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COVER NOTE

From:	European Commission
date of receipt:	8 January 2015
To:	General Secretariat of the Council
No. Cion doc.:	D036731/03
Subject:	COMMISSION REGULATION (EU) No .../.. of XXX amending Annex to Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Polyvinyl alcohol (E 1203)

Delegations will find attached document D036731/03.

Encl.: D036731/03



Brussels, **XXX**
SANCO/12346/2014
(POOL/E3/2014/12346/12346-EN.doc)
D036731/03
[...](2014) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Annex to Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Polyvinyl alcohol (E 1203)

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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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 Regulation (EC) No 1333/2008¹ of the European Parliament and of the Council of 16 December 2008 on food additives, and in particular Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008² 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, and in particular Article 7(5) thereof,

Whereas:

- (1) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) Those specifications 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) On 7 September 2011, an application was submitted for the amendment of specifications concerning the food additive polyvinyl alcohol (E 1203). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) The current specification as regards the solubility of the food additive polyvinyl alcohol (E 1203) states “Soluble in water; sparingly soluble in ethanol”. The Institute for Health and Consumer Protection (IHCP) of the European Commission’s Joint

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

Research Centre carried out solubility studies⁴ of polyvinyl alcohol to update the solubility data of the existing Union specifications vis-à-vis its solubility in ethanol.

- (5) The European Food Safety Authority ('the Authority') evaluated the results of the solubility test with polyvinyl alcohol carried out by the IHCP and the information provided by the applicant⁵. The Authority considers that the modification of the specification on the solubility of polyvinyl alcohol in ethanol has no impact on the safety of polyvinyl alcohol as a food additive.
- (6) Taking into account the submitted application, the studies carried out by the IHCP and the evaluation made by the Authority, it is appropriate to amend the description of the solubility of the food additive polyvinyl alcohol (E 1203) in ethanol (≥ 99.8 %) to "practically insoluble or insoluble".
- (7) Regulation (EU) No 231/2012 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

The Annex to Regulation (EU) No 231/2012 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*.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

⁴ João F. A. Lopes and Catherine Simoneau, 2014. Solubility of Polyvinyl Alcohol in Ethanol. EFSA supporting publication 2014:EN-660, 20 pp.

⁵ EFSA Journal 2014;12(9):3820.