



Brussels, **XXX**
SANTE/33002912/2025 CIS
(POOL/G5/2025/33002912/33002912-
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[...](2026) **XXX** draft

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

of **XXX**

**concerning the renewal of the authorisation of copper bislysinat and a preparation of
copper bislysinat as feed additives for all animal species and repealing Implementing
Regulation (EU) No 1230/2014**

(Text with EEA relevance)

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

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concerning the renewal of the authorisation of copper bislysinate and a preparation of copper bislysinate as feed additives for all animal species and repealing Implementing Regulation (EU) No 1230/2014

(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 nutrition¹, 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) Copper bilysinate (powder) and a preparation of copper bilysinate (granulate form) were authorised for 10 years as feed additive for all animal species by Commission Implementing Regulation (EU) No 1230/2014².
- (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 bislysinate and a preparation of copper bislysinate 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'. By mistake, the name of the additive in the authorisation was "copper bilysinate". This name is now replaced by the appropriate name "copper bislysinate". That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 March 2025³ that the applicant has provided evidence that copper bislysinate and the preparation of copper bislysinate remain safe for all animal species, the consumers and the environment. The Authority further stated that the preparation of copper bislysinate in granulated form is not irritant to the skin but the powder presentation can be eye irritant. The preparation should be considered skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) No 1230/2014 of 17 November 2014 concerning the authorisation of copper bilysinate as a feed additive for all animal species (OJ L 331, 18.11.2014, p. 18, ELI: http://data.europa.eu/eli/reg_impl/2014/1230/oj).

³ EFSA Journal. 2025;23:e9356. <https://doi.org/10.2903/j.efsa.2025.9356>

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or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additives. Therefore, it concluded that there is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation. The Authority considered that there is no need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of copper bislysinat as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005⁴, evaluation report of the Reference Laboratory is therefore not required.
- (6) Implementing Regulation (EU) No 1230/2014 provides that copper bislysinat is allowed to be placed on the market as a preparation in granulated form mixed with some technological additives, but indication that such additive was a preparation was not specified in the terms of the authorisation. In addition, copper bislysinat was authorised also in powder form as an active substance. A more accurate description of copper bislysinat authorised as a preparation in granulated form and as active substance in powder form should be provided. A new identification number should be allocated for the preparation. In addition, the name “copper bilysinat” that appeared in the former authorisation by Implementing Regulation (EU) No 1230/2014 was not correct and should be modified to ‘copper bislysinat’.
- (7) In view of the above, the Commission considers that the copper bislysinat and a preparation of copper bislysinat satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives 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 additives. Those protective measures should be without prejudice to other workers’ safety requirements under Union law.
- (8) As a consequence of the renewal of the authorisation copper bislysinat and the preparation of copper bislysinat, Implementing Regulation (EU) No 1230/2014 should be repealed.
- (9) Since safety reasons do not require the immediate application of the change of the name of the additive, and the new identification number given to the preparation, 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.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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 additive (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the authorisation

The authorisation of the substance and the preparation 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

Implementing Regulation (EU) No 1230/2014 is repealed.

Article 3

Transitional measures

1. The feed additives copper bilysinate powder form and copper bilysinate granulate form as authorised by Implementing Regulation (EU) No 1230/2014 and premixtures containing those additives, which are intended for all animal species and which are produced and labelled before *[6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are intended for all animal species and which are produced and labelled before *[12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are intended for all animal species and which are produced and labelled before *[24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned 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,

For the Commission
The President
Ursula VON DER LEYEN