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(2021)5988921

11TH MEETING OF THE SUBGROUP ON INGREDIENTS ESTABLISHED BY THE EXPERT GROUP ON TOBACCO POLICY

MEETING VIA VIDEOCONFERENCE
26 MAY 2021
09:30 – 13:30

~ DRAFT SUMMARY RECORD ~

(1) Welcome and Introduction

The Chair welcomed the participants and explained the house rules for the online WebEx meeting. The Chair introduced the team dealing with the ingredients issues as well as the team's newcomers. Several EU policy milestones relevant for tobacco control were enumerated: the end of the transitional period for the "menthol" characterising flavour, the EU Beating Cancer plan calling for a "Tobacco-Free Generation", and the publication of the report on the application of Directive 2014/40/EU (so-called 'Article 28 Report"). The agenda was presented, including an additional point proposed in advance of the meeting, and adopted without changes.

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

SANTE reminded Member States of the mechanism to determine tobacco products with a characterizing 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. Member States and the Commission may consult the IAP when determining whether a product has a characterizing flavour in the sense of the Commission Implementing Regulation (EU) 2016/779.

(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. A number of Member States brought up their exchanges with one of the manufacturers which was referring them to the ongoing procedure led by Sweden although the products were not reported as being the same in EU-CEG.

SANTE clarified that Member States are best placed to lead the investigation, as they know best their market. The Commission sees its role primarily in uniform application and avoiding heterogeneous.

SANTE highlighted the need that Member States properly inform all the other Member States of the initiation of a procedure, in order to ensure that all other Member States are aware and avoid duplication of procedures. SANTE will assist by providing an overview of the ongoing processes and facilitating secure exchange of relevant documents through S-CircaBC.

(4) Exchange of views/best practices on Article 7(6) of the TPD

Member States were informed about the legal nature of the Article 7(6) ban and its applicability to various product categories. A number of MSs referred to the robust evidence that menthol may facilitate inhalation, which was further supported by the review of the priority additives submissions by WP9 of JATC-1. They also shared their previous experience with the application of this provision and its indirect interface with the characterizing flavour determination. Member States were encouraged to take actions based on available scientific evidence.

(5) EU-CEG documentation upgrade

SANTE informed the participants on the upcoming upgrade of EU-CEG and encouraged Member States to maintain active communication with industry stakeholders in order to understand potential business impact of the XSD structure modification. While this ensures full backward compatibility of previously submitted XML files, some product files will have to be updated with mandatory information which has not been subject to a gateway validation previously. In this respect, SANTE will organise a webinar with the EU-CEG stakeholder groups on 2 June, where Member States are also welcome. Regular updates will be published on the EU-CEG website and all relevant documentation will be made available in the dedicated public CircaBC group.

(6) JATC-1 deliverables relevant for the Subgroup

Joint Actions represent an important platform for MSs' regulatory collaboration. SANTE emphasized the importance of the JATC-1 deliverables for the practical application of the product regulation at national level and provided an overview of the deliverables. Subsequently, the WP5 leader presented the mechanism for data sharing and the guidance on confidentiality aspects of data publication. The WP9 leader presented key outcomes of the priority additive assessment. All the JATC-1 deliverables are being published on www.jaotc.eu in due course.

(7) Update on the JRC laboratory work on tobacco and related products

The Commission Joint Research Centre (JRC) presented their technical work carried out for SANTE under the mutual Administrative Arrangement. This currently focuses on novel tobacco product, e-cigarettes and characterizing flavours.

(8) AOB

A number of participants provided updates on current or coming national regulations concerning herbal smoking products made of *Cannabis sativa L.* (leaves or flowers) and vaping products, based on low-THC cannabis extracts

Annex I: List of participants

European Commission:

DG SANTE B2	Thea Emmerling (Chair) Matus Ferech Anna Maria Wozniak Dimitrios Apostolou Agnieszka Kozakiewicz Ana Duarte Kleopatra-Maria Sakellari
JRC	Thomas Wenzl

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	(Excused)
Croatia	(Ministry of Health)
Cyprus	(Excused)
Czech Republic	(Ministry of Agriculture, Ministry of Health)
Denmark	(Danish Safety Technology Authority, Danish Health Authority)
Estonia	(Excused)
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,
Poland	(Bureau for Chemical Substances)
Portugal	(General Directorate of Health, Ministry of Health)
Romania	(Ministry of 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)