COMMISSION IMPLEMENTING REGULATION (EU) 2017/1086

of 19 June 2017

amending Regulation (EC) No 634/2007 as regards the characterisation of selenomethionine produced by Saccharomyces cerevisiae NCYC R397

(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 13(2) thereof,

Whereas:

- Commission Regulation (EC) No 634/2007 (2) as amended by Commission Implementing Regulation (EU) (1) No 427/2013 (3) authorises selenomethionine produced by Saccharomyces cerevisiae NCYC R397 as a feed additive.
- (2) The Commission received an application requesting a modification of the conditions of the authorisation as regards the characterisation of the feed additive. That application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority ('the Authority'). The applicant initially requested the inclusion of the selenocysteine content in the characterisation of the additive but finally withdrew this change; thus the application concerns merely an increase of the maximum selenium content in the current authorisation of the additive.
- (3) The Authority concluded in its opinion of 20 October 2016 (4) that the requested modification would not affect the safety and efficacy of the product, recalling the risk for user safety of the product. The current authorisation act contains a provision to adequately address this risk.
- The assessment of the modified preparation shows that it satisfies the conditions for authorisation, provided for (4) in Article 5 of Regulation (EC) No 1831/2003.
- (5) Regulation (EC) No 634/2007 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plant, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 634/2007

In the fourth column of the Annex to Regulation (EC) No 634/2007, the text between the heading 'Characterisation of the additive' and the heading 'Analytical method' is replaced by the following:

⁽¹) OJ L 268, 18.10.2003, p. 29. (²) Commission Regulation (EC) No 634/2007 of 7 June 2007 concerning the authorisation of selenomethionine produced by *Saccharomyces* cerevisiae NCYC R397 as a feed additive (OJ L 146, 8.6.2007, p. 14).

Commission Implementing Regulation (EU) No 427/2013 of 8 May 2013 concerning the authorisation of selenomethionine produced by Saccharomyces cerevisiae NCYC R646 as a feed additive for all animal species and amending Regulations (EC) No 1750/2006, (EC) No 634/2007 and (EC) No 900/2009 as regards the maximum supplementation with selenised yeast (OJ L 127, 9.5.2013, p. 20). (4) EFSA Journal 2016;14(11):4624.

EN

'Organic selenium mainly selenomethionine (63 %) content of 2 000 to 3 500 mg Se/kg (97 to 99 % of organic selenium)'.

Article 2

Entry into force

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 is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 June 2017.

For the Commission The President Jean-Claude JUNCKER