



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: 15 March 2018

Meeting venue: CCAB-2D

1. Welcome and Introduction

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

2. Implementation of the Tobacco Products Directive (TPD)

2.1. Follow up of transposition

SANTE informed the group that all Member States (MS) have now notified the complete transposition of the TPD. SANTE is continuing its assessment of the transposing measures. Some infringements for non-communication of the transposition measures were recently closed.

2.2. Court cases

SANTE informed the group about the state of play of court cases pending in the Court of Justice of the European Union.

2.3 List of competent authorities

An overview of the information collected to date from MSs was circulated in advance of the meeting. There was an agreement to update the list in line with a format presented at the meeting. The list including all available contact information will be published on the website (also to facilitate exchange among the authorities) while a full list of the competent authorities will be published in the Official Journal as outlined in Article 26 of the TPD.

2.4 Tour de Table - Fees collected by MSs

MSs reported on the type of fees they charge on the basis of the TPD and the corresponding calculation methods. With respect to the complexity of data collected, the MSs will be given an opportunity to review/complete the information in writing.

2.5. Report on Nordic enforcement/Market surveillance meeting

Denmark gave a quick presentation on the regional meeting focusing on the enforcement of the TPD. MSs welcomed the idea of exchange of best practices for market surveillance. In this respect, Austria offered to organize a workshop during its upcoming presidency.

3. Product Regulation and Reporting

3.1. Update from MSs on latest market and regulatory developments

3.1.1. Tour de table: Classification of chewing tobacco

MSs explained their approach on the classification of chewing products and outlined the underlying challenges. One MS pointed out that the lack of a uniform approach may raise certain concerns. One MS suggested that chewing products may be considered as a "food" category and to certain extent be regulated under the food legislation.

3.1.2. Update on Novel Products

MSs raised the issue of a product called "Juul" notified as a "novel tobacco product" in some MSs. It is a product resembling certain characteristics of e-cigarettes gaining global popularity recently. SANTE reminded that products falling under the e-cigarettes definition should comply with the TPD e-cigarette provisions.

MSs were also asked how they deal with heated tobacco products and e-cigarettes in smoke free environments. The legislation in a number of MSs include both products in their smoke-free legislation, others introduced a legal definition for "smoking tobacco" and "smoking E-cigarettes".

3.2. Determination of characterising flavours in tobacco products

The Chair of the Independent Advisory Panel (IAP) informed the group about the establishment and work of the Panel. SANTE informed about the work initiated by the Technical Group and informed the MSs on the possibility to comment on the compiled draft list of reference products, in particular with respect to possible niche products specific for their national markets.

Furthermore, concerns were raised about the growing market of water pipes, which are at the moment excluded from the scope of the TPD provisions on characterizing flavours. MSs also informed about their experience with emerging products with menthol capsules/strings, which should in principle not be exempted from the ban. MSs also exchanged their experience on products containing a reference to flavours in brand names.

3.3. Tour de Table: Sales Data

Commission Implementing Decision (EU) 2015/2186 encourages MSs to request submission of sales data in a semester following the year concerned. MSs present at the meeting provided more specific details on their national regimes and deadlines for submission of sales data for tobacco products and e-cigarettes.

3.4. Priority additives

SANTE reminded that the deadline for submission of reports on the additives included in the priority list specified in Commission Implementing Decision (EU) 2016/787 is **1 July 2018**.

A manufacturer/submitter shall submit a report for all priority additives contained in at least one of their cigarettes or roll-your-own tobacco. It is expected that in most cases, the same submission may be applicable for multiple company products and therefore SANTE presented a technical solution that may simplify both submission by manufacturer/importers and evaluation by regulators. All reports submitted for at least one product containing one of the listed additives will automatically appear in a new dedicated overview in MSREP. This was welcomed by the majority of MS's, however some MSs expressed a wish to reflect on possible consequences (which may e.g. require a disclaimer) and SANTE will look into practical solutions to link the submitted reports to specific products.

3.5. Electronic Cigarettes Regulation and Notification

SANTE informed that Directive 2014/40/EU has been listed in the ICSMS. MSs updated the group on emerging issues, including the “shake&vape” products, allowing home mixing of e-liquids.

SANTE has informed that it provided a reply to one MS on the use of products derived from the processing of *Cannabis sativa* in e-liquids. As regards the composition of the nicotine-containing liquid used in containers of electronic cigarettes, Article 20(3) of the Directive requires that only ingredients of high purity may be used. With the exception of nicotine, only ingredients that do not pose a risk to human health in heated or unheated form shall be used.

With regard to questions on rechargeable battery used to power an electronic cigarette, SANTE advised that when the battery is an integral part of the product it will in principle fall under the TPD. Nine MSs indicated that they have an access to a laboratories equipped for testing of e-liquids.

3.6 Joint Action on Tobacco Control (JATC)

The JATC coordinator introduced the objectives and structure of the JATC. The kick-off meeting took place in Athens in December 2017. He welcomed the involvement of national regulators in the JATC. In this respect, he referred to a questionnaire on key elements of the TPD which could be addressed within the remit of the joint action. This is under preparation, and will be circulated to all EU regulators in May.

The WP5 leader presented this work package in more detail as the data collected through EU-CEG represent crucial input for deliverables of remaining vertical WPs. WP5 will address, among others, the issue of data confidentiality and data sharing.

In line with Article 5(6) of the TPD, MSs should make data available to the Commission and other MSs for the purpose of the TPD implementation. WP5 of JACT will address the issue and come with possible practical solutions taking into account experience from other regulatory areas.

4. Track and Trace

SANTE provided a short feedback from the last Subgroup on Traceability and Security Features, which concerned the implementation of systems for traceability and security features. Subsequently, SANTE updated participants on the publication of the secondary legislation related to systems of traceability and security features for tobacco products. SANTE explained that the delegated and implementing Regulation would enter into force through publication in the Official Journal of the EU, and that both acts had to be published jointly due to the existence of cross-references. Furthermore, the group was informed that the delegated Regulation was still under review by the European Parliament, while the Council had already indicated no objections.

On the subject matter of the ID issuer, SANTE encouraged MS to carry out the appointment as soon as feasible given the importance of the ID issuer for the establishment and functioning of the traceability system. Further discussions on this topic would also follow in the upcoming Subgroup meeting in April.

SANTE then explained that a number of webinars would be organised in mid-April to provide a platform to stakeholders to ask further technical questions related to the implementation and functioning of the traceability system, in particular those stakeholders who were not in a position to attend a Regional Workshop.

5. Tobacco taxation

DG TAXUD has commissioned an external study feeding into an impact assessment of a possible revision of Council Directive 2011/64/EU the Directive on tobacco taxation setting out EU rules on the structure and rates of excise duty applied to manufactured tobacco.

The contractor presented the study and in particular a questionnaire aiming at gathering feedback from public health authorities of the Member States. The questionnaire, once finalized, will be circulated to the group.

6. Any other business

The Commission provided a brief update on the preparation for the 8th Framework Convention on Tobacco Control (FCTC) Conference of the Parties (COP8).

The next Expert Group meeting on Tobacco Control is tentatively scheduled for 26 November. The meeting of the Expert Subgroup on ingredients is tentatively scheduled to take place on 6 June.

Annex I List of participants

Commission services:

DG SANTE B2	Filip Borkowski (chair) Katja Broman Matus Ferech Agnieszka Kozakiewicz Andrea Schwarz Gaia Saffioti Anna Wartberger
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DG TAXUD	Annerie Bouw
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Member States:

Austria	(Federal Ministry of Health and Women's Affairs)
Belgium	(Federal Public Service of Health, Food Chain Safety and Environment)
Cyprus	(Permanent Representation of Cyprus to the EU)
Czech Republic	(Ministry of Agriculture, Ministry of Health)
Denmark	(The Danish Safety Technology Authority)
Finland	(National Supervisory Authority for Welfare and Health)
France	(Ministry of Social Affairs and Health, Direction Générale des Douanes et Droits Indirects)
Germany	(Federal Office of Consumer Protection and Food Safety, Federal Ministry of Finance)
Greece	(Ministry of Health, Hellenic Cancer Society)
Hungary	(Ministry of Human Capacities – Focal Point for Tobacco Control,)
Ireland	(Department of Health)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Luxembourg	(Ministry of Health)
Malta	(Ministry for Energy and Health – Environmental Health Directorate)
Poland	(Ministry of Health, Ministry of Finance)
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	(Permanent Representation of Sweden)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health and Social Care)

Observers:

Iceland (Ministry of Welfare)

Norway (Ministry of Health, the Norwegian Directorate of Health)

Montenegro (Mission of Montenegro to the EU)

Other participants:

Joint Action on Tobacco Control

Chair of IAP

Economisti Associati