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Inventory of Industry documents

A report on the type of information from the EU-CEG system on enhanced reporting of priority additives

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Background

Manufacturers and importers of cigarettes and RYO tobacco (individual or in consortia) are obliged to submit a report containing comprehensive studies on each priority additive (if used as additive) (Tobacco Product Directive 2014/40/EU Article 6; Commission Implementing Decision EU 2016/787; point 6 and annex 1). These studies should have been submitted by 1 July 2018, 18 months after the additive concerned has been included in the priority list (at 1 January 2017). The reports should be based on studies carried out to examine for each additive whether it contributes to or increases the toxicity and/or addictiveness of cigarettes or RYO tobacco to a significant degree (TPD Art. 6.2). Moreover, studies should be carried out to examine whether the additive results in a characterizing flavour, facilitates inhalation or nicotine uptake or leads to the formation of CMR (carcinogenic, mutagenic, or reprotoxic) properties. Those studies shall also take into account the intended use of the products concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also examine the interaction of that additive with other ingredients contained in the products concerned (TPD Art 6.3). Submitted studies and reports should be sufficiently comprehensive to allow a reliable assessment of whether an additive can contribute to or significantly increases the toxicity or addictiveness of cigarettes or RYO tobacco.

The Commission and the Member States concerned may require these reports to be peer reviewed by an independent scientific body (TPD art. 6.4). In order to facilitate the peer review of the submitted information, an inventory was made of the type of information submitted for each priority additive and provided in this deliverable.

Manufacturers that submitted reports on priority additives

Twelve tobacco manufacturers joined forces in a Priority Additives Tobacco Consortium (PATC). Participating companies in this consortium are: British American Tobacco (Investments) Limited, Imperial Tobacco Limited, JT International SA, Joh. Wilh. Von Eicken GmbH, Karelia Tobacco company inc., Landewyck Tobacco s.a., Mac Baren Tobacco Company A/S, Philip Morris Products S.A., Pöschl Tabak GmbH & Co. KG., Scandinavian Tobacco Group A/S., KT&G Corporation, Continental Tobacco). The members of the PATC jointly submitted reports on 14 out of 15 priority additives. Reports for the additive diacetyl were not provided, although several Member States reported to have cigarettes or RYO products containing this additive on their market.

A few manufactures outside of the Consortium have submitted documents on some of the priority additives. Inspection of these documents showed that none of the sampled documents contained relevant data about the additive. However, as these manufacturers are small and medium enterprises, they were exempted from the enhanced reporting obligations for any of the additives that the consortium already provided reports on (TPD Art. 5). See Annex I for an overview of manufacturers that submitted documents on priority additives, and Member States they were submitted to. Note that it is only indicated whether any document was submitted, regardless of the content of the document.

Content of Enhanced reporting documents

The reports delivered by the PATC were submitted in the EU-CEG system in European Member states with products containing the respective additive on the market. They were all in English. All reports of the consortium follow the same structure and count between 2458 and 2717 pages (except for the report on Titanium Dioxide which contains 219 pages). As an example of this common structure, the table of contents of the PATC report on cocoa is provided in Annex II. Although all PATC reports follow the same structure, there are some differences between reports of additives. First, transfer rates were only investigated for nine out of the 14 additives (i.e. cocoa powder, geraniol, glycerol, guaiacol, liquorice extract powder, maltol, menthol, propylene glycol and titanium dioxide). Smoke chemistry and in vitro toxicity tests were conducted for all additives except titanium dioxide. A human clinical study was performed for 10 out of 14 additives (i.e. Carob bean extract, cocoa powder, fenugreek extract, fig juice concentrate, glycerol, guaiacol, liquorice extract powder, menthol, propylene glycol).

Finally, the sensory analysis for characterizing flavor was only conducted for nine out of the 14 additives (i.e. Carob bean extract, cocoa powder, fenugreek extract, fig juice concentrate, geraniol, guaiacol, liquorice extract powder and menthol). Annex III contains the provided overview of the comprehensive testing program of the PATC. For a more detailed and in-depth description of the content of the reports a scientific independent review panel will publish their findings in reports on each priority additive.

Use of Priority additives

Results of the analysis on basic information on the use of priority additives is not available at this stage, but may be obtained from JATC WP 6 at a later time.

References

Tobacco Product Directive 2014/40/EU Article 6;
Commission Implementing Decision EU 2016/787; point 6 and annex 1

PRIORITY ADDITIVE		Member State																												
Company		AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GB	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	
Carob Bean																														
British American Tobacco (Germany) GmbH		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
BULGARTABAC HOLDING AD				X																										
Continental Tobacco PLC																X														
Imperial Tobacco Limited		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
KARELIA TOBACCO COMPANY INC.		X	X	X	X	X				X		X	X	X	X						X								X	
Kohlhase, Kopp & Co. GmbH & Co. KG		X					X																X						X	
Scandinavian Tobacco Group Eersel B.V.		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Heupink & Bloemen Tabak B.V.		X	X			X	X			X		X	X		X			X	X	X	X		X	X	X		X		X	
JT INTERNATIONAL SA		X	X			X	X		X	X						X			X	X	X	X	X			X	X			
Landewyck Tobacco s.a.		X	X				X			X		X				X		X	X	X	X		X	X	X		X			
Cocoa																														
BULGARTABAC HOLDING AD				X																										
Philip Morris Products S.A.										X																				
British American Tobacco (Germany) GmbH		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Continental Tobacco PLC		X				X										X														
HBI Europe GmbH		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Imperial Tobacco Limited		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
KARELIA TOBACCO COMPANY INC.		X	X	X	X	X			X	X		X	X	X	X						X								X	
Kohlhase, Kopp & Co. GmbH & Co. KG		X					X																X						X	
Scandinavian Tobacco Group Eersel B.V.		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Joh. Wilh. von Eicken GmbH		X				X	X		X	X			X		X						X	X	X	X	X		X	X	X	
Pöschl Tabak GmbH & Co. KG		X	X				X			X		X						X		X	X	X		X						
JT INTERNATIONAL SA		X	X		X	X	X		X	X				X		X		X	X	X	X	X	X	X	X	X	X	X	X	
Heupink & Bloemen Tabak B.V.		X	X	X	X	X	X		X	X		X	X	X	X			X	X	X	X	X	X	X	X		X		X	
YESMOKE SRL																		X												
Landewyck Tobacco s.a.		X	X				X	X		X		X				X		X	X	X	X		X	X	X		X			
Diacetyl																														
BULGARTABAC HOLDING AD				X																										
Imperial Tobacco Limited		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Fenugreek																														
BULGARTABAC HOLDING AD				X																										
Heupink & Bloemen Tabak B.V.		X	X	X	X	X	X			X		X	X		X				X	X	X	X	X	X	X		X		X	









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ANNEX III – OVERVIEW OF THE COMPREHENSIVE TESTING PROGRAM

Table 1: Overview of the comprehensive testing program.

	Comprehensive literature review	Transfer rates	Smoke chemistry Who list of 39 priority emissions	In-vitro toxicity			Human clinical study		Sensorial analysis Assessment for characterising flavour
				Ames	Neutral Red Uptake	In-vitro Micronucleus	Pharmacokinetics study	Smoking behaviour Assessment	
Carob bean extract	✓	✗	✓	✓	✓	✓	✓	✓	✓
Cocoa powder	✓	✓	✓	✓	✓	✓	✓	✓	✓
Fenugreek extract	✓	✗	✓	✓	✓	✓	✓	✓	✓
Fig juice concentrate	✓	✗	✓	✓	✓	✓	✓	✓	✓
Geraniol	✓	✓	✓	✓	✓	✓	✗	✗	✓
Glycerol	✓	✓	✓	✓	✓	✓	✓	✓	✗
Gualacol	✓	✓	✓	✓	✓	✓	✓	✓	✓
Guar Gum	✓	✗	✓	✓	✓	✓	✗	✗	✗
Liquorice extract powder	✓	✓	✓	✓	✓	✓	✓	✓	✓
Maltol	✓	✓	✓	✓	✓	✓	✗	✗	✗
Menthol	✓	✓	✓	✓	✓	✓	✓	✓	✓
Propylene glycol	✓	✓	✓	✓	✓	✓	✓	✓	✗
Sorbitol	✓	✗	✓	✓	✓	✓	✓	✓	✗
Titanium dioxide	✓	✓	✗	✗	✗	✗	✗	✗	✗
Mix1	not applicable	✗	✓	✓	✓	✓	✗	✗	✗
Mix2	not applicable	✗	✓	✓	✓	✓	✗	✗	✗
Mix3	not applicable	✗	✓	✓	✓	✓	✓	✓	✗