

COMMISSION IMPLEMENTING REGULATION (EU) No 1006/2013
of 18 October 2013
concerning the authorisation of L-cystine as a feed additive for all animal species
(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 L-cystine as a feed additive in the functional group 'amino acids, their salts and analogues'. 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 L-cystine as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 March 2013⁽²⁾ that, under the proposed conditions of use, L-cystine does not have an adverse effect on animal health, human health or the environment and that it may be considered

efficacious to contribute to the requirements for sulphur-containing amino acids in all animal species. 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 that substance shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised, as specified in the Annex to this Regulation.
- (6) 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

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

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, 18 October 2013.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(4):3173.

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 feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c391	—	L-cystine	<p><i>Additive composition</i></p> <p>Crystalline powder produced by hydrolysis of natural keratin from poultry feathers with a minimum L-cystine content of 98,5 %</p> <p><i>Characterisation of the active substance</i></p> <p>IUPAC name: (2R)-2-amino-3-[(2R)-2-amino-3-hydroxy-3-oxopropyl] disulfanyl-propanoic acid</p> <p>CAS number: 56-89-3</p> <p>Chemical formula: C₆H₁₂N₂O₄S₂</p> <p><i>Analytical methods</i> ⁽¹⁾</p> <p>For the determination of L-cystine in the feed additive:</p> <p>Titrimetry, European Pharmacopoeia (Ph. Eur. 6.0, method 01/2008-0998).</p> <p>For the determination of cystine in premixtures, compound feed and feed materials:</p> <p>Ion exchange chromatography method with post-column derivatisation and photometric detection: Commission Regulation (EC) No 152/2009 ⁽²⁾ (Annex III, F).</p>	All animal species	—	—	—	<p>1. For user safety: Breathing protection, safety glasses and gloves should be worn during handling.</p> <p>2. Indicate in the directions for use of the additive and premixtures:</p> <ul style="list-style-type: none"> — Processing stability and storage conditions. — Supplementation with L-cystine shall depend on the requirements of the target animals for sulphur-containing amino acids and the level of other sulphur-containing amino acids in the ration. 	8 November 2023

⁽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/authorisation/evaluation_reports/Pages/index.aspx

⁽²⁾ OJ L 54, 26.2.2009, p. 1.