

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1492**of 8 September 2022****concerning the authorisation of L-valine produced by *Escherichia coli* CCTCC M2020321 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-valine produced by *Escherichia coli* CCTCC M2020321 as a feed additive for all animal species. 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 *Escherichia coli* CCTCC M2020321 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 27 January 2022 ⁽²⁾ that, under the proposed conditions of use, L-valine produced by *Escherichia coli* CCTCC M2020321, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer safety or the environment. As regards the safety of the additive for the user, the Authority could not conclude on the potential of the additive to be toxic by inhalation, irritant to skin or eyes, or on its potential to be a dermal or a respiratory sensitiser, and noted that the endotoxin activity of the additive does not represent a hazard for users handling the additive. Furthermore, 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 did 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) In view of the Authority's opinion, the Commission therefore considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) The assessment of L-valine produced by *Escherichia coli* CCTCC M2020321 shows that the conditions for authorisation set out in Article 5 of Regulation (EC) No 1831/2003, are fulfilled.
- (7) The use of this substance should therefore be authorised as specified in the Annex to this Regulation.
- (8) 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 2022;20(2):7163.

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 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, 8 September 2022.

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.

3c371ii	-	L-valine	<i>Additive composition</i> L-valine with a minimum content of 98 % (on a dry matter basis) and a maximum content of 1,5 % water. Powder form	All species	-			1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. 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.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection.	29 September 2032
			<i>Characterisation of the active substance</i> L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by <i>Escherichia coli</i> CCTCC M2020321 Chemical formula: C ₅ H ₁₁ NO ₂ CAS number: 72-18-4						
			<i>Analytical method ⁽¹⁾:</i> 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 optical detection (IEC-VIS)						

			For the quantification of valine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and optical 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 or IEC-VIS/FLD)							
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en