

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1497

of 15 October 2020

concerning the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80 184 and *Escherichia coli* KCCM 80 096 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.
- (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 80 184 and *Escherichia coli* KCCM 80 096 as a feed additive for use in feed for all animal species. 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-methionine produced by *Corynebacterium glutamicum* KCCM 80 184 and *Escherichia coli* KCCM 80 096 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 12 November 2019 ⁽²⁾ that, under the proposed conditions of use, L-methionine produced by *Corynebacterium glutamicum* KCCM 80 184 and *Escherichia coli* KCCM 80 096 does not have an adverse effect on animal health, human health or the environment.
- (5) The Authority also concluded that L-methionine produced by *Corynebacterium glutamicum* KCCM 80 184 and *Escherichia coli* KCCM 80 096 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 additive should be protected against degradation in the rumen.
- (6) 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.
- (7) The assessment of this additive 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 additive should be authorised as specified in the Annex to this Regulation.
- (8) 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 2019;17(12):5917.

HAS ADOPTED THIS REGULATION:

Article 1

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 a feed additive 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, 15 October 2020.

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: amino acids, their salts and analogues									
3c305	-	L-methionine	<p><i>Additive composition</i> Powder with a minimum of 98,5 % L-methionine and a maximum moisture content of 0,5 %</p> <hr/> <p><i>Characterisation of the active substance</i> L-methionine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80 184 and <i>Escherichia coli</i> KCCM 80 096 Chemical formula: C₅H₁₁NO₂S CAS Number: 63-68-3.</p> <hr/> <p><i>Analytical methods</i> ⁽¹⁾ For the determination of L-methionine in the feed additive: — Food Chemical Codex 'L-methionine monograph' (identification) and — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17 180 (quantification) For the determination of methionine in premixtures — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17 180 and — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)</p>	All species	-	-	-	<ol style="list-style-type: none"> 1. L-methionine may be placed on the market and used as an additive consisting of a preparation. 2. L-methionine may be used via water for drinking. 3. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-methionine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 	5.11.2030

			<p>For the determination of methionine in compound feed and feed materials:</p> <ul style="list-style-type: none"> — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) <p>For the determination of methionine in water:</p> <ul style="list-style-type: none"> — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) 						
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(¹) 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>