COMMISSION IMPLEMENTING REGULATION (EU) 2020/229

of 19 February 2020

concerning the authorisation of L-tryptophan 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* KCCM 80135, *Escherichia coli* KCCM 80152, *Escherichia coli* CGMCC 7.248 or *Corynebacterium glutamicum* KCCM 80176. These applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation (EC).

(3) The applications concern the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80135, *Escherichia coli* KCCM 80152, *Escherichia coli* CGMCC 7.248 or *Corynebacterium glutamicum* KCCM 80176 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 opinions of 22 January 2019 ([2]), 2 April 2019 ([3]), 3 April 2019 ([4]) and of 16 May 2019 ([5]) that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* KCCM 80135, *Escherichia coli* KCCM 80152, *Escherichia coli* CGMCC 7.248 or *Corynebacterium glutamicum* KCCM 80176 does not have an adverse effect on the health of non-ruminant animal, 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* KCCM 80152 and *Escherichia coli* CGMCC 7.248. 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. The Authority considered L-tryptophan produced by *Escherichia coli* KCCM 80135, *Escherichia coli* KCCM 80152, *Escherichia coli* CGMCC 7.248 or *Corynebacterium glutamicum* KCCM 80176 an efficacious source of the essential amino acid tryptophan for non-ruminant animals; for the supplemental L- tryptophan to be fully efficacious in ruminants, it should be protected against degradation in the rumen. 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 L-tryptophan produced by *Escherichia coli* KCCM 80135, *Escherichia coli* KCCM 80152, *Escherichia coli* CGMCC 7.248 or *Corynebacterium glutamicum* KCCM 80176 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.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(2):5601.
([3]) EFSA Journal 2019;17(5):5694.
([4]) EFSA Journal 2019;17(5):5695.
([5]) EFSA Journal 2019;17(6):5729.

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, 19 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

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* KCCM 80135 or *Escherichia coli* KCCM 80152 or *Escherichia coli* CGMCC 7.248 or *Corynebacterium glutamicum* KCCM 80176. Chemical formula: $C_{11}H_{12}N_2O_2$ CAS No: 73-22-3 **Analytical methods** (2): For the identification of L-tryptophan in the feed additive: — Food Chemical Codex 'L-tryptophan monograph'. For the determination of tryptophan in the feed additive and premixtures: — High performance liquid chromatography with fluorescence detection (HPLC-FLD) – EN ISO 13904 For the determination of tryptophan in compound feed and feed materials:	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 risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air (1). 4. L-tryptophan may be used via water for drinking. 5. For ruminants, L-tryptophan shall be rumen protected. 6. The labelling of the additive shall indicate the moisture content.	11.3.2030

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						mg/kg of complete feed with a moisture content of 12 %			
			— High Performance Liquid Chromatography with fluorescence detection (HPLC-FLD) – Commission Regulation (EC) No 152/2009 (Annex III, G) For the determination of tryptophan in water: — High performance liquid chromatography with fluorescence detection (HPLC-FLD)					7. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-tryptophan, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	

(1) 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

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).