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 the authorisation Latochema Co. Ltd)

(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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of ammonium chloride. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of ammonium chloride as a feed additive for ruminants, cats and dogs to be classified in the additive category 'zootechnical additives'.

(4) The additive was already authorised for use in lambs for fattening by Commission Implementing Regulation (EU) No 832/2012 ([2]).

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 December 2015 ([3]) that, under the proposed conditions of use, the preparation of ammonium chloride is presumed not to have an adverse effect on animal health, human health or the environment and that its use can reduce the pH value in the urine. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment 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 use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) 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

Ammonium chloride as specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([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 Latochema Co. Ltd) (OJ L 251, 18.9.2012, p. 27).
([3]) EFSA Journal 2016; 14(1):4352.

Article 2

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, 22 June 2016.

For the Commission

The President

Jean-Claude JUNCKER

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 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	*Additive composition* Ammonium chloride ≥ 99,5 Solid form *Characterisation of the active substance* Ammonium chloride ≥ 99,5 % NH_4Cl CAS No: 12125-02-9 Sodium chloride ≤ 0,5 % Produced by chemical synthesis *Method of Analysis* (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')	Ruminants other than lambs for fattening Cats Dogs	—		10 000 for a feeding period not exceeding three months 5 000 for a feeding period exceeding three months 5 000	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 3. The mixture of different sources of ammonium chloride shall not exceed the permitted maximum levels in complete feedingstuffs for ruminants, cats and dogs.	13 July 2026

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports