



2026/1117

27.5.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/1117

of 26 May 2026

concerning the authorisation of L-isoleucine produced with *Escherichia coli* CCTCC M 20231916 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-isoleucine produced with *Escherichia coli* CCTCC M 20231916. 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-isoleucine produced with *Escherichia coli* CCTCC M 20231916 as a feed additive for use in feed and in water for drinking for all animal species, requesting that additive to be classified in the additive category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 September 2025 ⁽²⁾ that the use of L-isoleucine produced with *Escherichia coli* CCTCC M 20231916 in feed is safe for the target species when supplemented in appropriate amounts to the diet according to their nutritional needs. However, due to the risk of nutritional imbalances and hygienic reasons, the Authority has concerns on the use of L-isoleucine in water for drinking. The Authority also concluded that the use of L-isoleucine produced with *Escherichia coli* CCTCC M 20231916 in animal nutrition is safe for the consumers and the environment. In the absence of data, it could not conclude on the potential of the additive to be irritant to skin and/or eyes and to be a potential skin sensitiser but identified an inhalation risk to endotoxins for the users of the additive. The Authority further concluded that the substance is regarded as an efficacious source of the amino acid L-isoleucine for non-ruminant nutrition. For the supplemental L-isoleucine to be as efficacious in ruminants as in non-ruminant species, it requires protection 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 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2025, 23(10):e9687, <https://doi.org/10.2903/j.efsa.2025.9687>.

- (5) In view of the above, the Commission considers that L-isoleucine produced with *Escherichia coli* CCTCC M 20231916 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. The Commission considers that possible hygiene risks related to the use of this amino acid in water for drinking, are to be addressed by feed business operators under their obligations to ensure compliance with the relevant hygiene requirements laid down in Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁽⁷⁾ laying down requirements for feed hygiene. When fed to ruminants, L-isoleucine produced with *Escherichia coli* CCTCC M 20231916 should be protected 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-isoleucine 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 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.

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, 26 May 2026.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁷⁾ Regulation (EC) No 1831/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/183/oj>).

ANNEX

Identification number of the additive	Name of the 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								
3c384i	L-isoleucine	<i>Additive composition</i> L-isoleucine Solid form <i>Characterisation of the active substance</i> L-isoleucine ≥ 90 % (on a dry matter basis) produced with <i>Escherichia coli</i> CCTCC M 20231916 IUPAC name: (2S,3S)-2-amino-3-methylpentanoic acid Chemical formula: C ₆ H ₁₃ NO ₂ CAS number: 73-32-5 <i>Analytical method ⁽¹⁾</i> For the identification of L-isoleucine in the feed additive: — Food Chemical Codex 'L-isoleucine monograph'; For the determination of isoleucine in the feed additive: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD or IEC-VIS); For the determination of isoleucine in premixtures: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) or	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment and in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-isoleucine is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-isoleucine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances'.	16 June 2036

Identification number of the additive	Name of the 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			
		— Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 ^(?); For the determination of isoleucine in compound feed: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Regulation (EC) No 152/2009; For the determination of isoleucine in water for drinking: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS).					6. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air ^(?). 7. 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 skin, eye and breathing protective equipment.	

(?) 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.

(?) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).

(?) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

⁽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.

⁽²⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).

⁽³⁾ Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).