



Brussels, 15 October 2019  
SANTE B2/TE/KB/MF/AK/AS/JL/FB/JH

## MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY

15 OCTOBER 2019

MEETING VENUE: CCAB ~ ROOM: 2.B

–SUMMARY RECORD –

### (1) Welcome and introduction

The Chair welcomed the participants. The Chair informed that the agenda item regarding e-cigarettes would be moved up in the agenda given the recent developments in the USA. The agenda was adopted with three additional agenda items under AOB at the request of Member States. New participants introduced themselves. SANTE updated the group on the latest hearing and priorities of the new Commissioner-designate, Stella Kyriakides. SANTE further informed the group that new information regarding the UK's withdrawal from the EU was available on their website.

### (2) Implementation and Monitoring of the TPD

#### (a) Follow-up on the compliance assessment (transposition/conformity checks)

SANTE updated the group about the status of compliance assessments of national transposition measures, including transposition and conformity checks. Member States were reminded that new transposition measures are to be notified to the Commission. SANTE informed that bilateral contacts within the framework of the conformity checks are continuing. Further bilateral contacts took place since the last Expert Group meeting and more are planned.

#### (b) Court cases

Member States were updated on the International Tax Stamp Association (ITSA) appeal against the Order of the General Court on 16 May 2019 (Case: C-533/19) and the withdrawal of a reference for a preliminary ruling (Case: C-517/18).

#### (c) Article 28 report on the application of the Directive

Member States were updated on the planning and timelines of upcoming and ongoing studies in preparation for the Article 28 report on the application of the TPD. The contractor of a new study gathering relevant data presented their work plan and emphasised the importance of Member States' input. SANTE reminded Member States of their obligation to contribute to the report, e.g. via questionnaires and interviews.

Member States were encouraged to actively support and take part in preparations for the Article 28 report on the application of the Directive.

**(3) Updates by Member States on regulatory, enforcement and legal developments within and beyond the TPD**

**(a) National court cases, notifications and other regulatory updates**

Member States shared information on recent national court proceedings, judgments, upcoming notifications and other relevant regulatory issues for tobacco control.

**(b) Meeting of national enforcement officials**

Member States were briefed on the key points from the TPD Enforcement Meeting hosted by Denmark on 11-12 June 2019. The meeting brought together national officials working on market surveillance and enforcement. Member States were encouraged to repeat the success of this first meeting. SANTE could assist in planning such a meeting.

Member States interested in hosting a new enforcement meeting were invited to notify the Commission, ideally by 15 November 2019.

**(c) Exchange of best practice**

IT presented a recent decision on heated tobacco products (HTPs) and shared their national experience with the Member States.

**(4) Tobacco product regulation and reporting**

**(a) Joint Action on Tobacco Control (JATC)**

SANTE informed Member States about the recent JATC Steering Group meeting and the need to intensify the work of some WPs to ensure the timely conclusion of all project deliverables. The MSREP solution for sharing EU-CEG data is ready, and therefore those Member States who have signed the legal data sharing agreement with JATC will soon receive a request via their national administrators of EU-CEG to share data.

**(b) EU-CEG data publication**

Member States were informed about the recent MSREP release and further development priorities which will be discussed in the next EU-CEG webinar. WP5 of the JATC presented a draft document on public/confidential information in EU-CEG. Member States reflected on the draft and provided initial feedback to WP5. WP5 will proceed with the finalisation of the document which will form the basis of a new public reporting tool in MSREP. SANTE emphasised that the document is not legally binding and that Member States are free to assess the confidentiality status at national level, however, any technical support in MSREP will only be provided for one single format. SANTE also reminded Member States of their obligation to ensure that the information submitted through EU-CEG is made publicly available on a website (Article 5(4) of the TPD).

Member States endorsed the next steps proposed. The final document on public/confidential information in EU-CEG will be presented to Member States before finalising the publication module in MSREP.

Member States are encouraged to provide additional feedback on the draft document on public/confidential information in EU-CEG to WP5 by 15 November 2019.

**(c) Priority additives**

SANTE and WP9 of the JATC updated Member States on recent developments regarding the submission of the priority additives reports by the industry and the work of WP9.

On 19 June 2019, the Commission sent a letter on behalf of Member States to the industry, adding the initial observations of WP9 of the JATC and requesting additional information in line with Article 6(4) of the TPD. The letter was sent to the representatives of 12 tobacco manufacturers participating in an industry consortium developing joint reports on priority additives. The industry consortium responded on 3 July 2019 asking for a meeting to clarify certain points. The industry consortium subsequently submitted their comprehensive reply to the request from the Commission, with the exception of two pending issues raised by the WP9 review panel.

After a thorough discussion Member States agreed to continue to working jointly on this matter. They also saw no need for a meeting with industry at this point in time. They agreed that the Commission sends another letter to the industry consortium on their behalf, addressing the two questions raised by the industry. SANTE will prepare a draft letter to be circulated to the Member States for additional input and final approval.

Member States agreed to wait for the final assessment of all priority additives and recommendations by WP9 of the JATC before deciding on any future action. WP9 is expected to finalise its priority additives assessment in the beginning of 2020. SANTE reminded of the relevance of this assessment for regulatory purposes.

Member States agreed to continue to work jointly on the priority additives reports and to request the Commission to reply to the industry in a joint letter on their behalf. SANTE will prepare such a draft letter, for the approval by Member States, addressing the two questions raised by the industry consortium on the priority additives reports.

**(d) Characterising flavours**

Member States were updated on the latest development and work of the Independent Advisory Panel (IAP) and the Technical Group of Sensory and Chemical Assessors. The methodology will be further discussed in the upcoming meeting of the IAP in November and is expected to be finalized early next year.

**(e) Communication around the phase-out period in Article 7(14) - products with more than a 3% market share (e.g. menthol)**

SANTE urged Member States to communicate widely to stakeholders and consumers that the provisions of Article 7(14) of the TPD end of phase-out period for products with more than a 3% market share (e.g. menthol) will apply from 20 May 2020. Member States were reminded that there is no additional transitional period for the products covered by this provision.

**(5) E-cigarette regulation and reporting**

**(a) E-cigarettes and product safety**

Member States reported on measures being taken at national level, following adverse incidents and deaths linked to e-cigarette use in the USA. The group further discussed follow-up activities within the framework of the TPD. No EU cases similar to those found in the USA have been reported amongst Member States in either Safety Gate (RAPEX) or ICSMS.

Member States were encouraged to use ICSMS for market surveillance of products to encode all investigations. Safety Gate (RAPEX) should be used in all cases of products where a measure against a dangerous product has been adopted in their respective territories. Member States agreed to make better use of the existing reporting systems.

SANTE reported on the latest briefing concerning e-cigarettes from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), which was distributed to Member States via EMCDDA's Early Warning System Network, Reitox National Focal Points and by email within the Expert Group. Member States were encouraged to send information on adverse effects as regards health to the centre. SANTE presented an additional system, the Early Warning Rapid Response System (EWRS), which is a system for notifying serious cross-border threats to health at EU level. Member States also have this closed system at their disposal to notify of any serious cases linked to e-cigarette use.

SANTE emphasised that Member States are obliged to ensure compliance with the TPD and reminded that nicotine-containing liquids must not contain additives listed in Article 7(6) of the TPD. There was a common understanding among all Member States that additives are also ingredients. SANTE reminded Member States that the industry has the obligation to collect information on adverse effects and take corrective action should a product be identified as unsafe. Some Member States have already been in contact with the industry to obtain more information.

Member States were reminded that the responsibility for regulating flavours (including ban) remains with Member States (recital 47 of the TPD). Member States can also use provisions of Article 24(3) of the TPD and apply provisions of medicinal legislation. Some Member States have already implemented a flavour ban and other Member States are considering implementing such a ban. One Member State presented their national experience and approach on implementing their flavour ban.

A tour de table revealed that so far, no cases similar to the ones in the USA have been reported in the EU (except for an "imported case" – an American). SANTE and Member States agreed to continue monitoring the situation closely, and follow up with more in-depth discussions at the next Subgroup on E-cigarettes on 28 November 2019.

**(b) Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) mandate**

Member States were updated on the SCHEER work on e-cigarettes. Their mandate is to deliver a scientific opinion on e-cigarettes (health effects, cessation and initiation) and their work is well underway. A final opinion is expected in September/October 2020.

**(6) Track and Trace**

SANTE updated Member States on recent developments in the area of traceability and security features, in particular in relation to the launch of the EU traceability system. All components of the system are fully functioning. SANTE presented an overview of recent statistics on the number of UIs and registrations recorded in the system.

The Commission and Member States are currently working on a guidance document for stakeholders that outlines common reporting mistakes. The document will be published soon.

Participants were also informed that SANTE and OLAF would act, on behalf of the Commission, as key facilitators in the upcoming WHO FCTC Working Group on Track & Trace in November.

## **(7) Other tobacco control developments beyond the TPD**

### **(a) Tobacco and e-cigarettes advertising, promotion and sponsorship**

Member States hosting Formula One and MotoGP races informed the group about their monitoring and enforcement actions regarding sponsorship and promotion activities at this season's races. Relevant Member States shared the information in a short tour de table and agreed on the need to keep a close eye on such activities also in the next season.

SANTE updated Member States on the European Citizens Initiative, "Let's demand smarter vaping regulation!". The group discussed concerns that certain aspects of the initiative might breach relevant TPD provisions on e-cigarette advertising, promotion and sponsorship. Member States asked that the Commission sends a communication to the organisers of the initiative outlining those concerns. Some Member States noted that the Commission might be perceived as indirectly advertising the initiative and its sponsors by having a link to its website on the Commission website.

## **(8) Any other business**

### **(a) Upcoming meetings / save the date**

The next meeting of the Expert Group is tentatively scheduled for early next year.

Other meetings:

- Subgroup on Traceability and Security Features: 7 November 2019
- Subgroup on E-cigarettes: 28 November 2019
- Subgroup on Ingredients / JATC: February 2020

### **(b) Questions from Member States**

One Member States raised a discussion point on the notion of 'placing on the market', primarily in relation to inspections and enforcement activities. SANTE recalled that several provisions of the TPD referred to the intended destination market. In addition, the TPD contains provisions with obligations and requirements that already apply at the manufacturing or distribution stage, and as such, prior to the placing on the market (e.g. TNCO levels, traceability). Finally, it should be considered that, in principle, the actual destination market must be defined at the time of packaging, given its regulatory relevance with regard to TPD requirements (i.e. type of combined health warnings, traceability markings, and fiscal markings/security features).

Another Member State informed that they have been approached by the industry about a sustainability campaign related to the new single-use plastics legislation. SANTE reminded the group that the sustainability agenda and the single-use plastics legislation should not be allowed to be used by the industry for promotional purposes.

SANTE reminded Member States to use the Health Policy Platform for exchanges within the group, and that the Expert Group mailing list should contain only official email addresses.

Close of the meeting.

## **(9) Annex I: List of participants**

### **European Commission:**

DG SANTE B2

Thea Emmerling (Chair)  
Katja Bromen  
Matus Ferech  
Agnieszka Kozakiewicz  
Andrea Schwarz  
Julia Langer  
Sascha Löwenstein  
Jan Hoffmann  
Veronica Ann Miller  
Laerke Engell Petersen  
Sevasti Skeva  
Lenz Hesse

### **Member States:**

Austria	(Federal Ministry for Labour, Social Affairs, Health and Consumer Protection)
Belgium	(Federal Public Service Public Health)
Bulgaria	(Permanent Representation of Bulgaria to the EU)
Croatia	(Ministry of Health)
Cyprus	(Ministry of Health, Medical and Public Health Services)
Czech Republic	(Ministry of Agriculture, Ministry of Health)
Denmark	(Ministry of Health)
Estonia	(Ministry of Social Affairs)
Finland	(Ministry of Social Affairs and Health)
France	(Ministry of Social Affairs and Health)
Germany	(Federal Office of Consumer Protection and Food Safety)
Greece	(Permanent Representation of Greece to the EU)
Hungary	(Ministry of Human Capacities – Focal Point on Tobacco Control)
Ireland	(Department of Health, Tobacco and Alcohol Control Unit)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Lithuania	(Ministry of Health)
Luxembourg	(Ministry of Health)
Malta	(Ministry of Health – Environmental Health Directorate, Customs Department)
Poland	(Ministry of Health, Bureau for Chemical Substances, Permanent Representation of Poland to the EU)
Portugal	(General Directorate of Health, Ministry of Health)
Romania	(National Institute of Public Health)
Slovakia	(Public Health Authority, Permanent Representation of Slovakia to the EU)
Slovenia	(National Laboratory of Health, Environment and Food)
Spain	(Ministry of Health)
Sweden	(Ministry of Health and Social Affairs, Public Health Agency)
The Netherlands	(Ministry of Health, Welfare and Sport, Permanent Representation of the Netherlands to the EU)
United Kingdom	(Excused)

Norway (observer) (Ministry of Health, Directorate of Health)  
Iceland (observer) (Ministry of Health)