Commission Regulation (EU) 2017/1203 of 5 July 2017 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/1203

of 5 July 2017

amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and 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,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[(2)], and in particular Article 3(3) thereof,

Whereas:

(1) Annex II to Directive 2002/46/EC establishes the list of vitamin and mineral substances, which may be used in the manufacture of food supplements.

(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) Annex II to Regulation (EC) No 1925/2006 establishes the list of vitamin and mineral substances, and for each of them the forms, which may be added to foods.

(4) According to Article 3(3) of Regulation (EC) No 1925/2006, modifications to the list provided in Annex II to that Regulation are to be adopted taking account of the opinion of the Authority.

(5) Following a request for the addition of organic silicon as a source of silicon to the list set out in Annex II to Directive 2002/46/EC, on 9 March 2016 the Authority adopted a Scientific Opinion on the safety of organic silicon (monomethylsilanetriol; MMST) as a novel food ingredient for use as a source of silicon in food supplements and bioavailability of orthosilicic acid from the source[(3)].

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1203. (See end of Document for details)*

(6) It follows from that opinion that the use of organic silicon (monomethylsilanetriol) in food supplements is not of a safety concern as a source of silicon, provided that certain conditions are respected.

(7) Taking into account the Authority's favourable opinion, organic silicon (monomethylsilanetriol) should be included in the list set out in Annex II to Directive 2002/46/EC.

(8) Following a request for the addition of calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium to the list set out in Annex II to Directive 2002/46/EC and to the list set out in Annex II to Regulation (EC) No 1925/2006, on 26 April 2016 the Authority adopted a Scientific Opinion on the safety of calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium added for nutritional purposes to food, food supplements and foods for special medical purposes[(4)].

(9) It follows from that opinion that the addition of calcium phosphoryl oligosaccharides (POs-Ca®) to food and its use in food supplements is not of a safety concern as a source of calcium, provided that certain conditions are respected.

(10) Taking into account the Authority's favourable opinion, calcium phosphoryl oligosaccharides (POs-Ca®) should be included in the list set out in Annex II to Directive 2002/46/EC and in the list set out in Annex II to Regulation (EC) No 1925/2006.

(11) 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.

(12) Directive 2002/46/EC and Regulation (EC) No 1925/2006 should therefore be amended accordingly.

(13) 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

Annex II to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 2

Annex II to Regulation (EC) No 1925/2006 is amended in accordance with the Annex to this Regulation.

Article 3

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, 5 July 2017.

For the Commission

The President

Jean-Claude JUNCKER