COMMISSION IMPLEMENTING REGULATION (EU) 2021/719

of 30 April 2021

concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 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* CGMCC 7.358 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 ([2]) that, under the proposed conditions of use, L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer health or the environment. With respect to the safety of the user of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358, the Authority could neither exclude a risk by inhalation, nor that the substance it is irritant to skin or eyes, or a dermal sensitiser. Therefore, appropriate protective measures should be taken for this additive to prevent adverse effects on human health, in particular as regards the users of the additive. Furthermore, the Authority concluded that the substance is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that, in order to be 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 reports 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-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 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 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 a feed additive, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2020; 18(11):6286.

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, 30 April 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 additive/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c371i	-	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* CGMCC 7.358 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"	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 conditionally essential amino acids in order to avoid imbalances.' 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the	23.5.2031

			For the quantification of valine in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) 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)					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 protection, safety glasses and gloves.	

([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