Commission Implementing Regulation (EU) 2018/1936 of 10 December 2018 amending Implementing Regulation (EU) No 371/2011 as regards the maximum limit of dimethylaminoethanol (DMAE) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1936

of 10 December 2018

amending Implementing Regulation (EU) No 371/2011 as regards the maximum limit of dimethylaminoethanol (DMAE)

(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) and Article 13(3) 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) The use of dimethylglycine sodium salt as feed additive was authorised for 10 years for chickens for fattening by Commission Implementing Regulation (EU) No 371/2011[(2)].

(3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, the holder of the authorisation has proposed changing the terms of the authorisation by modifying the manufacturing process. That application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').

(4) The Authority concluded in its opinion of 17 April 2018[(3)] that the additive manufactured by the new manufacturing process does not have an adverse effect on animal health, human health or the environment. Furthermore, it also concluded that the presence of Dimethylaminoethanol (DMAE) at a level equal to or less than 0,1 % does not affect the efficacy of the additive. 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 the dimethylglycine sodium salt produced through the new manufacturing process shows that the conditions for authorisation, as 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 this Regulation.

(6) Implementing Regulation (EU) No 371/2011 should therefore be amended accordingly.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1936. (See end of Document for details)*

(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

In the Annex to Implementing Regulation (EU) No 371/2011, in the fourth column 'Composition, chemical formula, description, analytical method', under '*Active substance*', the following is inserted, at the end: 'Dimethylaminoethanol (DMAE) ≤ 0,1 %'.

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, 10 December 2018.

For the Commission

The President

Jean-Claude JUNCKER