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**SANTE/10349/2018 Annex**

**Annex to Draft Commission Regulation 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**

**ANNEX**

In Part E of Annex I to Regulation (EC) No 1334/2008 the following entry concerning [FL-no: 21.001] is added:

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Fl no.	Name	CAS no	JECFA No.	CoE No.	Purity of the named flavouring	Restrictions of use	Footnote	Reference
21.001	Pyroligneous distillate	-	-	-	Complex mixture of substances, obtained by distillation of reaction products of pyroligneous acid and ethanol. Liquid with rum-like tasting odour and taste. Constituents: - Ethanol	In the following spirits drinks only: <i>Tuzemský</i> and <i>tuzemak</i> falling under Regulation (EC) 110/2008 when marketed exclusively in the final package intended only for		EFSA

					<p>(determined by Gas Chromatography/Flame Ionization Detector); more than 40 % w/w)</p> <ul style="list-style-type: none"> <li>- Ethyl acetate: less than 25 % w/w)</li> <li>- Ethyl formate: less than 2 % w/w)</li> <li>- Ethyl propionate: less than 4 % w/w)</li> <li>- Ethyl butyrate: less than 1.5 % w/w)</li> <li>- Methyl acetate: less than 3.5 % w/w)</li> <li>- Furan equivalents (furan and 2 methyl furan) expressed as furan: less than 8 mg/l</li> <li>- Methanol and methanol derivatives, expressed as methanol equivalents: less than 2 % (w/w)</li> <li>- Benzopyrene: less than 1 µg/l</li> <li>- Benz(a)anthracene: less than 2 µg/l</li> </ul>	<p>the final consumer, 3800 mg/l.</p> <ol style="list-style-type: none"> <li>1. When reference is made to the flavourings in these spirit drinks the name or the FI number should be used.</li> <li>2. It is the responsibility of Member States to use the appropriate tools to inform about the specific risks linked to the presence of pyroligneous distillate in <i>tuzemský</i> and <i>tuzemak</i>.</li> <li>3. <i>Tuzemský</i> and <i>tuzemak</i> to which pyroligneous distillate [Fl. no. 21.001] has been added should not be used in the manufacture of other foodstuffs.</li> </ol>	
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					- cids (expressed as acetic acid): less than 1.00 g/l	4. When this flavouring is marketed as such, in addition to the requirements of Article 15 of Regulation (EC) No 1334/2008, it will be indicated that it is intended to be used only for the manufacture of the spirits drinks <i>tuzemský</i> and <i>tuzemak</i> .		
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