EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

Brussels, 08 July 2015

2ND MEETING OF THE SUBGROUP ON TRACK AND TRACE ESTABLISHED BY THE EXPERT GROUP ON TOBACCO POLICY

SUMMARY RECORD

Date: **3 July 2015**

Place: **CCAB-1C**

(1) Welcome and Introduction

The Chair welcomed the participating experts and introduced the Commission's team, colleagues from DG SANTE, DG TAXUD and OLAF. The Chair explained that the main purpose of the meeting was to give updates on the implementation of the Tobacco Products Directive (TPD) in the area of traceability and security features, the studies carried out and the stakeholder consultation.

(2) Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features

DG SANTE presented the results of the Feasibility Study on traceability and security features for tobacco products which was carried out by Eurogroup Consulting Portugal and its subcontractor, Sovereign Border Solutions. The study was launched in November 2013 and the final report was published on 7 May 2015, followed by a targeted stakeholder consultation which is open for contributions until end July.

The Feasibility Study covers two areas: traceability and security features. For each area, the contractor developed four main options, which can be combined. The proposed options were found by desk research, stakeholder involvement and structured assessment. The four options considered for traceability include: (1) an industry-operated solution, (2) a solution operated by a third party, (3) Member State selecting the entity responsible for product marking (as in Option 1 or 2) and (4) a unique identifier being integrated with a security feature and affixed in the same process as a security feature. The four options for security features are: (1) a security feature similar to a tax stamp, (2) a solution with reduced semi-covert elements (based on the presence of a unique identifier), (3) addition of fingerprinting technology for the semi-covert and covert levels of protection and (4) a security feature integrated with a unique identifier (as in Option 4 for traceability).

Next, DG SANTE presented the contractor's conclusions as to the cost-benefit analysis. According to this analysis, the costs between the options do not differ much and the benefits clearly override the costs for all options.

The Feasibility Study shows that the full traceability of EU tobacco products is achievable but some key decisions need to be further explored and considered. DG SANTE explained that the Feasibility Study should be primarily regarded as an input into the further implementation work. The further work is not restricted to the options presented in the Feasibility Study. Most likely the ultimate solution will be based on the combination of the options as commented on in the stakeholder consultation process and following in depth discussions in the subgroup.

Subsequently, DG SANTE asked participants to provide comments on several key questions concerning possible settings of the future system. DG SANTE clarified that at such an early stage, expert comments can only be of preliminary nature and will not be considered the final position of Member States. The first question relates to the marking process for traceability. The underlying issue is to which extent the industry can/should be involved in this process. The preliminary orientation was that industry should not be excluded from the marking process *per se,* but control is in particular required for the generation of the unique identifier and possibly the final control. The second question was if there is a preference for a single provider of the unique identifiers (per country or for the EU) or for an accreditation system (i.e. multiple accredited providers from which industry can choose). The preliminary orientation was a preference for an accreditation system, but it remained open whether the accreditation should take place at national level or at European level. Accreditation systems were also the preferred orientation for data storages. The third question was if data exchanges within the system should take place on the basis of pre-existing standards (e.g. GS1) or open standards and a pre-determined data dictionary. The experts underlined the need for standardization of the data (comparability) and pointed at past difficulties encountered in the context of operating cross-border database systems. The fourth question concerned the organisation of the independent data storage. The experts expressed a preference for a solution that makes it the easiest for Member States to retrieve the information. This would imply a need for the same data format for all the data. The last question was if the security feature should be affixed (stamp like), printed or possibly both (in combination or rotationally). The experts' orientations varied from tax stamps only, a combination to the printed version only. A combination was preferred by some because such a two layer approach would make a security feature more difficult to counterfeit. It was also argued that the only "affixed" security feature would be easy to take off.

(3) Stakeholder consultation

DG SANTE presented the main types of questions posed in the ongoing targeted stakeholder consultation launched at the same time when the Feasibility Study was published. The consultation started on 7 May 2015. The deadline for submitting comments is 31 July 2015. Targeted stakeholders are manufacturers, wholesalers and distributors, solution providers, governmental and non-governmental organisations (active in tobacco control and/or anti-illicit trade). DG SANTE invited Member States to actively contribute to the consultation.

DG SANTE explained the scope of the consultation including its primary focus on seeking views with respect to the appropriateness of the four options for traceability and the four options for security features. Extracts of the questionnaire were presented and the survey's structure explained. DG SANTE informed that some basic information on

the survey's outcome, e.g. the number of received submissions, can be expected by 14 August 2015. A summary of the comments should be available in late autumn 2015.

DG SANTE indicated the next steps. The next subgroup meeting is expected during the period December 2015 – February 2016. An impact assessment is envisaged to take place in the course of 2016. Major milestones prior to drafting the implementing and delegated acts are the review of the Feasibility Study in view of the stakeholder consultation, the selection of the optimal option for traceability and for security features and the work on defining the technical standards required for operating the optimal option.

(4) Report from OLAF

OLAF gave an update on the anti-fraud agreements with the tobacco companies and on the ratification of the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

Regarding the agreements, OLAF explained that the Commission had not yet concluded its analysis. No decision has been reached as to a potential prolongation of the first agreement (PMI) that will expire next year.

OLAF informed that the first discussions on the ratification of the Protocol took place in Council. OLAF invited Member States to support ratification of the Protocol as soon as possible in Council. OLAF also underlined the need to encourage production and transit countries to sign and ratify. The latest ratifying party is Congo, which brings the total number of parties to eight (in total 40 ratifications are required for the entry into force). OLAF and DG SANTE emphasized that it would be important that the Protocol is broadly ratified since this instrument has a potential to provide for a global tobacco control system against illicit products.

Certain experts asked for a legal analysis if the proposed options for traceability and security features are aligned with the FCTC Protocol. DG SANTE explained that the Commission's proposal will be aligned with the Protocol. As indicated during Council discussions Art. 15 and 16 of the TPD are considered compatible with the Protocol.

(5) Any other business

Concerns were expressed about CEN's proposal to develop a standard for track and trace systems and security features for the tobacco industry. It was argued that the CEN process would be an unnecessary duplication of the work that the Commission is in any event legally bound to carry out under the TPD. Even more importantly, the participation of public authorities in this process would be likely excluded on the basis of Article 5(3) FCTC. DG SANTE asked to be informed about any relevant development at national level.

(6) Conclusions

DG SANTE thanked participants and closed the meeting. The Chair indicated that the next expert subgroup meeting on track and trace will most likely take place in January 2016.

Annex I

List of participants

Members of Expert Subgroup:

Austria	(Permanent Representation of Austria)
Belgium	(Ministry of Finance/General Administration Customs and Excise/Ministry of Health)
Bulgaria	(Ministry of Finance - National Customs Agency)
Croatia	(Central Office – Sector for Customs Controls)
Cyprus	(Department of Customs and Excise)
Czech Republic	(Ministry of Agriculture of the Czech Republic/Ministry of Finance)
Denmark	(Ministry of Health, Ministry of Taxation, SKAT)
Estonia	(Estonian Tax and Customs Board)
Finland	(Finnish Customs – Crime Intelligence Unit)
France	(Direction Générale des douanes et droits indirects)
Germany	(Ministry of Finance)
Hungary	(Ministry for National Economy – Department of Indirect Taxes)
Ireland	(Indirect Taxes Policy & Legislation Division, revenue)
Italy	(Italian Customs Agency)
Latvia	(The State Revenue Service of Latvia)
Lithuania	(Drug, Tobacco and Alcohol Department/Permanent Representation of Lithuania to the EU)
Luxembourg	(Direction des douanes et accises)
Malta	(Environmental Health Directorate, Ministry for Energy and Health)
Poland	(Customs Service)
Portugal	(Imprensa Nacional – Casa de Moeda)
Romania	(Ministry of Public Finance)
Slovakia	(Tax and Customs Section)
Spain	(Permanent Representation of Spain, Agencia Estatal de Administracion Tributaria (AEAT))
Sweden	(Swedish Customs)
The Netherlands	(Netherlands Food and Consumer Product Safety Authority/Dutch Customs)
United Kingdom	(UK HM Revenue and Customs/UK Department of Health)

Commission:

DG SANTE D4	Dominik Schnichels (chair)
	Filip Borkowski
	Matus Ferech
	Emmanouil Daskalakis
	Kerstin Selbach
OLAF	Georg Roebling
	Corneliu Hoedlmayr
DG TAXUD	Annerie Bouw