II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2076

of 26 November 2021

concerning the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210 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-tryptophan produced by *Escherichia coli* KCCM 80210. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210 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 opinion of 27 January 2021 ([2]) that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* KCCM 80210 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 that the additive under assessment is considered a mild eye irritant. The endotoxin activity of the additive and its dusting potential indicate a risk 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.

(5) The Authority considered that L-tryptophan produced by *Escherichia coli* KCCM 80210 is an efficacious source of the essential amino acid tryptophan for non-ruminant animals; for the supplemental L-tryptophan produced by *Escherichia coli* KCCM 80210 to be as efficacious in ruminants as in non-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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(3):6425.

(6) The assessment of L-tryptophan produced by *Escherichia coli* KCCM 80210 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.

Done at Brussels, 26 November 2021.

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: nutritional additives **Functional group: amino acids, their salts and analogues**									
3c440i	-	L-tryptophan	*Additive composition* Powder with a minimum of 98 % L-tryptophan on a dry matter basis and a maximum moisture content of 1 %. 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 80210 Chemical formula: $C_{11}H_{12}N_2O_2$ CAS No: 73-22-3 *Analytical methods* (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 species	-	-	-	1. The feed business operator placing the additive on the market shall ensure that its endotoxin content and dusting potential result in a maximal endotoxin exposure of 1600 IU endotoxins/m³ air (2). 2. For ruminants, L-tryptophan shall be rumen protected. 3. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, skin 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	19 December 2031

			For the determination of tryptophan in compound feed and feed materials: — High performance liquid chromatography with fluorescence detection (HPLC-FLD); Commission Regulation (EC) No 152/2009 (3) (Annex III, G).					with personal protective equipment, including eyes, skin and breathing protection.	

(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* 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

(3) 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).