



2025/1787

9.9.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1787

of 8 September 2025

concerning the authorisation of L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 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-arginine produced with *Corynebacterium glutamicum* KCCM 80387. 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-arginine produced with *Corynebacterium glutamicum* KCCM 80387 as a feed additive for all animal species, requesting that additive to be classified in the category 'nutritional additives', functional group 'amino acids, their salts and analogues' and in the category 'sensory additives', functional group 'flavouring compounds'. The applicant requested the additives to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the applicant withdrew the application for water for drinking for the functional group 'flavouring compounds'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2025 ⁽²⁾ that, under the proposed conditions of use, L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 does not pose any safety concerns regarding the production strain and that the additive is safe for the target species, the consumers and the environment. The Authority has concerns on the use of L-arginine in water for drinking. It also concluded that L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 is not irritant to skin, and not a dermal sensitiser but is irritant to the eyes and respiratory tract. The Authority further concluded that the substance is regarded as an efficacious source of the amino acid L-arginine for all non-ruminant species, but for the substance to be fully efficacious in ruminants, it should be protected from ruminal degradation and that it is considered efficacious when used as a flavouring compound in animal nutrition. The Authority did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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) In view of the above, the Commission considers that L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance as a feed additive should be authorised. When fed to ruminants for the use under the functional group 'amino acids, their salts and analogues', L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 needs protection against degradation in the rumen. It is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids, in particular in the case of supplementation with L-arginine via water for drinking. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) The Commission considers that for the use of L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 as flavouring compounds, safety reasons do not require the setting of maximum contents. In order to allow for better control, the recommended maximum content should be indicated on the label of the feed additives. Where such contents are exceeded, certain information should be indicated on the label of the premixtures concerned.
- (7) 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2025; 23(2), e9258, <https://doi.org/10.2903/j.efsa.2025.9258>.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the category 'nutritional additives', functional group 'amino acids, their salts and analogues' and to the category 'sensory additives', functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 8 September 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								
3c367	L-arginine	<i>Additive composition</i> L-arginine ≥ 98 % (on a dry matter basis) Solid form <i>Characterisation of the active substance</i> L-arginine produced with <i>Corynebacterium glutamicum</i> KCCM 80387 IUPAC name: (S)-2-amino-5-guanidinopentanoic acid Chemical formula: C₆H₁₄N₄O₂ CAS number: 74-79-3 <i>Analytical method ⁽¹⁾</i> For the identification of L-arginine in the feed additive: — Food Chemical Codex ‘L-arginine monograph’; For the determination of arginine in the feed additive and water: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS);	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-arginine is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The label of the additive and premixtures shall indicate the following: ‘The supplementation with L-arginine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.’	29 September 2035

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			
		For the determination of arginine in premixtures and compound feed: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009.					6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal eye and breathing protective equipment.	

(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.

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: Sensory additives. Functional group: Flavouring compounds

3c367	L-arginine	<i>Additive composition</i> L-arginine ≥ 98 % (on a dry matter basis) Solid form <i>Characterisation of the active substance</i> L-arginine produced with <i>Corynebacterium glutamicum</i> KCCM 80387	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated.	29 September 2035
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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			
		IUPAC name: (S)-2-amino-5-guanidinopentanoic acid Chemical formula: C₆H₁₄N₄O₂ CAS number: 74–79-3 <i>Analytical method</i> ⁽¹⁾ For the identification of L-arginine in the feed additive: — Food Chemical Codex 'L-arginine monograph'; For the determination of arginine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS); For the determination of arginine in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009.					3. On the label of the additive and premixture the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.' 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3. 5. The moisture content shall be indicated on the label of the additive. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal eye and breathing protective equipment.	

⁽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.