COMMISSION IMPLEMENTING REGULATION (EU) 2015/1408

of 19 August 2015

concerning the authorisation of DL-methionyl-DL-methionine as a feed additive for fish and crustaceans

(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 DL-methionyl-DL-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 DL-methionyl-DL-methionine as a feed additive for all aquatic animal species, to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2015 ([2]) that, under the proposed conditions of use, DL-methionyl-DL-methionine does not have an adverse effect on animal health, human health or the environment and that it may be considered an efficacious source of the amino acid L-methionine for fish and crustacean 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 DL-methionyl-DL-methionine 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 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.

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*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2015;13(2):4012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 August 2015.

For the Commission
The President
Jean-Claude JUNCKER

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									
3c306	—	DL-methionyl-DL-methionine	*Additive composition* Crystalline powder from chemical synthesis with a minimum of 93 % DL-methionyl-DL-methionine, a maximum of 3 % DL-methionine and a maximum of 3 % sodium sulphate (on a dry matter basis) *Characterisation of the active substance* DL-methionyl-DL-methionine (2-[(2-amino-4-methylsulfanylbutanoyl)amino]-4-methylsulfanylbutanoic acid) Chemical formula: $C_{10}H_{20}N_2O_3S_2$ CAS number: 52715-93-2 *Analytical method* (1) For the quantification of DL-methionyl-DL-methionine in the feed additive: reversed-phase high performance liquid chromatography coupled to photometric detection at 205 nm (RP-HPLC-UV). For the quantification of DL-methionyl-DL-methionine in premixtures, compound feed and feed materials: ion exchange chromatography coupled with post-column derivatisation and photometric detection at 570 nm (IEC-UV).	Fish and crustaceans	—			The moisture content shall be indicated on the labelling.	9 September 2025

(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