COMMISSION IMPLEMENTING REGULATION (EU) 2017/873

of 22 May 2017

concerning the authorisation of L-tryptophan produced by *Escherichia coli* 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 82/471/EEC ([2]).

(2) L-tryptophan was authorised without a time limit pursuant to Directive 82/471/EEC by Commission Directive 88/485/EEC ([3]). This feed additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of L- tryptophan as feed additive for all animal species. Applications were also submitted for the authorisation of L- tryptophan for all animal species in accordance with Article 7 of that Regulation. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The applications concern the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 11132P, *Escherichia coli* DSM 25084, *Escherichia coli* FERM BP-11200, *Escherichia coli* FERM BP-11354, *Escherichia coli* CGMCC 7.59 or *Escherichia coli* CGMCC 3667 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 11 September 2013 ([4]), 10 April 2014 ([5]), 9 September 2014 ([6]), 29 January 2015 ([7]), 10 September 2015 ([8]), 1 December 2015 ([9]), 25 January 2017 ([10]) and of 25 January 2017 ([11]) that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* KCCM 11132P, *Escherichia coli* DSM 25084, *Escherichia coli* FERM BP-11200, *Escherichia coli* FERM BP-11354, *Escherichia coli* CGMCC 7.59 and *Escherichia coli* CGMCC 3667 does not have an adverse effect on animal health, human health or the environment, and that it is considered an efficacious source of the essential amino acid tryptophan for animal nutrition; the applicant for L-tryptophan produced by *Escherichia coli* DSM 25084 provided evidence that, after a change of the manufacturing process, the endotoxin level of the additive was reduced to an acceptable level; 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (OJ L 213, 21.7.1982, p. 8).
([3]) Commission Directive 88/485/EEC of 26 July 1988 amending the Annex to Council Directive 82/471/EEC concerning certain products used in animal nutrition (OJ L 239, 30.8.1988, p. 36).
([4]) EFSA Journal 2013;11(10):3368.
([5]) EFSA Journal 2014;12(5):3673.
([6]) EFSA Journal 2014;12(10):3826.
([7]) EFSA Journal 2015;13(2):4015.
([8]) EFSA Journal 2015;13(9):4238.
([9]) EFSA Journal 2016;14(1):4343.
([10]) EFSA Journal 2017;15(2):4712.
([11]) EFSA Journal 2017;15(3):4705.

(6) The assessment of L-tryptophan 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) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for L-tryptophan, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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

Transitional measures

1. The substance specified in the Annex authorised by Commission Directive 88/485/EEC and premixtures containing it may be placed on the market until 12 December 2017 in accordance with the rules applicable before 12 June 2017 and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substance referred to in paragraph 1 which are produced and labelled before 12 June 2018 in accordance with the rules applicable before 12 June 2017 may be placed on the market and used until the existing stocks are exhausted if they are intended for food producing animals.

3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 12 June 2019 in accordance with the rules applicable before 12 June 2017 may be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

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, 22 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

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									
3c440	—	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 11132P or *Escherichia coli* DSM 25084 or *Escherichia coli* FERM BP-11200 or *Escherichia coli* FERM BP-11354 or *Escherichia coli* CGMCC 7.59 or *Escherichia coli* CGMCC 3667. Chemical formula: $C_{11}H_{12}N_2O_2$ CAS No: 73-22-3	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 1 600 IU endotoxins/m³ air (²).	12 June 2027

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 %			
			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 coupled to fluorescence detection (HPLC-FD) — EN ISO 13904-2016 For the determination of tryptophan in the feed additive, premixtures, compound feed and feed materials: — High Performance Liquid Chromatography (HPLC) coupled with fluorescence detection, Commission Regulation (EC) No 152/2009 (OJ L 54, 26.2.2009, p. 1) (Annex III, G)					4. For ruminants, L-tryptophan shall be rumen protected. 5. Declarations to be made on the label of the additive: Moisture content.	

(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).