



Council of the
European Union

Brussels, 10 March 2017
(OR. en)

7180/17

DENLEG 17
AGRI 131
SAN 95

COVER NOTE

From:	European Commission
date of receipt:	9 March 2017
To:	General Secretariat of the Council

No. Cion doc.:	D048363/04
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations
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Delegations will find attached document D048363/04.

Encl.: D048363/04



Brussels, **XXX**
SANTE/11715/2016
(POOL/E2/2016/11715/11715-EN.doc)
D048363/04
[...](2017) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations

(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, food 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 of the European Parliament and of the Council², either on the initiative of the Commission or following an application.
- (3) An application for authorisation of the use of butane (E 943a), isobutane (E 943b) and propane (E 944) as propellants in colour preparations of group II and group III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008, was submitted on 26 January 2016. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) Butane, isobutane and propane used as propellants can produce the necessary pressure to expel colour preparations from a spray in order to obtain an appropriate homogenous coverage of colours on foods.
- (5) The Scientific Committee for Food evaluated safety of propane, butane and isobutane as extraction solvents in 1991 and found such use acceptable subject to a residue limit in food of 1 mg/kg per substance³.

¹ OJ L 354, 31.12.2008, p. 16.

² 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 (OJ L 354, 31.12.2008, p. 1).

³ Reports of the Scientific Committee for Food, Twenty-ninth series, 1992.

- (6) In 1999 the Scientific Committee for Food expressed its opinion on propane, butane and isobutane as propellant gases for vegetable oil-based aerosol cooking sprays and water-based emulsion cooking sprays⁴ concluding that in the view of the low residue level of propellant gases the use for baking and frying has no toxicological concerns.
- (7) Analytical data provided by the applicant confirmed that one hour after spraying various foods, the residues of butane (E 943a), isobutane (E 943b) and propane (E 944) are below the limit of 1 mg/kg.
- (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 ('the Authority') in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008, except where that update is not liable to have an effect on human health. Since the authorisation of use of butane (E 943a), isobutane (E 943b) and propane (E 944) as propellants in colour preparations constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (9) Therefore, it is appropriate to authorise the use of butane (E 943a), isobutane (E 943b) and propane (E 944) as propellants in colour preparations of groups II and III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008. Due to risk of ignition and the time needed to decrease the levels of propellants under the limit of 1 mg/kg it is appropriate to grant the authorisation for professional use only to ensure that the standardised industrial protocols are respected and the time between spraying and consumption is sufficient to comply with the acceptable residue limit.
- (10) Therefore, Annex III to Regulation (EC) No 1333/2008 should be amended accordingly.
- (11) 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

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.

⁴ Opinion on propane, butane and iso-butane as propellant gases for vegetable oil-based aerosol cooking sprays and water-based emulsion cooking sprays. Scientific Committee on Food, 29.3.1999.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER