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COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of an aqueous solution of choline chloride and a preparation of choline chloride as feed additives for all animal species and repealing Commission Implementing Regulation (EU) No 795/2013

(Text with EEA relevance)

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(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 an authorisation.

(2) Choline chloride was authorised in the form of solid and liquid preparations for 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 795/2013[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 choline chloride in aqueous solution and of the preparation of choline chloride, 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'. 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 29 January 2025[3] that the applicant has provided evidence that the use choline chloride in animal nutrition remains safe for all animal species, the consumers and the environment. The Authority further concluded that the active substance choline chloride should be considered a potential skin and respiratory sensitiser. Any exposure via skin or respiratory tract is therefore considered a risk. Although aqueous solutions of up to 70% choline chloride are considered non-irritant to eyes, no conclusion can be reached on the eye irritation potential of more concentrated forms. These conclusions would apply, in principle, to any preparations produced with the active substance. The

[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 795/2013 of 21 August 2013 concerning the authorisation of choline chloride as a feed additive for all animal species (OJ L 224, 22.8.2013, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2013/795/oj).

[3] EFSA Journal. 2025;23:e9264.https://doi.org/10.2903/j.efsa.2025.9264.

Authority stated that the application for renewal of the authorisation does 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. It did not considered that there is a 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 choline chloride 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 378/2005[4], evaluation report of the Reference Laboratory is therefore not required.

(6) Implementing Regulation (EU) No 795/2013 provides that choline chloride is allowed to be placed on the market in the form of preparations, but the composition of such preparations has erroneously not been specified in the terms of the authorisation. A more accurate description of the preparations containing choline chloride should be provided for by specifying the composition of the feed additives authorised as preparations. A different identification number should also be assigned to distinguish between the aqueous solution and the preparation.

(7) In view of the above, the Commission considers that the aqueous solution of choline chloride and the preparation of choline chloride satisfy the conditions as 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 additive. 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 the aqueous solution of choline chloride and the preparation of choline chloride, Implementing Regulation (EU) No 795/2013 should be repealed.

(9) Since the identification number of the additives has been modified, 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,

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The authorisation of the aqueous solution and the preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group

[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).

'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 795/2013

Implementing Regulation (EU) No 795/2013 is repealed.

Article 3

Transitional measures

1. The preparations of choline chloride as authorised by Implementing Regulation (EU) No 795/2013 and premixtures containing those preparations, 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 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 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