EUROPEAN
COMMISSION

Brussels, XXX
SANTE/3883219/2024 CIS
(POOL/G5/2024/AN/3883219/3883219-EN CIS.docx)
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of L-cystine as a feed additive for all animal species and repealing Implementing Regulation (EU) No 1006/2013

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of L-cystine as a feed additive for all animal species and repealing Implementing Regulation (EU) No 1006/2013

(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 authorisation.

(2) L-cystine was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1006/2013[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 L-cystine as a feed additive for all animal species, requesting that additive to be classified in the category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'. That 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 18 April 2024[3] that the use of L-cystine is of no safety concern for the target species, the consumers and the environment. As regards the safety for the user it also concluded that L-cystine is not considered irritant to skin or eyes and is not considered to be a skin sensitiser but that exposure by inhalation of persons handling the additive cannot be excluded. The Authority considered that there is no need for assessing the efficacy of L-cystine, as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation in this regard.

(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 methods of analysis of L-cystine as a feed additive in the context of the previous authorisation are valid and applicable for the current application. However, the

[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 1006/2013 of 18 October 2013 concerning the authorisation of L-cystine as a feed additive for all animal species (OJ L 279, 19.10.2013, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2013/1006/oj).

[3] EFSA Journal 2024;22:e8800.

Reference Laboratory subsequently updated the evaluation report submitted in the context of the previous authorisation, in order to take account of scientific and technological developments and to ensure a better suitability of the methods of analysis for official controls. The Authority verified the amended report on the method of analysis of L-cystine as a feed additive submitted by the Reference Laboratory[4].

(6) In view of the above, the Commission considers that L-cystine satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. As regards the methods of analysis, account should be taken of the updated evaluation report of the Reference Laboratory. It is appropriate to alert the user to take into account that supplementation with L-cystine is to 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. 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.

(7) As a consequence of the renewal of the authorisation of L-cystine as a feed additive, Implementing Regulation (EU) No 1006/2013 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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 1006/2013

Implementing Regulation (EU) No 1006/2013 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.

---

[4] Minutes of the meeting of 15-16 October 2024 of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), accessible at: https://www.efsa.europa.eu/sites/default/files/2024-10/178th-plenary-meeting-of-the-feedap-panel-minutes.pdf

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN