EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Health in all Policies, Global Health, Tobacco Control

MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY
SUMMARY RECORD

Date: October 9, 2017

Meeting venue: CCAB - AB~4A

1. Welcome and Introduction

The Chair welcomed the participants. The agenda was adopted without changes.

2. Track and Trace

SANTE presented the draft delegated regulation on key elements of data storage contracts for a tracking and tracing system under Art. 15(12) of the TPD. The presentation was followed by a short discussion round. One Member State inquired into the reasons for regulating the duration of contracts between manufacturers/importers and providers of data storage systems. SANTE explained that 'duration' is listed in the wording of Art. 15(12) of the TPD, which provides the Commission with delegating powers. A minimum duration of 5 years was chosen to ensure a certain level of continuity given the pivotal role of the data storages in the traceability system. Other Member States further asked for clarifications on the threshold for independence. SANTE noted that this provision mirrored the requirements set out in the draft implementing regulation under Art. 15(11) of the TPD and the possibility to include two thresholds (prior and post contracting providers) would be discussed in the upcoming Tobacco Product Committee.

3. Implementation of the TPD

3.1. Transposition status

SANTE informed the group that all Member States have now notified transposition of the TPD, with 26 Member States notifying complete transposition and 2 Member States notifying partial transposition. The Commission has just decided to close some infringements for non-communication of the transposition measures.

SANTE is currently carrying out its assessment of the transposing measures. As a first step, an external contractor has been charged with providing an initial assessment of the transposition by Member States.

3.1.1. Tour de Table Art. 18

MS reported on whether they have prohibited cross-border distance sales of tobacco products and electronic cigarettes to consumers and on their cooperation with other MS in this area.

3.1.2. Tour de Table Art. 19

MS reported on whether they have introduced a system for the authorisation of novel tobacco products as provided for in Art. 19(3) and on their experience with notification of these products.

3.2. Court cases pending

SANTE provided details on the five requests for a preliminary ruling referring to the TPD which are pending at the European Court of Justice, as well as on one case pending in the General Court.

3.3. Notifications under TPD

SANTE presented Member States with a list of TPD requirements that relate to the obligation of Member States to notify the Commission in the case of certain events. More specifically, the notifications requirements presented concerned Article 3(3), 4(4), 7(1), 7(9), 20(11) and 24(3). No questions were raised by participants in this regard.

4. Tobacco Product Regulation and Reporting

SANTE introduced the topic and briefly informed about the first meeting of the independent advisory panel (IAP) in June 2017 and the status of the technical group whose evaluation process was ongoing. The first tasks of the IAP would include the further specification of the overall methodology for the technical assessment of test products and the assessment of relevant information resulting from the reporting obligations pursuant to Article 5 of the TPD. It was foreseen to finalize the Rules of Procedures at the next meeting on 19 October. SANTE also reminded of the comprehensive studies on priority additives that should be submitted to Member States and the Commission by end of June 2018.

4.1. Report from MS on market monitoring and ingredients regulation

Member States then reported on their activities regarding market monitoring and ingredient regulation. While some Member States reported that compliance with the ban

on tobacco products with a characterising flavour and on capsules was rather high, others reported on the appearance of novel product features such as cigarettes with flow filter, blunt wraps made from reconstituted tobacco cigarettes as well as paraphernalia such as filters with menthol, and efforts to circumvent the TPD by marketing flavoured RYO tobacco as pipe tobacco or by referring to flavours via the use of certain colours. Following a short discussion on the application of the transitional period under Article 7(14) TPD, SANTE reminded the group of previous discussions in the EG, most notably at the previous meeting, and a Commission non-paper from 14 December 2015.

4.2. Product categorisation

4.2.1. Hybrid products

SANTE raised the issue of so-called 'hybrid products' which have been marketed in a number of Member States. A prominent example of such products appeared in a form that combines e-cigarette technology (i.e. it contains e-liquid that is heated into vapour to be inhaled) and a tobacco part (i.e. tobacco compartment through which the vapour passes). Several Member States confirmed that information on such products had been submitted to them. Moreover, several participants recognised that such products were likely to fall into more than one product category.

SANTE pointed out that it would be important that further discussions on hybrid products would take place within the group concerning these products. Furthermore, it also drew attention of the group to Recital 9 of the TPD, which may provide guidance for further discussions on this topic.

4.2.2. Reference cigarettes for laboratory use

The participants agreed that reference cigarettes are subject to the TPD provisions as long as they are placed on the EU market.

4.3. EU-CEG

4.3.1. Update on technical developments

SANTE updated the group as to the performance of EU-CEG and MSREP. On 8 October almost 190,000 products had been submitted by 1247 various importers and manufacturers. The MSREP interface provides for stable service. Further improvements will be presented at the next EU-CEG webinar scheduled for 20 October.

4.3.2. Confidentiality and data publication

Following the discussion during the EU-CEG webinar in June, 12 MSs provided their assessment of confidentiality status of the fields with the highest relevance for the general public. SANTE presented an overview of the fields with prevailing consensus as to their status; further fields will be discussed during the next webinar and subsequently in the “Joint Action”, which should be formally launched in mid-October.

4.3.3. Access to documents

SANTE informed the group about several "Access to Documents" requests concerning product data submitted via the EU-CEG. In this respect, it was recalled that MSs are the actual recipients of the data submitted via the EU-CEG; the Commission's services only provide a technical platform for the system. This situation further highlights how important it is that Member States determine and make available to the public the product data that is regarded as non-confidential and of public interest.

5. Electronic Cigarettes Regulation and Notification

5.1. Notification procedure under Art. 20(11) TPD

SANTE noted that it had received a number of questions from Member States regarding the notification obligation under Art. 20(11) of the TPD. It was reiterated that a notification to the Commission and other Member States was required under this Article whenever provisional measures were taken regarding an e-cigarette that could present a serious risk to human health. SANTE further explained that it had consulted DG GROW to determine the most effective notification mechanism that should be used for these purposes. Consequently, in line with other existing EU legislation (notably Reg. 765/2008), two notification mechanisms were identified that may be applicable under Art. 20(11): RAPEX and ICSMS. The TPD will be added to ICSMS in coming weeks and SANTE will also look into the possibility of adding a specific category for Art. 20(11) notifications.

With respect to ICSMS, one Member State asked whether there existed a legal obligation to use it. SANTE responded that existing Union law laid down requirements for when ICSMS should be used, that is, in general terms, whenever an investigation into a product is launched at national level.

5.2. Market developments and enforcement

SANTE informed the group that some Member States have raised questions with regard to the application of the requirements on health warnings and leaflets for e-liquid containers sold in small carton boxes. Subsequently, two Member States gave presentations on how they apply these requirements to such products. SANTE stressed the importance of a harmonised application of the relevant TPD provisions and the group agreed that further reflection was needed on this subject matter.

6. Any other business

Member States raised a number of additional points for consideration/further reflection:

- Use of cannabidiol in e-cigarettes;

- Availability of extendable tanks on the market;
- Applicability of TPD for rechargeable batteries sold separately (though it should be noted that these are in any case covered by the General Product Safety Directive);
- Labelling of delivery per dose on e-liquids, given that this might be affected by the use of different types of e-liquid in e-cigarettes;
- Availability of laboratories to test e-liquids and e-cigarette hardware to verify non-compliances with TPD;
- Organisation of a dedicated meeting of the Member State competent authorities to ensure a unified, consistent approach to the application and enforcement of the TPD.

Annex I List of participants

Commission:

DG SANTE B2	Filip Borkowski (chair) Katja Bromen Matus Ferech Jan Hoffmann Agnieszka Kozakiewicz Marta Legnaioli Patricia Murray
OLAF:	Ivan Sorensen

Member States:

Austria	(Federal Ministry of Health and Women´s Affairs)
Belgium	(Federal Public Service Public Health)
Bulgaria	(Permanent Representation of Bulgaria to the EU, Ministry of Agriculture and Foods)
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	(Ministry of Social Affairs)
Finland	(Ministry of Social Affairs and Health, National Supervisory Authority for Welfare and Health)
France	(Ministry of Solidarity and Health)
Germany	(Federal Ministry of Food and Agriculture, Federal Office of Consumer Protection and Food Safety)
Greece	(Permanent Representation of Greece to the EU)
Hungary	(Ministry of Human Capacities – Focal Point for Tobacco Control, Permanent Representation of Hungary to the EU)
Ireland	(Health Service Executive, Department of Health)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Lithuania	(Ministry of Health, Permanent Representation of Lithuania to the EU)
Luxembourg	(Ministry of Health)
Malta	(Ministry for Energy and Health – Environmental Health Directorate)
Poland	(Ministry of Health, Bureau for Chemical Substances)
Portugal	(General Directorate of Health)
Romania	(Ministry of Health)
Slovakia	(Ministry of Health – Public Health Authority)
Slovenia	(Ministry of Health)
Spain	(Ministry of Health, Social Services and Equality)
Sweden	(Ministry of Health and Social Affairs, Public Health Agency of Sweden)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health)

Iceland (observer)	(Ministry of Welfare)
Norway (observer)	(Ministry of Health)
Turkey (observer)	(Tobacco and Alcohol Market Regulatory Authority)
EFTA (observer)	