



2026/164

27.1.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/164

of 26 January 2026

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 Implementing Regulation (EU) No 795/2013

(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) Preparations of choline chloride in solid and liquid forms were authorised 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, provitamins 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 of 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 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 consider that there is a need for specific requirements of post-market monitoring.

⁽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>).

- (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 '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.

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

*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 16 August 2026 in accordance with the rules applicable before 16 February 2026 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 16 February 2027 in accordance with the rules applicable before 16 February 2026 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 16 February 2028 in accordance with the rules applicable before 16 February 2026 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, 26 January 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a890i	Choline chloride	<i>Additive composition</i> Aqueous solution containing a minimum of 74 % of choline chloride <i>Characterisation of the active substance</i> Choline chloride C ₅ H ₁₄ Cl·NO CAS number: 67-48-1 Solid form, produced by chemical synthesis Purity criteria: min. 99 % anhydrous basis 2-chloroethanol: maximum 30 mg/kg <i>Analytical method ⁽¹⁾</i> For the determination of choline chloride in the feed additive, premixtures, compound feed and water for drinking: ion chromatography with conductivity detection (IC-CD)	All animal species	—	—	—	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. Simultaneous use of choline chloride in feed and water for drinking shall not be allowed. 4. The labelling of feed for poultry and pigs containing choline chloride shall indicate: 'Recommended not to exceed supplemental levels of 1 000 mg of choline chloride/kg of complete feed for poultry and pigs.'	16 February 2036

Identification number of the additive	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
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
							5. In the directions for use of feed for poultry or pigs containing choline chloride shall be indicated: ‘Simultaneous use with water for drinking in which choline chloride has been added shall not be allowed.’ 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	

(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.

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Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a890ii	Choline chloride	<i>Additive composition</i> Preparation with a minimum of 50 % of choline chloride Solid form <i>Characterisation of the active substance</i> Choline chloride C ₅ H ₁₄ Cl·NO CAS number: 67-48-1 Solid form, produced by chemical synthesis Purity criteria: min. 99 % anhydrous basis 2-chloroethanol: maximum 30 mg/kg <i>Analytical method ⁽¹⁾</i> For the determination of choline chloride in the feed additive, premixtures, compound feed and water for drinking: ion chromatography with conductivity detection (IC-CD)	All animal species	—	—	—	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. Simultaneous use of choline chloride in feed and water for drinking shall not be allowed. 4. The labelling of feed for poultry and pigs containing choline chloride shall indicate: 'Recommended not to exceed supplemental levels of 1 000 mg of choline chloride/kg of complete feed for poultry and pigs.'	16 February 2036

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