

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

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

**of XXX**

**amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards inclusion of pyroligneous distillate in the Union list of flavourings**

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13<sup>1</sup>, and in particular Article 11(3) thereof,

Having regard to 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<sup>2</sup>, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.
- (2) Commission Implementing Regulation (EU) No 872/2012<sup>3</sup> adopted the list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008. Commission Regulation (EU) No 872/2012 also introduced parts B (Flavouring preparations), C ('Thermal process flavourings'), D ('Flavour precursors'), E ('Other flavourings') and F ('Source materials') in Annex I to Regulation to Regulation (EC) No 1334/2008. Parts B to F of Annex I correspond to the categories of flavourings and source materials referred to in Article 9(b) to (f) of the Regulation (EC) 1334/2008. Parts B to F contained no entries.
- (3) Commission Regulation (EU) No. 873/2012<sup>4</sup> laid down a series of transitional measures concerning the Union list of flavourings and source materials set out in Annex I of Regulation (EC) No 1334/2008 2008 of the European Parliament and of the Council.

---

<sup>1</sup> OJ L 354, 31.12.2008, p. 34.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1.

<sup>3</sup> Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

<sup>4</sup> Commission Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council (OJ L 267, 2.10.2012, p. 267).

- (4) Article 4 of this Regulation (EU) No. 873/2012 laid down a transition period for foods to which flavourings belonging to the categories B, C, D, E and F have been added and which have been the object of an application before 22 October 2015 pursuant to Article 3 thereof. Article 4 laid down that the end of this transition period was set on 22 April 2018.
- (5) Annex I of Regulation (EC) No 1334/2008 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 submitted by a Member State or by an interested party.
- (6) An application for authorisation of the product pyroligneous distillate [Fl no. 21.001] with the name 'rum ether' was submitted to the Commission on 16 October 2012 under the category 'other flavourings'. According to the application this flavouring is used in a number of food products such as confectionery, bakery wares and alcoholic beverages.
- (7) On 24 August 2017 The European Food Safety Authority ('the Authority') completed the evaluation of the safety of pyroligneous distillate [Fl no. 21.001] when used as a flavouring under the category 'other flavourings' in its 'Scientific Opinion of Flavouring Group Evaluation 500 (FGE.500): rum ether'<sup>5</sup>. This product is a complex mixture composed of more than eighty individual constituents. The Authority indicated serious safety concerns relating to a number of constituents like furans and derivatives, and other constituents, associated with genotoxicity risks, and also mentioned the carcinogenicity risks involved in the presence of ethanol.
- (8) Recital 7 of the Regulation 1334/2008 indicates that the approval of flavourings should exceptionally also take into account other aspects relevant to the matter under consideration, including societal and traditional factors. On that basis, the Czech Republic and Slovakia have requested to use this exception for their specified traditional spirit drinks *tuzemský* and *tuzemak* to which this flavouring is added. These spirits have been on the market for decades.
- (9) These spirit drinks are not intended to be consumed by children or vulnerable populations and there are already labelling provisions in place for them like for all alcoholic beverages regarding the labelling of their ethanol content. It is the responsibility of the Member States to inform about the specific risks linked to the presence of pyroligneous distillate [Fl no. 21.001] in these traditional alcoholic spirits.
- (10) The submitted application names the product as 'rum ether'. However this product does not come from rum or sugar cane and it is not chemically an ether. Therefore, the name 'rum ether' is likely to mislead consumers and food business operators. It is important to clearly identify and characterise this product. The Opinion of the Authority identifies a number of constituents of the product which help characterize the product and make it clearly distinguishable from other products.
- (11) The spirit drinks to which pyroligneous distillate [Fl no. 21.001] has been added should not be used in the manufacture of other foodstuffs.
- (12) When reference is made to the flavouring in the labelling of the spirits *tuzemský* and *tuzemak*, the name or the Fl number should be used.
- (13) When pyroligneous distillate [Fl no. 21.001] is marketed as such not intended for the sale to the ultimate consumer it shall be indicated in the labelling that this flavouring is

---

<sup>5</sup> EFSA Journal 2017;15(8):4897.

only intended for the manufacture of the spirits *tuzemský* and *tuzemak* in addition to the requirements of Article 15 of Regulation (EU) No. 1334/2008.

- (14) Part E of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (15) 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 E of Annex I to Regulation (EC) No 1334/2008 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.

It shall be applicable since 23 April 2018.

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*