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SANTE/10165/2017

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Regulation (EC) No 900/2009 as regards the characterisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399

(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 nutrition¹ and in particular Article 13(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 900/2009² as amended by Commission Implementing Regulation (EU) No 427/2013³ 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').
- (3) The Authority concluded in its opinion of 5 July 2017⁴ 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 Authority suggests to include the selenocysteine content in the characterisation of the additive but due to a lack of an analytical method for selenocysteine this suggestion cannot be followed.

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Regulation (EC) No 900/2009 of 25 September 2009 concerning the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 as a feed additive (OJ L 256, 29.9.2009, p. 12).

³ 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 2017;15(7):4937.

- (4) The assessment of the modified preparation shows that it satisfies the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003.
- (5) Regulation (EC) No 900/2009 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 900/2009

In the fourth column of the Annex to Regulation (EC) No 900/2009, the text between the heading ‘Characterisation of the additive’ and the heading ‘Characterisation of the active substance’ is replaced by the following:

“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,

For the Commission
The President
Jean-Claude JUNCKER