

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)****(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.

(2) Ammonium chloride was authorised in accordance with Directive 70/524/EEC as a feed additive, without a time limit, for use on cats and dogs and with a time limit for all pets with the exception of cats and dogs by Commission Directive 86/525/EEC⁽³⁾. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of ammonium chloride as a feed additive for cats and dogs and, in accordance with Article 7 of that Regulation, for a new use for ruminants, requesting that additive to be classified in the additive category 'technological additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 24 May 2012⁽⁴⁾ that,

under the proposed conditions of use, the ammonium chloride does not have an adverse effect on animal health, human health or the environment. It recognised that the ammonium chloride is a potent urinary acidifier and a supplementation of feed for ruminants, cats and dogs results in a decrease of the urinary pH. 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.

(5) The assessment of the 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 additive should be authorised as specified in the Annex to this Regulation.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1***Authorisation**

The ammonium chloride 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.

*Article 2***Transitional measures**

The additive specified in the Annex for use for cats and dogs and feed containing that additive, which are produced and labelled before 16 August 2015 in accordance with the rules applicable before 16 August 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ OJ L 310, 5.11.1986, p. 19.

⁽⁴⁾ EFSA Journal 2012; 10(6):2738.

Article 3

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 July 2013.

For the Commission
The President
José Manuel BARROSO

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/kg of complete feedingstuff with a moisture content of 12 %			

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

4d8	BASF SE	Ammonium chloride	<i>Additive composition</i> Ammonium chloride ≥ 99,0 % (Solid form) <i>Characterisation of the active substance</i> Ammonium chloride ≥ 99,0 % NH ₄ Cl CAS No: 12125-02-9 Sodium chloride ≤ 0,5 % Produced by chemical synthesis <i>Method of analysis</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).	Ruminants	—	—	10 000 for a period not exceeding three months 5 000 for a period exceeding three months	1. The additive shall be incorporated into feed in the form of a premixture. 2. For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling. 3. The mixture of different sources of ammonium chloride shall not exceed the permitted maximum levels in complete feedingstuffs for ruminants.	16 August 2023
				Cats and dogs			5 000		

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx