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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2183

of 29 October 2025

concerning the renewal of the authorisation of L-valine produced with *Corynebacterium glutamicum* KCCM 80058 as a feed additive for all animal species and repealing Implementing Regulation (EU) No 848/2014

(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 and renewing such an authorisation.

(2) L-valine produced with *Corynebacterium glutamicum* KCCM 80058 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 848/2014 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-valine produced with *Corynebacterium glutamicum* KCCM 80058 as a feed additive for all animal species, requesting that additive to be classified in the category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2025 ([3]) that the use of L-valine produced with *Corynebacterium glutamicum* KCCM 80058 remains safe for all animal species, consumers and the environment under the authorised conditions of use. The Authority also concluded that the additive is not an irritant to skin or eyes nor a skin sensitiser. The Authority also indicated that there is no need for assessing the efficacy of L-valine produced with *Corynebacterium glutamicum* KCCM 80058, as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of L-valine produced with *Corynebacterium glutamicum* KCCM 80058 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([4]), an evaluation report of the Reference Laboratory is therefore not required.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) 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 (OJ L 232, 5.8.2014, p. 13, ELI: http://data.europa.eu/eli/reg_impl/2014/848/oj).
([3]) *EFSA Journal*, 23(2), e9251, https://doi.org/10.2903/j.efsa.2025.9251.
([4]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

(6) In view of the above, the Commission considers that L-valine produced with *Corynebacterium glutamicum* KCCM 80058 satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. It is appropriate that feed business operators ensure the protection of L-valine from rumen degradation and that the label of the additive and premixtures indicates that the supplementation with L-valine must take into account essential and conditionally essential amino acids in order to avoid imbalances.

(7) As a consequence of the renewal of the authorisation of L-valine produced with *Corynebacterium glutamicum* KCCM 80058 as a feed additive, Implementing Regulation (EU) No 848/2014 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of L-valine produced with *Corynebacterium glutamicum* KCCM 80058, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(9) 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

Renewal of the authorisation

The authorisation of 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 renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 848/2014

Implementing Regulation (EU) No 848/2014 is repealed.

Article 3

Transitional measures

1. The feed additive L-valine produced with *Corynebacterium glutamicum* KCCM 80058, as authorised by Implementing Regulation (EU) No 848/2014 and premixtures containing that additive, which are produced and labelled before 19 May 2026 in accordance with the rules applicable before 19 November 2025, may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 19 November 2026 in accordance with the rules applicable before 19 November 2025, may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 19 November 2027 in accordance with the rules applicable before 19 November 2025, may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

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, 29 October 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c370	L-valine	*Additive composition* L-valine with a minimum content of 98 % (on a dry matter basis). Solid form. *Characterisation of the active substance* L-valine produced with *Corynebacterium glutamicum* KCCM 80058 IUPAC name: (2S)-2-amino-3-methylbutanoic acid) 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 determination of valine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) For the determination of valine in premixtures and compound feed: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 2. Feed business operators shall ensure that L-valine is rumen protected, when fed to ruminants. 3. The moisture content shall be indicated on the label of the additive. 4. The label of the additive and premixtures shall indicate the following: 'The supplementation with L-valine shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.'	19 November 2035

(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.