November 2023<sup>3</sup> 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 reiterates its previous conclusion that, based on the data available, the efficacy of the additive cannot be demonstrated. In the third opinion of 6 May 2025<sup>4</sup> the authority concluded that 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,

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,

*For the Commission  
The President  
Ursula VON DER LEYEN*

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

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