EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Cross-border healthcare and tobacco control
Head of Unit

Brussels,
SANTE B2/Ares

12TH MEETING OF THE SUBGROUP ON INGREDIENTS ESTABLISHED BY THE EXPERT GROUP ON TOBACCO POLICY

26 SEPTEMBER 2022
10:00 – 17:00
CCAB, Room 2C (hybrid meeting)

~ DRAFT SUMMARY RECORD ~

(1) Welcome and Introduction

The Chair welcomed the participants and explained the house rules for the online WebEx meeting. The Chair emphasized the opportunity to meet (at least partially) in person following the restrictions COVID-19 pandemic. He reminded the adoption of a delegated directive extending certain rules to heated tobacco products as the most recent policy milestone, which will be discussed further during the day. The agenda was adopted, including two additional points proposed in advance of the meeting.

(2) Update on the Independent Advisory Panel (IAP) and its methodology

SANTE reminded Member States of the mechanism to determine whether tobacco product has a characterising flavour and its operationalization. Dr Efthimios Zervas, chair of the Independent Advisory Panel ('IAP' or 'the panel'), presented the key aspects of the approved methodology (as published on the IAP website) and the ongoing work performed by the panel. To date, the panel had addressed four requests submitted by the Member States and issued opinions concerning 18 unique TP-IDs. The opinions are published on the IAP website upon the conclusion of the respective regulatory procedures. In practice, all foreseen steps could be conducted in line with the IAP methodology despite some minor logistical issues with products shipment, which delayed some of the testing steps.

The approved IAP methodology, complemented with extensive background documentation produced by the technical group in its preparation, is published on the IAP website. This should address frequent criticism of affected companies concerning the absence of methodological details, which were also subject to access to documents requests.

Following the adoption of the Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, the methodology will need to be further extended to cover the determination of characterising

flavours in heated tobacco products. Furthermore, newly launched heated tobacco products are subject to notification prior to their actual placing on the market. This should allow for considering the suspected presence of potential characterising flavour at that stage (including the possibility to request carrying out additional tests). For products already placed on the market, the procedure would be identical to the one currently applied to cigarettes and RYO tobacco as Regulation (EU) 2016/779 does not distinguish between tobacco products categories.

In this context, Member States provided an update on their national approaches towards notification, respectively authorisation of novel tobacco products. They also informed on the number of products notified to date, including the outcome of their assessment.

(3) State of play of the national characterising flavour procedures

Participants gave via a Tour de Table updates on the status of ongoing national procedures (or their preparation) as well as on products, which are or may be concerned. Some Member States shared more detailed experience, including assessment techniques applied at the national level to detect products with suspected characterising flavours. A number of Member States brought up their exchanges with various manufacturers concerning their products assessments and, in some cases, references to procedures ongoing in other Member States.

While the Member States are the best placed to lead the product investigation, the Commission sees its role in uniform application of the rules and avoiding heterogeneous outcomes across the Member States. In this respect, SANTE highlighted the importance of proper communication among the Member States, including the secure exchange of relevant documents through S-CircaBC.

(4) Exchange of views/best practices in the regulation of ingredients

The discussion followed up on the topics raised in the preceding TdT, including the ban of certain additives on the basis of their properties falling in the scope of Article 7(6) of the TPD and practical aspects of the characterising flavour determination. Member States were encouraged to take actions based on available scientific evidence.

(5) EU-CEG update

SANTE informed the participants of the EU-CEG system upgrade implemented on 15 September. This minor upgrade addressed a few known issues, and primarily it should further improve the quality of submitted data. It has affected the XSD structure, gateway/validation, XML Creator and both data dictionaries. As a consequence of stricter validation of phone and e-mail formats, certain XML submitted with success previously may not be accepted anymore. MSREP improvements are mainly discussed in the WP5 of JATC-2, which is also finalising practical aspects of the files to be generated on a regular basis to assist the MS with the publication of the EU-CEG data in line with the principles developed by JATC-1.

(6) JATC-2 work of relevance for the Subgroup

Member States were updated on the progress of JATC-2, which will conclude its first year of operation in October. Special attention was devoted to WP5 (EU-CEG data handling and laboratory collaboration) and WP7 (e-cigarettes and novel tobacco products), which are of the main relevance for the subgroup. Member States were encouraged to be actively involved in the JATC-2, both working on its deliverables but also using and implementing these deliverables in their regulatory work. A number of the subgroup members showed

interest in participating in the annual meeting, which will take place in person in Copenhagen and is scheduled for November.

(7) AOB

Member States exchanged their views and regulatory approaches concerning the use of anatabine in e-liquids in light of its CLP classification (toxic if swallowed, serious eye irritation).

Member States discussed ongoing ISO activities related to heated tobacco products. In the context of current work on a draft for the project ISO 6080 "Tobacco Heating Systems – Terms and Definitions" (ISO TC 126/WG 22), it was emphasised that regulation of tobacco products, including their definitions, is in the competence of regulators and cannot be driven by the standardisation processes. Any standards cannot be legally binding until incorporated in the relevant EU and national legislation.

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Annex I: List of participants

European Commission:

DG SANTE B2	Filip Borkowski (Chair)

Member States:

Austria	(Federal Ministry for Labour, Social Affairs, Health and Consumer Protection)
Belgium	(Ministry of Health, Federal Public Service Health, Food Chain Safety and Environment)
Bulgaria	(Ministry of Economy and Industry, National Administrator for Bulgaria - Section Tobacco)
Croatia	(Ministry of Health), Croatian Institute of Public Health
Cyprus	(Public Health Services, Ministry of Health)
Czech Republic	(Ministry of Agriculture, Ministry of Health)
Denmark	(Danish Safety Technology Authority, Danish Health Authority)
Estonia	(Health Board, Ministry of Social Affairs)
Finland	(National Supervisory Authority for Welfare and Health)
France	(French Agency for Food, Environmental and Occupational Health and Safety)
Germany	(Federal Office for Consumer Protection and Food Safety, Chemical and Veterinary Investigation Office)
Greece	(Independent Authority for Public Revenue – General State Laboratory)
Hungary	(Ministry of Human Capacities, Focal Point for Tobacco Control)
Ireland	(Department of Health, Health Service Executive)
Italy	(Ministry of Health)
Latvia	(Health Inspectorate)
Lithuania	(Ministry of Health, Drug, Tobacco and Alcohol Control Department)
Luxembourg	(Ministry of Health)
Malta	(Environmental Health Directorate, Ministry of Health, Department for Health Regulation)
Poland	(Bureau for Chemical Substances)
Portugal	(General Directorate of Health, Ministry of Health)
Romania	National Institute of Public Health
Slovakia	(Public Health Authority)
Slovenia	(National Laboratory of Health, Environment and Food)
Spain	(Ministry of Health, Ministry of Consumption, Center for Research and Quality Control)
Sweden	(Public Health Agency)
The Netherlands	(Ministry of Health, Welfare and Sport, National Institute for Public Health and the Environment, Permanent Representation of the Netherlands)
Norway (observer)	(Directorate of Health, Institute of Public Health)
Iceland (observer)	(Excused)

External experts

Efthimios Zervas	Independent Advisory Panel on characterising flavours
Alberto del Rio	Independent Advisory Panel on characterising flavours