COMMISSION IMPLEMENTING REGULATION (EU) No 852/2014

of 5 August 2014

concerning the authorisation of L-methionine 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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-methionine as a feed additive. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of L-methionine produced by *Escherichia coli* (KCCM 11252P and KCCM 11340P) 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 8 October 2013 ([2]) that, under the proposed conditions of use, L-methionine produced by *Escherichia coli* (KCCM 11252P and KCCM 11340P) does not have an adverse effect on animal health, human health or the environment and that it may be considered efficacious source of the amino acid L-methionine for all animal species. 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.

(5) The assessment of that substance shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised, as specified in the Annex to this Regulation.

(6) The Authority expressed in its opinion concerns over the safety of L-methionine for the target species when administered via water for drinking. However, no maximum content for L-methionine is proposed by the Authority. Thus, it is in the case of administration of L-methionine via drinking water appropriate to instruct the user to consider all different methionine sources in order to achieve an optimal supply with the essential amino acids without affecting the performance of the animals.

(7) 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

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2013; 11(10):3428.

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, 5 August 2014.

For the Commission

The President

José Manuel BARROSO

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 of nutritional additives. Functional group: amino acids, their salts and analogues									
3c305	—	L-methionine	*Additive composition* L-methionine with a purity of at least 98,5 % *Characterisation of the active substance* L-methionine ((2S)-2-amino-4-(methylthio) butanoic acid) produced by fermentation with *Escherichia coli* (KCCM 11252P and KCCM 11340P) Chemical formula: $C_5H_{11}NO_2S$ CAS number: 63-68-3 *Analytical method* (1) For the identification of L-methionine in the feed additive: infrared absorption and optical rotation — FCC monographs methods. For the quantification of methionine in the feed additive and premixtures containing more than 10 % of methionine: ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-VIS/FD) — ISO/DIS 17180. For the determination of methionine in premixtures containing less than 10 % of methionine, compound feed, feed materials and water: ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC/VIS) — Commission Regulation (EC) No 152/2009 (2) (Annex III, F).	All species	—			1. L-methionine can be also used via water for drinking. 2. Declarations to be made on the labelling of the additive and premixtures: 'If the additive is administered via water for drinking, excess protein should be avoided.' 3. Where voluntary declaration of the additive is made on the labelling of feed materials and compound feed, the following shall be included: — name and identification number of the additive, — added amount of the additive.	26 August 2024

(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
(2) OJ L 54, 26.2.2009, p. 1.