



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/6055399/2025 CIS
(POOL/G5/2025/6055399/6055399-EN
CIS.docx)
[...](2025) **XXX** draft

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

of **XXX**

concerning the renewal of the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species and repealing Implementing Regulation (EU) 2015/897

(Text with EEA relevance)

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

of XXX

concerning the renewal of the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species and repealing Implementing Regulation (EU) 2015/897

(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 an authorisation.
- (2) Thiamine hydrochloride and thiamine mononitrate were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 2015/897².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, two applications were submitted for the renewal of the authorisation of thiamine hydrochloride and thiamine mononitrate and for one preparation of thiamine mononitrate as feed additives for all animal species, requesting the additives to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003. One of the applicants, requesting the authorisation of the preparation of thiamine mononitrate as a feed additive for all animal species, withdrew its application for the preparation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 18 March 2025 and 4 April 2025³ that the applicants have provided evidence that thiamine hydrochloride and thiamine mononitrate remain safe for all animal species, as well as for the consumers, the users and the environment under the conditions of use currently authorised. The Authority further concluded that thiamine hydrochloride

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oi>).

² Commission Implementing Regulation (EU) 2015/897 of 11 June 2015 concerning the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species (OJ L 147, 12.6.2015, p 8, ELI: http://data.europa.eu/eli/reg_impl/2015/897/oi).

³ EFSA Journal. 2025;23:e9405. <https://doi.org/10.2903/j.efsa.2025.9405>.

and thiamine mononitrate are skin and eye irritants and are considered skin and respiratory sensitisers. Any dermal and respiratory exposure is considered a risk. The Authority stated that the applications for renewal of the authorisation do not include a proposal for amending 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 methods of analysis of thiamine hydrochloride and thiamine mononitrate as feed additives 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, the evaluation reports of the Reference Laboratory are therefore not required.
- (6) In view of the above, the Commission considers that thiamine hydrochloride and thiamine mononitrate 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.
- (7) As a consequence of the renewal of the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives, Implementing Regulation (EU) 2015/897 (EU) should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation resulting from the fact that the preparations of thiamine mononitrate as a feed additives for all animal species are not renewed, 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.
- (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 I
Renewal of the Authorisation

The authorisation of the substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is renewed subject to the conditions laid down in that Annex.

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>).

Article 2
Repeal

Implementing Regulation (EU) No (EU) 2015/897 is repealed.

Article 3
Transitional measures

1. The preparations of thiamine mononitrate, as authorised by Implementing Regulation (EU) 2015/897 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*