Commission Regulation (EU) No 244/2013 of 19 March 2013 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Tricalcium phosphate (E 341 (iii)) in nutrient preparations intended for use in foods for infants and young children (Text with EEA relevance)

COMMISSION REGULATION (EU) No 244/2013

of 19 March 2013

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Tricalcium phosphate (E 341 (iii)) in nutrient preparations intended for use in foods for infants and young children

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(1)], and in particular Articles 10(3) and 30(5) thereof,

Whereas:

(1) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

(2) That list may be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(2)].

(3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.

(4) An application for the authorisation of use of Tricalcium phosphate (E 341 (iii)) as an anti-caking agent added to nutrient preparations intended for use in infant formulae and follow-on formulae as defined by Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC[(3)] was submitted on 19 June 2009 and has been made available to the Member States.

(5) The application concerns a new entry in Section B of Part 5 of Annex III to Regulation (EC) No 1333/2008. The technological need of Tricalcium phosphate (E 341 (iii)) as a food additive relates to its ability to provide unique properties as a free-flowing agent to mixtures in powder form. The product may take up to 10 % of its own weight of moisture (humidity) from the environment avoiding any lumps in a mix and keeping preparations free-flowable, which is considered to be a benefit to the consumer.

(6) The Scientific Committee for Food advised on the safety of Tricalcium phosphate (E 341 (iii)) as a food additive in nutrient preparations intended for use in infant formulae and follow-on formulae and expressed its opinion on 7 June 1996[(4)], concluding that its use is acceptable provided that the total levels of calcium, phosphorus and the ratio between them are not exceeded.

(7) Calcium salts of orthophosphoric acid, including tricalcium phosphate, are mineral substances that are authorised for use in infant formulae and follow-on formulae in accordance with Annex III to Directive 2006/141/EC. The authorisation of the use of Tricalcium phosphate (E 341 (iii)) as an anti-caking agent in nutrient preparations intended for use in infant formulae and follow-on formulae is therefore not considered of safety concern, as long as the total amounts of calcium and phosphorus remain within the limits for these two minerals and within the calcium:phosphorus ratio as set in that Directive.

(8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.

(9) Since the authorisation of use of Tricalcium phosphate (E 341 (iii)) as an anti-caking agent in nutrient preparations intended for use in infant formulae and follow-on formulae should comply with the limit for calcium, phosphorus and the calcium:phosphorus ratio set in Directive 2006/141/EC, the update of that list is not liable to have an effect on human health. For that reason, it is not necessary to seek the opinion of the European Food Safety Authority.

(10) It is therefore appropriate to authorise the use of Tricalcium phosphate (E 341 (iii)) as an anti-caking agent in nutrient preparations intended for use in infant formulae and follow-on formulae.

(11) Consequently, Annex III to Regulation (EC) No 1333/2008 should be amended accordingly.

(12) 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

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

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.

Done at Brussels, 19 March 2013.

For the Commission

The President

José Manuel BARROSO