COMMISSION IMPLEMENTING REGULATION (EU) 2021/969

of 16 June 2021

concerning the authorisation of L-threonine produced by *Escherichia coli* CGMCC 13325 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 13325 as a feed additive for use in feed for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-threonine produced by *Escherichia coli* CGMCC 13325 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 18 November 2020 ([2]) that, under the proposed conditions of use, L-threonine produced by *Escherichia coli* CGMCC 13325 does not have an adverse effect on animal health, consumer health or the environment. It could not conclude on the potential of L-threonine produced by *Escherichia coli* CGMCC 13325 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 needs to 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 13325 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,

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2020;18(12):6332.

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, 16 June 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 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 13325 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.	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. The labelling of the additive shall indicate the moisture content. 4. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (2). 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 conditionally essential amino acids in order to avoid imbalances.'	7.7.2031

			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 optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the determination of threonine in compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical 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).					6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal 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 appropriate personal protective equipment, including breathing, skin and eye 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).