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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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Subject:	COMMISSION REGULATION (EU) No .../.. of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of caramel colours (E 150a-d) in beer and malt beverages

Delegations will find attached document D031883/02.

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of caramel colours (E 150a-d) in beer and malt beverages

(Text with EEA relevance)

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of caramel colours (E 150a-d) in beer and malt beverages

(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 II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) That list may be amended 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) Caramel colours are food colours currently approved for use and listed in Annex II to Regulation (EC) No 1333/2008. That approval takes into account the Acceptable Daily Intakes (ADI) established by the Scientific Committee for Food in 1987, 1990 and 1996.
- (4) The European Food Safety Authority ('the Authority') issued an opinion on 3 February 2011 as regards the re-evaluation of the safety of caramel colours as food additives³. In that opinion the Authority established a group ADI of 300 mg/kg bw/day. Within this group ADI an individual ADI of 100 mg/kg bw/day was established for E 150c ammonia caramel. The Authority concluded that the anticipated dietary exposure of child and adult populations may exceed the ADIs for plain caramel (E 150a), ammonia caramel (E 150c) and sulphite ammonia caramel (E 150d).
- (5) On 3 December 2012, the Authority issued a statement providing a refined exposure assessment for caramel colours E 150a, E 150c and E 150d and concluded that the anticipated dietary exposure was considerably lower than that estimated in the

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 EFSA Journal 2011; 9(3):2004.

previous opinion⁴. However, the Authority concluded that toddlers and adults could still exceed the ADI for ammonia caramel (E 150c). Whilst the ADI was only slightly exceeded (6%) at the high levels in toddlers in one Member State, for adults the ADI was exceeded by 5-51% in five Member States. After considering more detailed national information about the real uses of ammonia caramel (E 150c), the Member States concerned demonstrated that the actual intake is significantly lower. However, taking into account that beer is the main contributor to the exposure in adults, it is appropriate to amend the conditions of use and to establish maximum use levels for ammonia caramel (E 150c) in food subcategory 14.2.1 'Beer and malt beverages' to guarantee a high level of protection of human health.

- (6) Pursuant to Article 11(4) of Regulation (EC) No 1333/2008 the maximum levels for colours shall apply to the quantities of colouring principle contained in the colouring preparation unless otherwise stated. However, the complex nature and limited knowledge of chemical composition of caramel colours makes their identification in food products a challenge. Therefore, in performing official controls the competent authorities could also consider verifying the level of 2-acetyl-4-tetrahydroxybutylimidazole, i.e. the impurity which can be analytically determined and which was taken into account in establishing an individual ADI for ammonia caramel (E 150c).
- (7) An application for authorisation of the use of caramel colours (E 150a-d) in malt beverages was submitted on 4 June 2013 and was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (8) Beer is not defined in the Union legislation and the national definitions vary among the Member States. Consequently a particular product classified as beer in one Member State could be classified as malt beverage in another. Since there is a technological need for caramel colours (E 150a-d) in malt beverages and the use of caramel colours is authorised in beer only, the current situation has a negative impact on the internal market and hinders the free movement of those products. Therefore it is appropriate to rectify this situation.
- (9) The common characteristic of malt beverages is the absence of malt as such in the final product and similarities in the technology and in the need for food additives with beers. There is a need for caramel colours to restore a consistent colour which has been affected by the production processes and/or to make malt beverages made from pale malts visually more appealing. Roasted malts cannot be used to provide the dark colour since they impart strong flavour which is not appropriate for those products.
- (10) Malt beverages are niche products providing an alternative to products in which the use of caramel colours is currently authorised (i.e. flavoured drinks and beers). Therefore, it is not expected that the authorisation of use of caramel colours in malt beverages would have a significant impact on total exposure to caramel colours.
- (11) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where such update is not liable to have an effect on human health. Since the extension of use of caramel colours (E 150a-d) to malt beverages constitutes an update of that list which is not liable to

⁴ EFSA Journal 2012; 10(12):3030.

have an effect on human health, it is not necessary to seek the opinion of the Authority.

- (12) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II 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
José Manuel BARROSO