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 26 2016

Place: VLM

1. Welcome and Introduction

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

2. Transposition of the Tobacco Products Directive in Member States

2.1. Status of the transposition checks and update on timelines

The group was informed that as of 25 October 2016, 22 MS had notified transposition (16 complete transpositions and 6 partial transpositions). Six MS had not notified any transposing measures.

DG SANTE reminded the group of the infringement procedure in case of failure to notify (or only partial notify) national measures transposing the TPD. DG SANTE stated that letters of formal notice for non-communication were sent to MS in July 2016 and that reasoned opinions are expected to be delivered by mid-December for those MS that have not notified complete transposition.

2.2. Conformity Assessment

DG SANTE informed the group that they have started the compliance checks for those MS that have notified transposition with the assistance of an external contractor.

2.3. Notification of national competent authorities (Article 26)

DG SANTE asked that MS that have not yet officially notified their competent authorities do so as soon as possible.

3. Track and Trace

3.1. Short update from EC

DG SANTE gave an update of the work by the external contractor who will assist the Commission in a new implementation study on tobacco traceability and security features and briefly described the main work packages of the contract.

DG SANTE also gave a debrief from the meeting of the subgroup on track and trace in June 2016 including an indicative timeline for the implementing legislation an update on the public consultation for Commission's Inception Impact Assessment and the establishment of a list of national contact points to assist the contractor in collecting the relevant information.

DG SANTE informed the group that the EU deposited the instrument of ratification of the Illicit Trade Protocol at UN Head Quarters in New York on 24 June 2016 and stated that five EU Member States have ratified the Protocol.

3.2. Update from MS

A tour de table was conducted on possible discussions or co-operation between national regulators and the tobacco industry or any provider of technologies that would aim to develop or to test a system for tobacco traceability and/or security features.

Four MS indicated that they are discussing or have already started traceability projects with specific track and trace providers. Some other MS said they were not aware but would need to check also with other departments (e.g. customs and tax).

DG SANTE explained the risk of signing cooperation agreements on tracking and tracing before the necessary secondary legislation is in place as these solutions/agreements might not be compliant with the future EU tracking and tracing system under TPD. DG SANTE requested the group raise awareness on this issue among authorities at national level and report back to the Commission in case of existence of traceability projects.

4. Products Regulation, Reporting and Notification

4.1. Characterising flavours

DG SANTE informed the group that they are currently evaluating the applicants to the Independent Advisory Panel assisting MS and the Commission in determining whether tobacco products have a characterising flavour, DG SANTE also gave an update regarding the establishment of the technical group.

4.2. Priority Additives

DG SANTE informed the group about the results of the public consultation on the opinion issued by SCHEER which was held from 22 July to 22 September 2016. There were 21 contributors and the vast majority of the 213 comments were from the industry.

DG SANTE also informed about the work of the external contractor, DIRECT, on how to request comprehensive studies from manufacturers. The project in its final stage and the report will be soon published.

In addition, MS were reminded that the Commission has no legal mandate to design the enhanced reporting format, but is willing to coordinate discussions among MS who are responsible for implementing this obligation at national level.

4.3. List of approved laboratories

DG SANTE informed the group that the list of approved laboratories will be published soon. MS were asked to send any updates to the list as soon as possible. The use of the list by MS will be discussed in the ingredients subgroup on 5 December 2016.

4.4. Communication on EU-CEG

DG SANTE gave a short update on the EU-CEG. Conclusions from the last webinar were presented with a focus on implemented updates and planned follow-ups. In this respect, MS were informed about detected errors in the product ID format used by a few submitters; a formal request was sent to MS asking permission to implement the necessary corrections in order to guarantee quality and consistency of product data.

Following the question of one MS, DG SANTE confirmed that it was MS competence to assess confidentiality clams notified by submitters. MS should in particular use the opportunity of the Joint Action to arrive at a common understanding on confidentiality.

DG SANTE announced that a range of stress tests of the EU-CEG system were required to ensure that servers were ready for the large volume of submissions expected around the deadline of 20 November. MS were asked to encourage industry to make their submissions as early as possible and not to wait until the last minute.

DG SANTE reminded participants that, as stipulated in the SLAs, the Commission was providing a service to MS for handling/storing product data. A lot of inquiries were received by SANTE on substantive questions related to the TPD, and such should be dealt with by national authorities. DG SANTE underlined that they would still support MS and facilitate coordination between MS in answering difficult or unclear questions. MS were further encouraged to offer information and support to industry on how to comply with their notification/reporting obligations.

4.5. Questions from MS/Industry on product submissions

MS gave their input on how they are addressing several questions related to product submissions. Several topics were discussed: the information on a responsible legal or natural representative in the EU according to the Art 20(2)(a), reporting flavours, products marketed in the Union by several different entities, reporting of non-compliant products, use of the sub-brands type field by submitters, new type of tobacco product and CLP classification.

DG SANTE presented the Joint Action on Tobacco Control and described its Working Packages: four horizontal and five substantive (EU-CEG, Tobacco, E-cigs, Labs, Priority) packages. DG SANTE encouraged MS to use the opportunity of the JA to discuss with each other difficult issues related with interpretation of the TPD and stated that the first opportunity to exchange views will be the ingredients subgroup in December.

5. Electronic cigarettes

5.1. Questions from MS

One MS asked the group how they had transposed the 2ml maximum tank size for refillable e-cigarettes. Most MS confirmed the conclusions of previous discussions that tanks larger than 2 ml should not be allowed under the TPD, although some had transposed the Directive differently (http://ec.europa.eu/health/tobacco/docs/ev_20151120_mi_en.pdf). DG SANTE explained that they will look at this issue in the context of the transposition checks.

One MS reported that they have had complaints from their e-cigarette industry regarding the ban of flavours in e-cigarettes by some MS. The MS in question stated that they had done so on the basis of national circumstances and scientific evidence. DG SANTE

informed the group that MS who have banned specific flavours in e-cigarettes in general have notified the Commission through TRIS.

Following a MS question on emissions testing, DG SANTE reminded MS that a group of MS have developed further information on emissions testing that have been circulated to the expert group. DG SANTE also informed the group that the Commission will continue to follow the CEN working group on emission measurements for e-cigarettes.

DG SANTE encouraged cooperation between MS on cross-border distance sales and mentioned that a list of competent authorities has been circulated to the group.

5.2. Market surveillance of e-cigarettes

In the context of market surveillance under TPD Article 20 (9), DG GROW presented the electronic system ICSMS which allows for a comprehensive exchange of information between market surveillance authorities. ICSMS and the Rapid Alert System for dangerous non-food products (RAPEX), through which MS are legally required to report measures taken against dangerous products made available on their market, are complementary. MS expressed interest in the system and were asked to reflect if including e-cigarettes (and/or tobacco) in the ICSMS platform would be beneficial to their national authorities.

6. Labelling and Packaging

6.1. Short update from EC

DG SANTE informed MS that work on the new health warning website is ongoing and reminded those MS that have not yet done so to send information on their national health warnings as soon as possible.

6.2. Claims

DG SANTE informed MS that they have received a large number of requests from citizens claiming that they or their relatives are depicted in the EU pictorial health warnings. DG SANTE informed the MS that a Q&A on the development of the pictures in EN, FR and DE has been published on the SANTE website to address the most commonly asked questions from journalists and citizens.

6.3. Article 13

Two MS presented their transposition of Article 13

6.4. Package dimensions

One MS presented a slim package (with a width less than 20mm) still being sold on their market. Participants who took the floor generally agreed that the 20mm minimum width of the general warning and information message must be interpreted to mean the width of the packet and not the warning (especially considering that cuboid packages must be at least 44mm high).

7. Any other business

DG SANTE informed the group that the EU positions for COP7 have been agreed in the Council (Working Party Public Health) and asked if any experts will be attending the meeting as part of their national delegations.

Annex I

List of participants

Austria	(Federal Ministry of Health)
Belgium	(Federal Public Service Public Health)
Cyprus	(Ministry of Health – Medical and Public Health)
Czech Republic	(Ministry of Agriculture; Ministry of Health, Permanent Representation of the Czech Republic to the EU)
Denmark	(Ministry of Health, Danish Safety Technology Authority)
Estonia	(Ministry of Social Affairs)
Finland	(Ministry of Social Affairs and Health)
France	(Direction Générale de la Santé)
Germany	(Federal Ministry of Food and Agriculture)
Greece	(Ministry of Health)
Hungary	(National Institute for Health Development, Hungarian Permanent Representation)
Ireland	(Department of Health)
Italy	(Ministry of Health)
Latvia	(Permanent Representation to the EU)
Luxembourg	(Ministry of Health)
Malta	(Environmental Health Directorate Ministry for Energy and Health)
Poland	(Ministry of Health)
Portugal	(General Directorate of Health)
Slovakia	(Ministry of Health)
Slovenia	(Ministry of Health of the Republic of Slovenia)
Spain	(Ministry of Health)
Sweden	(Ministry of Health and Social Affairs)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health)
Norway	(Ministry of Health)
Serbia	(Mission of Serbia to the EU)
Turkey	(Tobacco and Alcohol Market Regulatory Authority)

Commission:

DG SANTE B2	Anna-Eva Ampélas (chair)
	Filip Borkowski
	Katja Bromen
	Matus Ferech
	Jan Hoffmann
	Isabel Holmquist
	Marta Legnaioli
	Patricia Murray
	Sinziana Oncioiu