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: March 30, 2017

Meeting venue: CCAB - AB~2B

1. Welcome and Introduction

DG SANTE welcomed the participants. The agenda was adopted without changes.

2. Implementation of the Tobacco Products Directive (TPD)

2.1. Status of the transposition in MSs and transposition checks

DG SANTE informed the group that 22 Member States have now notified complete transposition. A further three MSs have notified partial transposition. Three MS have yet to send any notification. The six Member States that have not yet completed transposition were encouraged to do so as soon as possible and keep the Commission fully informed about their timetables and any obstacles or delays encountered.

DG 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.

2.2. Competent authorities (Article 26 TPD)

DG SANTE asked Member States that have not yet done so to communicate their competent authorities for the implementation and enforcement of the Directive's provisions as soon as possible. MS with more than one competent authority should indicate for which articles of the Directive the authorities are competent.

3. Ingredients regulation

3.1. Update from the Ingredients Subgroup

DG SANTE gave a short update on the Subgroup on Ingredients held on 2 December 2016. Minutes have been published on the Commission webpage. Regarding priority additives, the group was reminded that studies on priority additives should be conducted as of 1 January 2017 (with reports due by 30 June 2018).

3.2. Characterising flavours

DG SANTE informed the group about the appointment of the Panel on Characterising Flavours established pursuant to Commission Implementing Decision (EU) 2016/786. The panel is composed of six members selected from a list of suitable candidates on the basis of applications received in response to the open call for experts launched in July 2016. The members were selected by an evaluation panel and appointed in their personal capacity to act independently in the public interest.

Addressing actual market trends, some MSs reported on new products and product features appearing on their markets (e.g. flavoured cigarillos, flavoured capsules in filter, flavour threads and additional flavouring items in packs).

A short discussion was held about the application of the transitional period under Article 7(14) TPD. DG SANTE reminded the group of previous discussions in the EG and a Commission non-paper from 14 December 2015, suggesting that the transitional period in Article 7(14) does not apply to components containing flavours and that it is for the industry to demonstrate that Union-wide sales volumes represent 3% or more in the relevant product category in order to benefit from the transitional period.

3.3. EU-CEG

DG SANTE informed the group about the outcomes of the last webinar of the EU-CEG Technical Working Group held on 29 March. This included figures and statistics regarding submissions successfully received via the EU-CEG system and the number of accounts created up to March 2017. The main discussion concerned the technical improvements introduced in MSREP 1.5 (released on 15 February 2017) and further features that will be added to MSREP 1.6 (e.g. product withdrawals, active/inactive lists, additional submission types). MSs were reminded to submit their priorities for further improvement of the system by 7 April 2017.

Some MS reiterated the importance of being able to extract a full set of data via MSREP. The group also raised concerns regarding excessive marking of data as confidential by manufacturers and importers in their submissions. DG SANTE reminded the group that MSs are responsible for assessing whether the information is confidential before making it available to the public. The implementing acts only provide the possibility for submitters to indicate what information they consider to be confidential from their perspective. Participants said that they would appreciate possible IT solutions that could help to mitigate the additional burden caused by the excessive marking of data as confidential.

DG SANTE took note of this request and indicated that it was ready to facilitate coordination of this assessment among MS, which will also be covered by the Joint Action.

3.4. Enforcement in the MSs

Participants were invited to share their experiences and findings regarding the enforcement of the TPD. One Member State gave a presentation of their enforcement activities, in particular in relation to oral tobacco and e-cigarettes.

Several common challenges in terms of enforcement were identified, including limits on tank size for e-cigarettes, ensuring that e-cigarettes are child-resistant and leakage-free, importation of oral tobacco for private use and enforcing the prohibition of cross-border distance sales (in particular internet sales).

Regarding e-cigarettes, certain MS reported on the recent market developments. Certain MS also reported seeing that e-cigarettes that do not comply with TPD requirements are continued to be sold illegally. Some MS reported banning free sample bars for e-liquids as they are considered as a form of advertising and promotion.

One MS raised the question whether only the packaging or also the e-cigarette device should be child- and tamper proof. MS agreed that both the e-cigarette device and the packaging should be child- and tamper proof.

Some MS reported discussions with stakeholders concerning the precise scope of notification and reporting obligations. The group agreed that according to the TPD, notification or reporting for e-cigarettes and tobacco products is mandatory in each MS where products are intended to be placed on the market. Although there is a common format in the EU for such notifications or reports, manufacturers and importers must follow national obligations, such as the payment of fees, in each MS where they market their products.

DG SANTE proposed to organise a webinar to allow authorities to discuss enforcement issues and asked experts to indicate possible interest for such a webinar and to suggest items to discuss.

3.5. TNCO verification and mutual recognition

It was clarified that, while the TPD provides for an equivalence of the approved laboratories, it does not oblige Member States to automatically recognise verification schemes applied in other Member States. The Directive does not require that Member States have an approved laboratory on their territory. In this case, the approved laboratory in another Member State may be used for verification.

4. Track and Trace

The group was informed about the results and main comments received via the public consultation carried out from July to November 2016. The consultation was based on the Inception Impact Assessment previously published by the Commission, and more than 300 responses were received.

DG SANTE provided an overview of the main options under evaluation for the implementation of Articles 15 and 16 TPD, as discussed in the 4th meeting of the Subgroup on Traceability and Security Features in December 2016. Some MS asked that

specific consideration be given to SMEs and producers of products other than cigarettes and roll-your-own tobacco. They also enquired how small manufacturers would be affected by the costs of introducing the system and how to avoid competitive disadvantages for them. In this respect, DG SANTE clarified that the TPD requires all tobacco products to be tracked and traced although provides for a longer transitional period for other products than cigarettes and roll-your-own tobacco, and acknowledged that the situation of SMEs needs to be considered in implementing the provisions.

The next meeting of the Subgroup on T&T will be held in mid-May.

DG SANTE informed that only six MSs have ratified the FCTC Protocol so far and urged other Member States to do so as soon as possible.

5. Developments in MSs

5.1. Product classification

Regarding oral tobacco, one Member State presented new methods for determining if a product should be considered oral or chewing tobacco, including appearance, composition and reaction to physical pressure.

Regarding heat-not-burn tobacco products, a number of Member States reported that they are still reflecting on certain aspects of their classification. MS are also considering how to regulate the device, in particular whether it falls under the TPD or national legislation. The group also agreed that Article 13 TPD prohibits the presentation of heat-not-burn as a less harmful tobacco product.

5.2. Slim packages

Regarding slim cigarette packages, it was acknowledged by all Member States except for one that unit packages must be at least 20mm deep. It was also agreed that this was clearly the intention of the co-legislators who sought to ensure the legibility of the general warning and information message. Member States asked the Commission to provide official guidance on this matter. DG SANTE provided a further clarification that, in any case, slim cigarettes themselves are not prohibited under the TPD.

5.3. Updates from MSs

One MS gave an update on its implementation of Article 13, in particular the ban of promotional or misleading brand names.

One MS presented their work to ensure that health warnings are not hidden by promotional cards at points of sale or in vending machines. Some MS have taken measures to ensure that health warnings are not hidden when products are displayed for sale. Conversely, some Member States have adopted full ban on the display of tobacco products at the point of sale.

Annex I

List of participants

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, Croatian Institute of Public Health)
Cyprus	(Ministry of Health – Medical and Public Health)
Czech Republic	(Ministry of Agriculture; Ministry of Health)
Denmark	(Ministry of Health, Danish Safety Technology Authority)
Estonia	(Ministry of Social Affairs)
Finland	(National Supervisory Authority for Welfare and Health)
France	(Ministère des affaires sociales et de la santé)
Germany	(Federal Ministry of Food and Agriculture, Federal Office of Consumer Protection and Food Safety)
Greece	(Permanent Representation to the EU)
Hungary	(National Institute for Health Development - Hungarian Focal Point for Tobacco Control)
Ireland	(Department of Health)
Italy	(Ministry of Health)
Latvia	(Ministry of Health of the Republic of Latvia)
Lithuania	(Ministry of Health)
Luxembourg	(Ministry of Health)
Malta	(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 of the Republic of Slovenia)
Spain	(Ministry of Health, Social Services and Equality)
Sweden	(Ministry of Health and Social Affairs)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health)
Norway (observer)	(Ministry of Health)
Turkey (observer)	(Tobacco and Alcohol Market Regulatory Authority)

Commission:

DG SANTE B2	Anna-Eva Ampélas (chair)
	Filip Borkowski
	Katja Bromen
	Aniello Cigliano
	Matus Ferech
	Jan Hoffmann
	Isabel Holmquist
	Chi-Yuan Hu
	Agnieszka Kozakiewicz
	Marta Legnaioli
	Patricia Murray