Commission Implementing Regulation (EU) 2020/238 of 20 February 2020 concerning the authorisation of L-threonine as a feed additive for all animal species (Text with EEA relevance)

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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, applications were submitted for the authorisation of L-threonine produced by *Corynebacterium glutamicum* KCCM 80117 or by *Corynebacterium glutamicum* KCCM 80118 as a feed additive for use in feed for all animal species. These applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) Those applications concern the authorisation of L-threonine produced by *Corynebacterium glutamicum* KCCM 80117 or by *Corynebacterium glutamicum* KCCM 80118 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 opinions of 22 January 2019[(2)(3)] that, under the proposed conditions of use, L-threonine produced by *Corynebacterium glutamicum* KCCM 80117 or *Corynebacterium glutamicum* KCCM 80118 does not have an adverse effect on animal health, human health or the environment. 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 *Corynebacterium* glutamicum KCCM 80117 and by *Corynebacterium glutamicum* KCCM 80118 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.

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, 20 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/238. (See end of Document for details)*

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.									
3c410	—	L-threonine	*Additive composition* Powder with a minimum of 98 % L-threonine (on a dry matter basis). *Characterisation of the active substance* L-threonine produced by fermentation with *Corynebacterium glutamicum* KCCM 80117 or *Corynebacterium glutamicum* KCCM 80118 Chemical formula: $C_4H_9NO_3$ CAS Number: 72-19-5.	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 labelling	12.3.2030

a 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

			Analytical methods[a] 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				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.’

a 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