

COMMISSION IMPLEMENTING REGULATION (EU) No 1236/2014**of 18 November 2014****concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* (DSM 25202) 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 produced by *Corynebacterium glutamicum* (DSM 25202). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of L-valine produced by *Corynebacterium glutamicum* (DSM 25202) 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 2 July 2014 ⁽²⁾ that, under the proposed conditions of use, the L-valine produced by *Corynebacterium glutamicum* (DSM 25202) does not have an adverse effect on animal health, human health or the environment and that it is considered an efficacious source of the essential amino acid L-valine for animal nutrition. 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-valine produced by *Corynebacterium glutamicum* (DSM 25202) 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***Authorisation**

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 2014; 12(7):3795.

*Article 2***Entry into force**

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, 18 November 2014.

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.

3c369	—	L-valine	<p><i>Additive composition</i></p> <p>L-valine minimum 98 % (on a dry matter basis).</p> <p><i>Characterisation of the active substance</i></p> <p>L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by fermentation with <i>Corynebacterium glutamicum</i> (DSM 25202).</p> <p>Chemical formula: C₅H₁₁NO₂</p> <p>CAS number: 72-18-4</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>For the determination of L-valine in the feed additive: Food Chemical Codex 'L-valine monograph'.</p> <p>For the determination of valine in premixtures, compound feed and feed materials: ion exchange chromatography coupled with post-column derivatisation and spectrophotometric detection (HPLC/VIS) — Commission Regulation (EC) No 152/2009.</p>	All species	—			<ol style="list-style-type: none"> Declarations to be made on the labelling of the additive: <ul style="list-style-type: none"> — moisture content. For user safety: breathing protection, safety glasses and gloves should be worn during handling. Where voluntary declaration of the additive is made on the labelling of feed materials and compound feed, the following shall be included: <ul style="list-style-type: none"> — name and identification number of the additive, — added amount of the additive. 	9 December 2024
-------	---	----------	--	-------------	---	--	--	--	-----------------

⁽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>