COUNCIL OF THE EUROPEAN UNION

Brussels, 12 December 2012

17675/12

DENLEG 120
SAN 328

COVER NOTE

from:	European Commission
date of receipt:	7 December 2012
to:	General Secretariat of the Council
No Cion doc.:	D024415/02
Subject:	COMMISSION REGULATION (EU) No …/.. of XXX amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Sodium ascorbate (E 301) in vitamin D preparations intended for use in foods for infants and young children

Delegations will find attached Commission document D024415/02.

Encl.: D024415/02

EUROPEAN
COMMISSION

Brussels, XXX
SANCO/12081/2012
(POOL/E3/2012/12081/12081-EN.doc)
D024415/02
[…](2012) XXX draft

COMMISSION REGULATION (EU) No …/..

of XXX

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(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

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amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Sodium ascorbate (E 301) in vitamin D 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 Sodium ascorbate (E 301) as an antioxidant in vitamin D preparations intended for use in infant formulae and follow-on formulae as defined by Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC[3], was submitted on 15 December 2009 and has been made available to the Member States.

(5) Ingredients used in the manufacture of infant formulae and follow-on formulae must meet a much stricter microbiological standard than general food, in particular for Enterobacteria and *Cronobacter sakazakii*. In order to achieve this, ingredients such as

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1 OJ L 354, 31.12.2008, p. 16.
2 OJ L 354, 31.12.2008, p. 1.
3 OJ L 401, 30.12.2006, p. 1.

vitamin D preparations are subjected to a heat treatment. Such treatment in turn requires the presence of an antioxidant which is water-soluble and of neutral pH. Sodium ascorbate (E 301) was identified and proved to be the suitable antioxidant to meet that technological need.

(6) 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.

(7) The European Food Safety Authority evaluated the use of Sodium ascorbate (E 301) as a food additive in vitamin D preparations intended for foods for infants and young children and expressed its opinion on 8 December 2010[4]. It concluded that the proposed extension of use of the food additive Sodium ascorbate (E 301) to be used as an antioxidant for the vitamin D preparations for use in infant formulae and follow-on formulae, is not of safety concern.

(8) It is therefore appropriate to authorise the use of Sodium ascorbate (E 301) as an antioxidant in vitamin D preparations intended for use in foods for infants and young children.

(9) For that reason, Annex III to Regulation (EC) No 1333/2008 should 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 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*.

[4] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of sodium ascorbate as a food additive in vitamin D preparations intended to be used in formulae and weaning food for infants and young children. EFSA Journal 2010;8(12):1942.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

ANNEX

In Section B of Part 5 of Annex III to Regulation (EC) No 1333/2008, the entry for food additive E 301 is replaced by the following:

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E 301	Sodium ascorbate	100 000 mg/kg in vitamin D preparation and 1 mg/l maximum carry-over in final food	Vitamin D preparations	Infant formulae and follow-on formulae as defined by Directive 2006/141/EC
		Total carry-over 75 mg/l	Coatings of nutrient preparations containing polyunsaturated fatty acids	Foods for infants and young children

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