EUROPEAN
COMMISSION

Brussels, XXX
SANCO/11369/2014 CIS
(POOL/E4/2014/11369/11369-EN
CIS.doc)
[…](2014) XXX draft

COMMISSION REGULATION (EU) No …/..

of XXX

amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

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amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[1], and in particular Article 4(5) thereof,

Whereas:

(1) Annex II to Directive 2002/46/EC establishes the list of vitamin and mineral substances, and for each of them the forms, which may be used in the manufacture of food supplements. Commission Regulation (EC) No 1170/2009[2] has replaced Annexes I and II to Directive 2002/46/EC.

(2) According to Article 14 of Directive 2002/46/EC, provisions on vitamin and mineral substances in food supplements which may have an effect upon public health are to be adopted after consultation with the European Food Safety Authority ('the Authority').

(3) Following a request for the addition of (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt as a source of folate to the list set out in Annex II to Directive 2002/46/EC, the Authority adopted on 11 September 2013 a Scientific Opinion on (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt as a source of folate added for nutritional purposes to food supplements and the bioavailability of folate from this source[3].

(4) It follows from the Authority's opinion that the use of (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt in food supplements is not of safety concern as a source of folate.

(5) The Authority noted in the conclusions set out in its opinion that given the manufacturing process, the specifications proposed by the petitioner, and referred to in

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1 OJ L 183, 12.7.2002, p. 51.
2 OJ L 314, 1.12.2009, p. 36.
3 EFSA Journal 2013;11(10): 3358.

the opinion of the Authority, for (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt should include an indication for the absence of mycotoxins.

(6) Following the Authority's favourable opinion, (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt should be added to the list set out in Annex II to Directive 2002/46/EC.

(7) (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt is a novel food ingredient the placing on the market of which has been authorised by Commission Implementing Decision 2014/154/EU[4].

(8) Interested parties were consulted through the Advisory Group on the Food Chain and Animal and Plant Health and the comments provided were taken into consideration.

(9) Directive 2002/46/EC should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex II to Directive 2002/46/EC the following point (c) is added in Heading 10 (FOLATE) of Section A:

'(c) (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt(*)

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* The specifications for (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt must include an indication for the absence of mycotoxins.'

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.

[4] Commission Implementing Decision 2014/154/EU of 19 March 2014 authorising the placing on the market of (6*S*)-5-methyltetrahydrofolic acid, glucosamine salt as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 85 of 21.3.2014, p. 10).

Done at Brussels,

For the Commission
The President
José Manuel BARROSO