

**COMMISSION IMPLEMENTING REGULATION (EU) No 848/2014****of 4 August 2014****concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* as a feed additive for all animal species and amending Regulation (EC) No 403/2009 as regards the labelling of the feed additive L-valine****(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 <sup>(1)</sup>, and in particular Article 9(2) and Article 13(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 and modifying such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-valine. 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* (KCCM 80058) 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 8 October 2013 <sup>(2)</sup> that, under the proposed conditions of use, the L-valine produced by *Corynebacterium glutamicum* (KCCM 80058) 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 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) Commission Regulation (EC) No 403/2009 <sup>(3)</sup> authorised L-valine produced by *Escherichia coli*. In order to ensure the differentiation of the additives in the final feed, their identification number should be labelled on feed materials and compound feed together with their name and added amount.
- (7) Regulation (EC) No 403/2009 should therefore be amended accordingly. Since the modifications to the conditions of authorisation are not related to safety reasons, it is appropriate to provide for a transitional period during which existing stocks may be used up.
- (8) 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.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2013; 11(10):3429.

<sup>(3)</sup> Commission Regulation (EC) No 403/2009 of 14 May 2009 concerning the authorisation of a preparation of L-valine as a feed additive (OJ L 120, 15.5.2009, p. 3).

*Article 2***Amendment to Regulation (EC) No 403/2009**

In the ninth column of the Annex to Regulation (EC) No 403/2009, the following paragraph is added:

‘Where voluntary declaration of the additive is made on the labelling of feed materials and compound feed, the following shall be included:

- name and identification number of the additive,
- added amount of the additive.’

*Article 3***Transitional measures**

Feed materials and compound feed as referred to in Article 2 which are produced and labelled before 25 February 2015 in accordance with the rules applicable before 25 August 2014 may continue to be placed on the market and used until the existing stocks are exhausted. As regards feed intended for pet animals, the time period for production and labelling referred to in the first sentence shall end 25 August 2016.

*Article 4***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, 4 August 2014.

*For the Commission*

*The President*

José Manuel BARROSO

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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.**

3c370	—	L-valine	<p><i>Additive composition</i></p> <p>L-valine minimum 98 % (on dry matter basis)</p> <p><i>Characterisation of the active substance</i></p> <p>L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by <i>Corynebacterium glutamicum</i> (KCCM 80058)</p> <p>Chemical formula: C<sub>5</sub>H<sub>11</sub>NO<sub>2</sub></p> <p>CAS number: 72-18-4</p> <p><i>Analytical method</i> <sup>(1)</sup></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 (OJ L 54, 26.2.2009, p.1).</p>	All species	—			<p>1. Declarations to be made on the labelling of the additive:</p> <p>— moisture content.</p> <p>2. Where voluntary declaration of the additive is made on the labelling of feed materials and compound feed, the following shall be included:</p> <p>— name and identification number of the additive,</p> <p>— added amount of the additive.</p>	25 August 2024
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<sup>(1)</sup> 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>