



## 12<sup>TH</sup> MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY

26 NOVEMBER 2018

### SUMMARY RECORD

#### **1 WELCOME AND INTRODUCTION**

The Chair welcomed the participants. The agenda was adopted without changes. New participants introduced themselves.

#### **2 IMPLEMENTATION AND MONITORING OF THE TOBACCO PRODUCTS DIRECTIVE (TPD)**

SANTE informed the group about the status of transposition in the Member States (MS) and progress on compliance assessments of national measures, including transposition and conformity checks.

The Commission has closed further infringements for non-communication of national transposition measures. SANTE informed that the first bilateral contacts in the framework of conformity checks have taken place and more will follow.

SANTE informed that a Commission Report on exercise of the power to adopt delegated acts pursuant to the TPD was adopted on 8 August 2018. SANTE furthermore informed about the planning, timelines and preparatory work for the implementation report outlined in Article 28 of the TPD, due in May 2021. As outlined in that article, Member States are expected to contribute to the report and will be contacted during its preparation (e.g. via questionnaires).

##### **2.1 Court cases**

SANTE informed the group about recent judgments of the Court of Justice of the European Union on the Tobacco Products Directive (TPD) (Case C-151/17-Swedish Match AB and C-425/17 Günter Hartmann Tabakvertrieb) and the state of play of additional court cases currently pending in the Court (Cases: C-220/17, C-517/18 and T-396/18).

##### **2.2 List of competent authorities**

SANTE informed that all Member States have sent updated information concerning the list of competent authorities. As outlined in Article 26 of TPD the list will be published in the Official Journal and on the Commission website as soon as the final update and assessment of the information provided is concluded.

It was agreed that Member States would have another 14 days to verify the correctness of information in the final version.

### **3 UPDATES BY MEMBER STATES ON RELEVANT REGULATORY, ENFORCEMENT AND LEGAL DEVELOPMENTS WITHIN AND BEYOND THE TPD**

#### **3.1 Update on a market surveillance meeting**

SANTE followed up on the agreement from the last meeting to exchange on best practices for market surveillance. As it has not been possible for AT to host a workshop under its presidency, SANTE asked if another Member State would propose to organise this. Member States interested in hosting such a workshop should contact SANTE.

#### **3.2 Tour de table**

Member States reported on recent **judgments** and **pending national court proceedings** relevant for tobacco control as well as on upcoming **notifications** under Directive 2015/1535. Furthermore, they informed of intentions to introduce **plain packaging** in their national legislations and of plain packaging legislation already in place/about to enter into force.

Member States were encouraged to share any additional information within 14 days after the meeting.

### **4 PRODUCT REGULATION AND REPORTING**

#### **4.1 Reporting from the Ingredient Subgroup Meeting**

SANTE informed of the Ingredient Subgroup meeting from 6 June 2018. Minutes have been published on the Commission webpage.

#### **4.2 Determination of characterising flavours in tobacco products**

The acting chair of the Independent Advisory Panel (IAP) and the coordinator of the Technical Group updated the participants on the deliberations of the Independent Advisory Panel (IAP) and the work of the Technical Group (TG), in particular on the establishment of the group of reference products and training of the sensory panel. The TG coordinator thanked the Member States for the purchase and shipment of potential reference products. The products have now reached the reference laboratory and the TG is ready to move ahead with their chemical and sensory testing. He informed of the training and performance of the sensory assessors. The next step is further specifying the decision criteria for determining whether a product imparts a charactering flavour. Further discussions on procedures and progress would be addressed in meetings of the ingredient subgroup.

Upon request by a Member State, SANTE clarified that a decision whether a product has a characterising flavour should apply in a uniform manner throughout the EU. Therefore, the procedure outlined in Commission Implementing Regulation (EU) 2016/779 should be followed to avoid discrepancies in decision taking among the Member States. This process also foresees coordination among Member States and the Commission regarding products identified for further assessment. In line with Article 7(2), the Commission would determine by means of implementing acts whether a tobacco product has a characterising flavour.

### **4.3 Reporting of Ingredients in EU-CEG**

SANTE informed of the outcomes of the webinar of 10 October 2018 and reminded of the collaboration with JATC and the agreement to share data with Member States. SANTE presented the new release of MSREP (version 2.0) with new reporting/filtering options and customised reports (e.g. on annual sales). Regarding the use of EU-CEG, SANTE informed about an upcoming workshop on best practices in data processing at national level (4 December 2018).

The WP5 leader gave a presentation of their work and informed that they have drafted an agreement of non-disclosure and other obligations concerning data sharing and legal aspects between a Member State and the JATC. Relevant aspects of the General Data Protection Regulation are covered by the agreement. At present 14 Member States have signed the agreement. Six Member States are in the process of signing.

It was clarified that data is only shared between Member States who have signed the agreement in the framework of the JATC. Technical aspects of data sharing would be further discussed in WP5 of the JATC. According to Article 5(7) of the TPD, Member States must store information electronically and also make it accessible to other Member States' Service Level Agreements between a Member State and the Commission would not preclude data sharing between Member States.

SANTE presented an overview of the deadlines for reporting sales data as collected in the last meeting.

SANTE will send a draft overview for the final confirmation by Member States with the aim to publish the deadlines on the EU-CEG website.

### **4.4 Priority additives**

SANTE informed that major documents on 14 (out of 15) priority additives have been submitted. SANTE asked Member States to check the completeness of their submissions.

The independent review panel identified an extensive list of serious shortcomings in the documents. The issue will be further discussed in the subgroup.

SANTE concluded that priority additives will be on the agenda of the next meeting of the JATC on 6 and 7 February 2019. SANTE asked Member States to check if data can be published and reminded that independent scientific work will also benefit from published data.

### **4.5 Joint Action on Tobacco Control (JATC)**

The JATC coordinator informed on the status of work in the JATC, in particular on the vertical packages:

- WP6 - tobacco products evaluation
- WP7 - e-cigarette product evaluation

- WP8 - laboratory capacity building - The next meeting is in Milan on 17-18 January 2019.
- WP9 - Priority additives - The next meeting is tentatively scheduled on 8 February 2019.

The Chair thanked all Member States active in the JATC.

#### **4.6 Electronic Cigarettes Regulation and Notification**

SANTE informed that a new type of e-cigarette recently entered the EU market, which had previously caused concerns and triggered regulatory action in the USA. The JATC representative briefly presented work of WP7.

SANTE further informed on its discussion with SCHEER on a mandate concerning scientific advice on certain aspects of e-cigarette use (health effects, cessation, and initiation).

The upcoming meeting of the e-cigarettes subgroup, tentatively foreseen for May 2019, should specifically address any pending issues in this area.

#### **4.7 Novel Tobacco Products**

The Chair thanked Member States for their support before and during COP8 allowing adoption of the decision on novel and emerging tobacco products.

SANTE informed of the ongoing World Customs Organization (WCO) nomenclature review, which also deals with the customs classification of novel tobacco products, including heated tobacco products, nicotine products and electronic cigarettes. In view of the SANTE, this classification should be in line with the FCTC COP8 decision on novel and emerging tobacco products (FCTC/COP8(22)). Given the wider policy implications of customs classifications, it would be preferable that for novel tobacco products 1) any reference to combustion and 2) classification in one group with e-liquids should be avoided in the future HS 2022 nomenclature.

However, the WCO Harmonized System Committee (HSC) favours an option classifying products on the basis of their "intention for inhalation without combustion" and, moreover, does not distinguish between e-liquids and novel tobacco products. The issue will be put for further discussion in the March 2019 meeting of HSC and alternative proposals are still admissible. The EU position will be coordinated in the Council Customs Union Working Party in early 2019.

The Chair invited the participants to support the discussed policy line in advance of the upcoming negotiations in the Council and encouraged them to get in touch with their customs colleagues at national level as the FCTC provisions should be followed by all governmental departments.

## **5 EXTENDED PRODUCER RESPONSIBILITY SCHEME FORESEEN IN THE “SINGLE USE PLASTICS” PROPOSAL**

DG ENV informed on the state of play of the Commission proposal for a Directive on the reduction of the impact of certain plastic products on the environment (also known as Single-use Plastics Strategy), which was being discussed in a trilogue with the European Parliament and the Council.

The Commission proposal introduced amongst others an extended producer responsibility scheme on tobacco products, mandating their producers to cover the costs of waste management and clean-up. In addition, the European Parliament has suggested certain marking requirements, which may also affect labelling of tobacco products with filters.

Participants raised the concern that the industry may use certain environmental messages for promotional purposes. It was clarified, that any additional information would go beyond the space already reserved for health warnings on the packaging.

<p>SANTE encouraged Member States to share their thoughts and knowledge on the health aspects of the proposal with SANTE and send it as soon as possible as the negotiations of the new Directive is expected to be closed by December 2018. Further, the participants were encouraged to engage in dialogue with environment colleagues.</p>
---

## **6 TRACK AND TRACE**

### **6.1 Update on implementation in 2018**

SANTE informed that the secondary legislation on systems of traceability and security features for tobacco products entered into force on 6 May 2018. The first obligation of Member States under this legislation was to inform economic operators of the composition of security features. Another important obligation concerned the appointment of ID issuers, which Member States had to carry out by 6 May 2019. Progress on these obligations would be recorded on a regular basis during feedback rounds in the Subgroup on Traceability and Security Features.

Until now, the Commission had approved thirty-one notifications of data storage contracts and proposed providers of primary repositories. Information on the approved providers was published on the SANTE website.

The Commission informed about the process of appointing a provider to operate the secondary repository. SANTE indicated that it did its utmost to finalise the appointment procedure before the end of 2018, subject to the procedural rules applicable.

Lastly, SANTE informed about various activities that were carried out in 2018 in order to support national authorities and stakeholders with the establishment of systems of traceability and security features, notably on the application of the relevant secondary legislation. These activities included four regional workshops, multiple country visits, four Meetings of the Subgroup, as well as publication of technical documentation on the Commission website.

## **6.2 Implementation in 2019**

SANTE explained that there was a need for further discussion and cooperation among all national authorities in advance of 20 May 2019, when the secondary legislation would become applicable. This would be mainly facilitated by means of frequent meetings of the Subgroup in 2019.

In particular, the appointment of ID issuers would illustrate an important discussion point in the first half of the coming year. In this context, the Chair reminded that the Commission would consider all means available in the case of non-compliance by Member States with their legal obligations.

Member States should give high priority to ensuring timely appointment and operation of ID issuers. Furthermore, Member States were encouraged to participate actively in the subgroup discussions next year, in order to ensure smooth establishment of the traceability system.

## **7 Any other business**

The next Expert Group meeting on Tobacco Control is tentatively scheduled for 21 March 2019.

Future meetings in the following subgroups are tentatively scheduled on:

- Ingredients/JATC : 6 and 7 February 2019
- Tobacco traceability : 14-15 February 2019
- E-cigarettes : 7 May 2019

## **Annex I**

## **List of participants**

### **Commission:**

DG SANTE B2

Thea Emmerling (Chair)

Filip Borkowski

Katja Broman

Matus Ferech

Agnieszka Kozakiewicz

Julia Langer

Sascha Löwenstein

Demetra Papastephanou

Rikke Karlsson

DG ENVI

Werner Bosmans

JATC, TG

Constantine Vardavas

IAP

Efthimios Zervas

### **Member States:**

Austria

(Federal Ministry of Health and Women´s Affairs)

Belgium

(Federal Public Service Public Health)

Bulgaria

(Excused)

Croatia

(Ministry of Health)

Cyprus

(Ministry of Health – Medical and Public Health Services – Health Services)

Czech Republic

(Ministry of Agriculture, Ministry of Health)

Denmark

(Ministry of Health, Danish Safety Technology Authority)

Estonia

(Estonian Tax and Customs Board)

Finland

(Ministry of Social Affairs and Health)

France

(Ministry of Social Affairs and Health)

Germany

(Federal Ministry of Food and Agriculture, Federal Office of Consumer Protection and Food Safety)

Greece

(Ministry of Health)

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 of the Republic of Lithuania)

Luxembourg

(Excused)

Malta

(Ministry for Energy and Health – Environmental Health Directorate)

Poland

(Ministry of Health)

Portugal

(General Directorate of Health)

Romania

(Ministry of Health)

Slovakia

(Ministry of Health)

Slovenia

(Ministry of Health)

Spain

(Ministry of Health)

Sweden

(Ministry of Health and Social Affairs, Public Health Agency)

The Netherlands

(Ministry of Health, Welfare and Sport)

United Kingdom

(Department of Health)

Iceland (observer)

(Ministry of Welfare)

Norway (observer)

(Ministry of Health)