COMMISSION IMPLEMENTING REGULATION (EU) 2025/188

of 31 January 2025

concerning the authorisation of L-tryptophan produced with *Escherichia coli* CGMCC 7.460 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-tryptophan produced with *Escherichia coli* CGMCC 7.460. 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-tryptophan produced with *Escherichia coli* CGMCC 7.460 as a feed additive for use in feed and in water for drinking 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'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 March 2024 ([2]) that, under the proposed conditions of use, L-tryptophan produced with *Escherichia coli* CGMCC 7.460 is safe for non-ruminant target species but there may be a risk for an increased production of the toxic metabolite skatole when unprotected tryptophan is used in ruminants. The Authority has concerns on the safety for the target species resulting from the simultaneous oral administration of L-tryptophan via water for drinking and feed due to possible amino acid imbalances and hygienic reasons. The use of l-tryptophan produced with *E. coli* CGMCC 7.460 in animal nutrition is considered safe for the consumers and for the environment. In the absence of data, the Authority cannot conclude on the potential of the additive to be irritant to skin or eyes, or on its potential to be a dermal sensitiser. It concluded that the endotoxin activity of the additive in combination with the high dusting potential may represent a risk of exposure by inhalation to endotoxins for users. The Authority further concluded that the substance is regarded as an efficacious source of the essential amino acid L-tryptophan for all non-ruminant species and that for the substance to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority did 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) In view of the above, the Commission considers that L-tryptophan produced with *Escherichia coli* CGMCC 7.460 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance as a feed additive should be authorised. When fed to ruminants, L-thryptophan needs to be protected against degradation in the rumen. It is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids, in particular in the case of supplementation with L-tryptophan via water for drinking. 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.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal* 2024;22(4), e8707.

(6) 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

Authorisation

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

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.

Done at Brussels, 31 January 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c442	L-tryptophan	*Additive composition* Powder with a minimum content of L-tryptophan of 98 % (on a dry matter basis) and ≤ 0,5% water Maximum content of 10 mg/kg 1,1′-ethylidene-bis-L-tryptophan (EBT) *Characterisation of the active substance* L-tryptophan produced with *Escherichia coli* CGMCC 7.460 Chemical formula: $C_{11}H_{12}N_2O_2$ CAS number: 73-22-3 *Analytical method* ([1]) 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	All animal species	–	–	–	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-thryptophan is rumen protected, when fed to ruminants. 4. The labelling of the additive and premixtures shall indicate the following: — 'The supplementation with L-tryptophan, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.'	23 February 2035

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		For the determination of tryptophan in compound feed: — High performance liquid chromatography with fluorescence detection (HPLC-FLD) – Commission Regulation (EC) No 152/2009 ([2])					5. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air ([3]). 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

([2]) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/152/oj).

([3]) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (*EFSA Journal* 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).