

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1710**of 7 September 2023**

concerning the renewal of the authorisation of a preparation of ammonium chloride as a feed additive for all ruminants and cats and dogs, an authorisation of a preparation of ammonium chloride as a feed additive for sows (holder of the authorisation: Latochemia Co. Ltd) and repealing Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007

(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 Articles 9(2),

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 a period of 10 years as a feed additive for lambs for fattening by Commission Implementing Regulation (EU) No 832/2012 ⁽²⁾ and for ruminants other than lambs for fattening, cats and dogs by Commission Implementing Regulation (EU) 2016/1007 ⁽³⁾.
- (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 for all ruminants, cats and dogs. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of that preparation for sows. Those applications requested that additive to be classified in the category 'zootechnical additives' and in the functional group 'other zootechnical additives' and were accompanied by the particulars and documents required respectively under Article 7(3) and Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 22 November 2022 ⁽⁴⁾, that the preparation of ammonium chloride remains safe for lambs for fattening, ruminants other than lambs for fattening, cats and dogs, as well as for the consumers and the environment under the conditions of use currently authorised. The Authority also concluded that this preparation is safe and efficacious in reducing the urinary pH for sows at the inclusion level of 5 000 mg/kg feedingstuffs from week 9th to 11th of gestation and from week 15th of gestation to 1st of lactation and that is safe for the consumers and the environment when used as a feed additive for sows. The Authority further concluded that the preparation should be considered a potential respiratory sensitiser but not a skin sensitiser nor irritant to the skin. It could not conclude on its eye irritation potential. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 832/2012 of 17 September 2012 concerning the authorisation of a preparation of ammonium chloride as a feed additive for lambs for fattening (holder of authorisation Latochemia Co. Ltd) (OJ L 251, 18.9.2012, p. 27).

⁽³⁾ Commission Implementing Regulation (EU) 2016/1007 of 22 June 2016 concerning the authorisation of ammonium chloride as a feed additive for ruminants other than lambs for fattening, cats and dogs (holder of authorisation Latochemia Co. Ltd) (OJ L 165, 23.6.2016, p. 10).

⁽⁴⁾ EFSA Journal 2023;21(1):7696.

- (5) In accordance with Article 5(4), points (a) and (c) of Commission Regulation (EC) No 378/2005 ⁽ⁱ⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the preparation of ammonium chloride in feed are valid and applicable for the current applications.
- (6) The assessment of the preparation of ammonium chloride shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed for all ruminants, cats and dogs and the use of that additive should be authorised for sows. 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.
- (7) As a consequence of the renewal of the authorisation of the preparation of ammonium chloride for all ruminants, cats and dogs as a feed additive, Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007 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 specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is renewed for ruminants, cats and dogs, subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised for sows, subject to the conditions laid down in that Annex.

Article 3

Repeal

Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007 are repealed.

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*.

⁽ⁱ⁾ 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).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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 of zootechnical additives. Functional group: other zootechnical additives (reduction of urinary pH).

4d7	Latochema Co Ltd	Ammonium chloride	<i>Additive composition</i> Preparation of ammonium chloride ≥ 99,5 % Solid form	Lambs for fattening	—	—	10 000	- 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 the feed in the form of a premixture. - For lambs for fattening, the additive shall be used for a feeding period which does not exceed three months. - For ruminants other than lambs for fattening the additive shall be used under the following conditions: — 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. - For sows the additive shall only be used from 9th to 11th week of gestation and from 15th week of gestation to 1st week of lactation.	28 September 2033
			<i>Characterisation of the active substance</i> Ammonium chloride ≥ 99,5 % Chemical formula: NH ₄ Cl CAS No: 12125-02-9 Sodium chloride ≤ 0,5 % Produced by chemical synthesis	Ruminants other than lambs for fattening	—	—	5 000/10 000		
			<i>Analytical method</i> ⁽¹⁾ Quantification of ammonium chloride in feed additive: titration with sodium hydroxide (European Pharmacopoeia, monograph 0007) or titration with silver nitrate (JECFA monograph 'ammonium chloride')	Cats and dogs	—	—	5 000		
				Sows	—	—	5 000		

								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 eye and breathing protective equipment. 7. The mixture of different sources of ammonium chloride shall not exceed the permitted maximum levels in complete feedingstuffs for ruminants, including lambs for fattening, for cats, dogs and sows.	
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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.