



Council of the
European Union

Brussels, 29 January 2015
(OR. en)

5746/15

DENLEG 24
AGRI 42
SAN 31

COVER NOTE

From:	European Commission
date of receipt:	29 January 2015
To:	General Secretariat of the Council
No. Cion doc.:	D036750/02
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 silicon dioxide (E 551) in polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209)

Delegations will find attached document D036750/02.

Encl.: D036750/02



Brussels, **XXX**
SANCO/12183/2014
(POOL/E3/2014/12183/12183-EN.doc)
D036750/02
[...] (2014) **XXX** draft

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 silicon dioxide (E 551) in polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer (E 1209)

(Text with EEA relevance)

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 silicon dioxide (E 551) in polyvinyl alcohol-polyethylene glycol-*graft-co-polymer* (E 1209)

(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 additives¹, and in particular Article 10(3) 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, flavourings, nutrients and their conditions of use.
- (2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (3) Commission Regulation (EU) No 685/2014² authorizes the use of polyvinyl alcohol-polyethylene glycol-*graft-co-polymer* (PVA-PEG *graft co-polymer*) (E 1209) in food supplements in solid form.
- (4) In order to improve the flow properties of the polymer powder, silicon dioxide (E 551), is used in PVA-PEG *graft co-polymer*. The expected carry-over of silicon dioxide in the final food via the use of PVA-PEG *graft co-polymer* is 300-500 mg/kg. At this level silicon dioxide has no technological function in the food supplement.
- (5) The European Food Safety Authority evaluated the safety of PVA-PEG *graft co-polymer* when used as a food additive and concluded that its use in food supplements as film coating is of no safety concern for the proposed uses³. The safety assessment also included the specified use of silicon dioxide in PVA-PEG *graft co-polymer*.

¹ OJ L 354, 31.12.2008, p. 16.

² Commission Regulation (EU) No 685/2014 of 20 June 2014 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards polyvinyl alcohol-polyethylene glycol-*graft-co-polymer* in solid food supplements (OJ L 182, 21.6.2014, p. 23).

³ EFSA Journal 2013; 11(8):3303.

- (6) It is therefore appropriate to authorise the use of silicon dioxide in PVA-PEG *graft* co-polymer.
- (7) Part 2 of Annex III to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (8) 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

Part 2 of 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,

For the Commission
The President
Jean-Claude JUNCKER