COMMISSION IMPLEMENTING REGULATION (EU) 2019/1289

of 31 July 2019

concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* KCCM 11201P 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-valine. 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-valine produced by *Corynebacterium glutamicum* KCCM 11201P 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 28 November 2018 ([2]) that, under the proposed conditions of use, L-valine produced by *Corynebacterium glutamicum* KCCM 11201P when supplemented to diets in appropriate amounts does not have an adverse effect on animal health, human health or the environment. Further, the Authority concluded that it is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that in order to be efficacious in ruminants, 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 that substance 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.

(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*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019; 17(1):5538.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 July 2019.

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.									
3c371	—	L-valine	*Additive composition:* Powder with a minimum content of L-valine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water *Characterisation of the active substance:* L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by *Corynebacterium glutamicum* KCCM 11201P Chemical formula: $C_5H_{11}NO_2$ CAS number: 72-18-4 *Analytical method* (1): For the identification of L-valine in the feed additive: — Food Chemical Codex 'L-valine monograph' For the quantification of valine in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)	All species	—			1. L-valine may be placed on the market and used as an additive consisting of a preparation. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. The label of the additive and premixture shall indicate the following: 'The supplementation with L-valine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	21 August 2029

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						mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of valine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of valine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD)						

(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