



2024/1786

28.6.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1786

of 27 June 2024

concerning the renewal of the authorisation of a preparation of ammonium chloride as a feed additive for ruminants, cats and dogs (holder of the authorisation: BASF SE) and repealing Implementing Regulation (EU) No 725/2013

(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) A preparation of ammonium chloride was authorised for 10 years as a feed additive for ruminants, cats and dogs by Commission Implementing Regulation (EU) No 725/2013 ⁽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 the preparation of ammonium chloride as a feed additive for ruminants, cats and dogs in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives (reduction of urinary pH)'. The application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 March 2022 ⁽³⁾ that the preparation of ammonium chloride remains safe for ruminants, cats and dogs, the consumers and the environment under the conditions of use currently authorised. The Authority concluded that ammonium chloride is considered an eye and skin irritant and a potential respiratory sensitiser, but that it is not a dermal sensitiser. It further concluded 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 additive. It did not consider 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 ammonium 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⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of ammonium chloride satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive 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.

⁽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 725/2013 of 26 July 2013 concerning the authorisation of ammonium chloride as a feed additive for ruminants, cats and dogs (holder of the authorisation BASF SE) (OJ L 202, 27.7.2013, p. 17, ELI: http://data.europa.eu/eli/reg_impl/2013/725/oj).

⁽³⁾ EFSA Journal 2022;20(4):7255.

⁽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>).

- (7) As a consequence of the renewal of the authorisation of the preparation of ammonium chloride as a feed additive, Implementing Regulation (EU) No 725/2013 should be repealed.
- (8) 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

Renewal of the authorisation

The authorisation of the preparation of ammonium chloride, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is renewed subject to the conditions laid down in the Annex.

Article 2

Repeal

Implementing Regulation (EU) No 725/2013 is repealed.

Article 3

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, 27 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	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 the additive /kg of complete feedingstuff with a moisture content of 12 %			

Category: zootechnical additives. Functional group: other zootechnical additives (reduction of urinary pH)

4d8	BASF SE	Ammonium chloride	<p><i>Additive composition</i> Preparation of ammonium chloride $\geq 99,0$ %. Solid form.</p> <p><i>Characterisation of the active substance</i> Ammonium chloride $\geq 99,0$ % NH₄Cl CAS No: 12125-02-9 Sodium chloride $\leq 0,5$% Produced by chemical synthesis.</p> <p><i>Method of Analysis</i> (1) Quantification of ammonium chloride in the feed additive: titration with sodium hydroxide (European Pharmacopoeia monograph 0007) or titration with silver nitrate (JECFA monograph 'ammonium chloride').</p>	Ruminants	-	-	5 000 / 10 000	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The additive shall be incorporated into feed in the form of a premixture. For ruminants, the additive shall be used under the following conditions: <ul style="list-style-type: none"> — maximum content of 5 000 mg additive/kg complete feed for a feeding period exceeding three months, or — maximum content of 10 000 mg additive/kg complete feed for a feeding period not exceeding three months The mixture of different sources of ammonium chloride shall not exceed the permitted maximum levels in complete feedingstuffs for ruminants, cats and dogs. 	18 July 2034
				Cats and dogs			5 000		

									5. 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 breathing, eye and skin protective equipment.	
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(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