

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1493**of 8 September 2022****concerning the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 as feed additives 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 as feed additives 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 23 March 2022 ⁽²⁾ that, under the proposed conditions of use, neither of the two products of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 has an adverse effect on animal health, consumer health or the environment. As regards the safety of the user of that substance, the Authority concluded that the substance, in either products, is not an irritant to skin/eyes nor a dermal sensitiser and shows no toxicity by inhalation. However, the product L-methionine ≥ 90 % presents a risk to the user considering the exposure to endotoxins by inhalation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of that form of the substance.
- (5) The Authority further concluded that L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 is an effective source of methionine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the substance should be protected against degradation in the rumen. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of this 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 this substance should be authorised as specified in the Annex to this Regulation.
- (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.

⁽²⁾ EFSA Journal 2022;20(4):7247.

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues' are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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 2022.

For the Commission
The President
Ursula VON DER LEYEN

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	Mini-mum content	Maxi-mum 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

3c305	-	L-methionine	<i>Additive composition</i> L-methionine with a minimum content of 98,5 % and a maximum moisture content of 0,5 % Powder form	All species	-	-	-	1. L-methionine may be used via water for drinking. 2. The labelling of the additive and pre-mixtures shall indicate the following: 'The supplementation with L-methionine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. The endotoxin content of the additive and its dusting potential shall ensure that the maximal endotoxin exposure of 1 600 IU endotoxins/m ³ air (?) is not exceeded.	29 September 2032
			<i>Characterisation of the active substance</i> L-methionine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80245 and <i>Escherichia coli</i> KCCM 80246 Chemical formula: C ₅ H ₁₁ NO ₂ S CAS Number: 63-68-3.						
			<i>Analytical methods</i> (1) For the determination of L-methionine in the feed additive: — Food Chemical Codex 'L-methionine monograph' and — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180						

			For the determination of methionine in premixtures — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 and — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 ⁽²⁾ (Annex III, F) For the determination of methionine in compound feed and feed materials: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) For the determination of methionine in water: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)					5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including breathing protection.	
3c305ii	-	L-methionine	<i>Additive composition</i> Preparation of L-methionine with a minimum content of 90 % and a maximum moisture content of 0,5 % — other amino acids ≤ 0,63 %; Powder form	All species	-	-	-	1. L-methionine may be used via water for drinking. 2. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-methionine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.'	29 September 2032
			<i>Characterisation of the active substance</i> L-methionine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80245 and <i>Escherichia coli</i> KCCM 80246						

		Chemical formula: C₅H₁₁NO₂S CAS Number: 63-68-3. <i>Analytical methods</i> ⁽¹⁾ For the determination of L-methionine in the feed additive: — Food Chemical Codex 'L-methionine monograph' and — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 For the determination of methionine in premixtures — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 and — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) For the determination of methionine in compound feed and feed materials: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) For the determination of methionine in water: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)					3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. The endotoxin content of the additive and its dusting potential shall ensure that the maximal endotoxin exposure of 1 600 IU endotoxins/m³ air ⁽³⁾ is not exceeded. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including breathing protection.	
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⁽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).

⁽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).