Commission Regulation (EU) No 119/2014 of 7 February 2014 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 chromium enriched yeast used for the manufacture of food supplements and chromium(III) lactate tri-hydrate added to foods (Text with EEA relevance)

COMMISSION REGULATION (EU) No 119/2014

of 7 February 2014

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(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,

After consulting the European Food Safety Authority (EFSA),

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. Commission Regulation (EC) No 1170/2009[(3)] has replaced Annexes I and II to Directive 2002/46/EC. Annex II to Directive 2002/46/EC has been amended by Commission Regulation (EU) No 1161/2011[(4)].

(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 EFSA.

(3) On 31 October 2012, EFSA adopted a scientific opinion on ChromoPrecise® cellular bound chromium yeast added for nutritional purposes as a source of chromium in food supplements and the bioavailability of chromium from this source[(5)].

(4) EFSA stressed that the conclusions set out in its opinion apply only to ChromoPrecise® chromium yeast and not to other chromium-enriched yeasts. Furthermore it

considered that the specifications for ChromoPrecise® chromium yeast should include specifications for loss on drying and for chromium(VI) maximum content.

(5) If follows from the opinion adopted by EFSA on 31 October 2012 that the use of ChromoPrecise® chromium yeast in food supplements is not of safety concern, provided that certain conditions detailed in the opinion are respected.

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

(7) 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 EFSA.

(8) On 13 September 2012 EFSA adopted a scientific opinion on chromium(III) lactate tri-hydrate as a source of chromium(III) added for nutritional purposes to foodstuff[(6)].

(9) It follows from the opinion adopted by EFSA on 13 September 2012 that the addition of chromium(III) lactate tri-hydrate to food is not of safety concern, provided certain conditions detailed in the opinion are respected.

(10) Substances for which EFSA expressed a favourable opinion should be added to the lists set out in Annex II to Directive 2002/46/EC and 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 the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

In point B of Annex II to Directive 2002/46/EC, the following entry is inserted after the entry ‘chromium(III) chloride’:

chromium enriched yeast[(7)]

Article 2

In point 2 of Annex II to Regulation (EC) No 1925/2006, the following entry is inserted after the entry ‘chromium picolinate’:

chromium(III) lactate tri-hydrate.

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*.