Commission Regulation (EU) 2018/1246 of 18 September 2018 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of pyroligneous distillate in the Union list of flavourings (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/1246

of 18 September 2018

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the 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 (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC[(1)], 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[(2)], 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[(3)] adopted the list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008. Regulation (EU) No 872/2012 also introduced Part B ('Flavouring preparations'), Part C ('Thermal process flavourings'), Part D ('Flavour precursors'), Part E ('Other flavourings') and Part F ('Source materials') in Annex I 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) No 1334/2008. Parts B to F contain no entries.

(3) Commission Regulation (EU) No 873/2012[(4)] lays down transitional measures concerning the Union list of flavourings and source materials set out in Annex I of Regulation (EC) No 1334/2008.

(4) Article 4 of Regulation (EU) No 873/2012 lays down a transitional period for foods to which flavourings belonging to the Parts B to F of Annex I to Regulation (EC) No 1334/2008 have been added which have been the object of an application before

22 October 2015 pursuant to Article 3 thereof. Article 4 lays down that the end of the transitional period for placing on the market of such foods is 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) On 16 October 2012, an application was submitted to the Commission for the authorisation of the product pyroligneous distillate [FL no. 21.001] with the name 'rum ether' under the category 'other flavourings'. The applicant requested this flavouring to be used in edible ices, confectionery, chewing gum, cereals and cereal products derived from cereal grains, roots and tubers and pulses and legumes, bakery wares, meat and meat products, salts, spices, soups, sauces, salads, non-alcoholic beverages, and alcoholic beverages up to certain levels.

(7) The application was sent to the European Food Safety Authority ('the Authority') for its opinion. The application was also made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(8) On 24 August 2017, the Authority adopted its 'Scientific Opinion of Flavouring Group Evaluation 500 (FGE.500): rum ether', concerning the evaluation of the safety of pyroligneous distillate [FL no. 21.001] when used as a flavouring under the category 'other flavourings'[(5)]. This product is a complex mixture composed of more than eighty individual constituents. The Authority concluded that according to the overall strategy for the risk assessment of flavouring substances, the presence of genotoxic substances as constituents of rum ether is of safety concern. It indicated serious safety concerns relating to a number of constituents like furans and derivatives, and other constituents, associated with genotoxicity and carcinogenicity, and also mentioned the carcinogenicity risks involved in the presence of ethanol.

(9) Czech Republic and Slovak Republic have informed the Commission about the use of pyroligneous distillate [FL no. 21.001] in the traditional spirit drinks *tuzemák* and *tuzemský* and asked to maintain this use for these specific spirit drinks.

(10) According to Recital 7 of the Regulation (EC) No 1334/2008 the approval of flavourings should also take into account other factors relevant to the matter under consideration, including societal and traditional factors. Since the use of this flavouring is currently necessary for maintaining the specific traditional organoleptic characteristics of the spirit drinks *tuzemák* and *tuzemský* in Czech Republic and Slovak Republic, it is appropriate to authorise this substance under the conditions of use laid down in the Annex to this Regulation.

(11) Those spirit drinks, like all spirit drinks and alcoholic beverages in general, are not intended to be consumed by children or other vulnerable parts of the population. In addition to existing labelling requirements, Member States should require additional information to be provided regarding the specific risks linked to the presence of pyroligneous distillate (FL no. 21.001] in those traditional alcoholic beverages.

(12) The spirit drinks to which pyroligneous distillate [FL no. 21.001] has been added should not be used in the manufacture of other foodstuffs.

(13) When reference is made to the flavouring in the labelling of the spirit drinks *tuzemák* and *tuzemský*, the name or the FL number should be used.

(14) In addition to the requirements of Article 15 of Regulation (EC) No 1334/2008, when pyroligneous distillate [FL no. 21.001] is marketed as such not intended for the sale to the ultimate consumer, it should be indicated in the labelling that this flavouring may only be used for the manufacture of the spirit drinks *tuzemák* and *tuzemský*.

(15) In order to ensure legal certainty, this Regulation should be applicable as from 23 April 2018.

(16) This Regulation should be in force for a period of 5 years in order to allow for alternatives to pyroligneous distillate [FL no. 21.001] to be developed for the use in traditional spirit drinks *tuzemák* and *tuzemský*.

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

(18) 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.

The product pyroligneous distillate [FL no.21.001] is authorized in traditional spirit drinks *tuzemák* and *tuzemský* subject to restrictions of use laid in 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 apply from 23 April 2018 until 19 September 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1246. (See end of Document for details)*