COMMISSION IMPLEMENTING REGULATION (EU) 2020/1091

of 24 July 2020

concerning the authorisation of L-threonine 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-threonine produced by *Escherichia coli* CGMCC 11473 as a feed additive for use in feed for all animal species. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) This application concerns the authorisation of L-threonine produced by *Escherichia coli* CGMCC 11473 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 opinion of 5 July 2017 ([2]) combined with the opinion of 4 October 2019 ([3]) that, under the proposed conditions of use, L-threonine produced by *Escherichia coli* CGMCC 11473 does not have an adverse effect on animal health, consumer health or the environment. It also could not conclude on the potential of L-threonine produced by *Escherichia coli* CGMCC 11473 to be a skin sensitiser and irritant to the skin and eyes, and stated an inhalation risk to endotoxins for the users of the additive. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive is an efficacious source of the amino acid L-threonine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additive 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-threonine produced by *Escherichia coli* CGMCC 11473 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive 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* 2017;15(7):4939.
([3]) *EFSA Journal* 2019;17(11):5885.

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, 24 July 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									
3c411	-	L-threonine	**Additive composition:** Powder with a minimum of 98 % L-threonine and a maximum moisture content of 1 % **Characterisation of the active substance:** L-threonine produced by fermentation with *Escherichia coli* CGMCC 11473 Chemical formula: $C_4H_9NO_3$ CAS Number: 72-19-5. **Analytical methods** (1): For the determination of L-threonine in the feed additive: — Food Chemical Codex 'L-threonine monograph' and — Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the determination of threonine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 and — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).	All species	-	-	-	1. L- threonine may be placed on the market and used as an additive consisting of a preparation. 2. L-threonine may be used via water for drinking. 3. 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. 4. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air (2).	16.8.2030

			For the determination of threonine in compound feed and feed materials: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS): Commission Regulation (EC) No 152/2009 (Annex III, F). For the determination of threonine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD).					5. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-threonine, 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(7):4939); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).