Commission Implementing Regulation (EU) 2020/1379 of 1 October 2020 concerning the authorisation of L-cystine produced by Pantoea ananatis NITE BP-02525 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1379

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concerning the authorisation of L-cystine produced by *Pantoea ananatis* NITE BP-02525 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 produced by *Pantoea ananatis* NITE BP-02525 as a feed additive in feed and water for drinking for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of L-cystine produced by *Pantoea ananatis* NITE BP-02525 as a feed additive for all animal species to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’, and in the additive category ‘sensory additives’, functional group ‘flavouring compounds’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 January 2020[(2)] that, under the proposed conditions of use, L-cystine produced by *Pantoea ananatis* NITE BP-02525 does not have an adverse effect on animal health, consumers health or the environment, and that it is slightly irritating by inhalation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Moreover, the Authority stated that the supplementation with L-cystine produced by fermentation with *Pantoea ananatis* NITE BP-02525 should respect the requirements for sulphur-containing amino acids. Therefore, a respective labelling provision should be established. The Authority also concluded that the additive may be considered efficacious to contribute to the requirements for sulphur-containing amino

acids in all animal species and that for the supplemental L-cystine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed in its opinion a concern over potential nutritional imbalances of when L-cystine is administered as amino acid via water for drinking. However, no maximum content for L-cystine is proposed by the Authority. Thus, in the case of supplementation of feed and water for drinking with L-cystine as amino acid, it is appropriate to take into account the dietary supply with all essential and conditionally essential amino acids.

(5) As regards the use as flavouring, the Authority states that no further demonstration of efficacy is necessary when used at the recommended dose. The use of L-cystine as flavouring compound is not authorised in water for drinking. At the recommended dose, L-cystine as flavouring compound is unlikely to pose any concern. The fact that the use of the L-cystine is not authorised as flavouring in water for drinking does not preclude its use in compound feed which is administered via water.

(6) Restrictions and conditions should be provided for to allow for a better control of L-cystine as flavouring compound. For L-cystine, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures.

(7) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment of L-cystine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

(9) 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

1 The substance L-cystine produced by *Pantoea ananatis* NITE BP-02525 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 a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2 The substance L-cystine produced by *Pantoea ananatis* NITE BP-02525 specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’ is authorised as a feed 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, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1379. (See end of Document for details)*

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: nutritional additives. Functional group: amino acids, their salts and analogues.									
3c392		L-cystine	**Additive composition:** Powder with a minimum content of 98 % L-cystine **Characterisation of the active substance:** L-cystine produced by fermentation with *Pantoea ananatis* NITE BP-02525 IUPAC name: (2R)-2-amino-3-[(2R)-2-amino-3-hydroxy-3-oxopropyl] disulfanyl-propanoic acid	All animal species				1. L-cystine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. For users of the additive and premixture, feed business	22.10.2030

a 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

b OJ L 54, 26.2.2009, p. 1.

c 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

			CAS number: 56-89-3 Chemical formula: $C_6H_{12}N_2O_4S_2$						operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment. In the directions for use
			Analytical method[a]: For the identification of L-cystine in the feed additive: —	Food Chemical Codex ‘L-cystine monograph’				4.	
			For the quantification of cystine in the feed additive and premixtures: —	ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), as described in					

a 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

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