Commission Implementing Regulation (EU) 2020/1372 of 1 October 2020 concerning the authorisation of L-tryptophan produced by Escherichia coli CGMCC 7.267, CGMCC 11674 or KCCM 10534 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1372

of 1 October 2020

concerning the authorisation of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, CGMCC 11 674 or KCCM 10 534 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 applications were submitted for the authorisation of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534. These applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The applications concern the authorisation of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 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’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 26 February 2019[(2)], 28 January 2020[(3)], 18 March 2020[(4)] and 25 May 2020[(5)] that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 does not have an adverse effect on the health of non-ruminant animals, consumer safety or the environment. To be safe for ruminants, the L-tryptophan should be protected against degradation in the rumen. The Authority stated a risk for the users of the additive upon inhalation due to the endotoxin levels of the L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 and could not exclude a potential of L-tryptophan produced by *Escherichia coli* CGMCC 11 674 or *Escherichia coli* CGMCC 7.267 to be an irritant to skin and eyes or

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1372. (See end of Document for details)*

to be a skin sensitiser. 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.

(5) The Authority considered L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 an efficacious source of the essential amino acid tryptophan for non-ruminant animals; for the supplemental L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 to be fully efficacious in ruminants, it should be protected against degradation in the rumen. In its opinions, the Authority raised concerns about potential nutritional imbalances for amino acids, when they are administered via water for drinking. However, the Authority did not propose a maximum content for the supplementation with L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 as amino acid via water for drinking. 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 L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 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 substance 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

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1372. (See end of Document for details)*

Done at Brussels, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

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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.									
3c441		L-tryptophan	**Additive composition:** Powder with a minimum of 98 % L-tryptophan (on a dry matter basis) Maximum content of 10 mg/kg 1,1′-ethylidene-bis-L-tryptophan (EBT) **Characterisation of the active substance:** L-tryptophan produced by fermentation with *Escherichia coli* CGMCC 7.267 or	All species				1. L-tryptophan may be placed on the market and used as an additive consisting of a preparation. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential	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 Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6013 and EFSA Journal 2020;18(4):6071); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).