



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Stakeholder Workshop on implementation of Articles 15 & 16 of Directive 2014/40/EU

Final Summary record

Meeting date: 12 December 2016, 09.30 – 18:00

(1) Welcome and Introduction

The Chair opened the meeting and welcomed all participants, including those joining via web-stream. It was explained that the contractor responsible for carrying out the implementation study was present and would outline the key points of its work to date. Following each point participants would have the opportunity to comment. A brief outline of the general context for the workshop was then provided by the Chair recalling that Articles 15 & 16 of the Tobacco Products Directive (TPD) require the Commission to adopt secondary legislation laying down technical requirements for the establishment and operation of an EU-wide traceability and security feature system, as well as for the system's interoperability across the Union. To date a Feasibility Study,¹ targeted stakeholder consultation² and public consultation³ have been carried out and an Inception Impact Assessment⁴ has been published. The Chair said that the input of stakeholders is central in this process and participants were thanked for their contributions to date. It was explained that the objectives of the workshop were to present and discuss the various policy options for implementation of the system as refined by the contractor, and to seek stakeholder input/comments on the implications of these options. Finally the Chair highlighted that all findings presented would be those of the contractor and would not necessarily represent the views of the European Commission.

(2) Presentations by the contractor and participant interventions

The contractor began by outlining the work it has completed to date. It explained it is currently in work package 2 of the project, the objective of which is to define a concept for a high level design of the optimum system for tracking and tracing. The various policy options under review by it for this purpose are based on five key decision points elaborated in the Inception Impact Assessment: choice of governance model; data storage model; allowed data carriers; allowed delays in reporting events; method of adding a security feature.

¹http://ec.europa.eu/health/sites/health/files/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

²http://ec.europa.eu/health/tobacco/consultations/2015_tpd_consultation_en

³http://ec.europa.eu/health/tobacco/consultations/2016_traceability_security_features_en

⁴http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf

Choice of governance model

The contractor presented the three policy options under evaluation for this decision point: an industry-operated solution, a third party-operated solution and a mixed model solution

On the whole, representatives of **NGOs** strongly supported a third party solution, arguing that this is the only option that fully meets the requirements of the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products. In general **solution provider** representatives also favoured a third party solution. In contrast, representatives of **manufacturers** strongly favoured an industry-operated solution. They argued that any requirement to install third-party operators along production lines would be disruptive and that full assignment of key tasks to third parties was unlikely to be technically feasible and would raise liability issues. They stressed the need to take real-life practices into account and that sufficient control measures are already in place by Member States. It was nevertheless acknowledged by some manufacturers that the process of marking and recording data should be transparent to authorities. Representatives of **wholesaler/operators** stressed that the system will only work if commercially available equipment and open standards to ensure interoperability are employed. Stakeholders from the majority of groupings agreed with this. Finally, representatives of SMEs (manufacturers and wholesalers/operators) stressed the need to limit financial and administrative burden on their sector.

Data storage model

Next, the contractor presented the main policy options under evaluation for the data storage model. These are a centralised model (B1); a decentralised model as per manufacturer/importer (B2); a decentralised model as per Member State (B3); and a combined model: centralised for surveillance and decentralised for recording (as per manufacturer/importer) (B4).

Opinions on this point again varied and the issue was recognised as a complex one. **Manufacturers** largely favoured a decentralised model according to manufacturer, arguing that decentralisation according to Member State would require complex levels interoperability. In addition they believed that a centralised system would represent a heightened technical risk and a single potential point of failure. Some said the system should enable them to track their products and they should have access to the database. In response, representatives of **wholesalers/operators** reminded that not all supply chain data is owned by the manufacturer, while **NGO** representatives said that granting the industry access to the data would contravene TPD and FCTC requirements. On the whole NGOs favoured a decentralised system according to Member State, arguing that this would ease cross border investigation efforts, provided that a centralised element is also in place – otherwise the effectiveness of the system will be hampered. They also stressed the need to ensure real-time access to data for key users. Several NGOs pointed to article 8(14) of the FCTC Protocol, which sets out that Parties may require the tobacco industry to bear any costs of the system. The majority of stakeholders agreed that the optimal solution should be secure and based on open standards, which are critical to promote interoperability.

Allowed data carriers

The contractor then presented the options under consideration for allowed data carriers: two options with single data carriers (C1 and C2), two options with multiple data carriers (C3 and C4), and a free system of data carriers (C5). It was clarified that the aim at this stage was not

to assess or prescribe individual data carriers but to evaluate the optimum quantity of allowed carriers per packaging level.

Representatives of **manufacturers** stressed that prescribing a single data carrier would not facilitate operations and may lead to additional problems, such as in the case of imports/exports of products from/to third countries which may select different carriers. They therefore favoured a limited number of data carriers. One manufacturer stressed the importance of having human readable codes. Representatives of **wholesalers/operators** stressed that the operational impact of the choice of data carrier on their sector should be carefully analysed and the scanning requirements should remain feasible. One indicated that allowing the possibility to implicitly scan unit packs via the scanning of aggregated packs would likely mitigate many of their concerns. One **solution provider** said that flexibility and adaptability should be priorities as various factors such as pack type, printing speeds and production lines can affect the choice of data carrier. On the whole, representatives of **NGOs** favoured a single data carrier. Representatives of SMEs (manufacturers and operators) stressed that the choice should not have a disproportionate impact on their sector and reminded that that niche products are often packaged together with other tobacco products at aggregated levels. Several organisations once again stressed that recognised global standards should be employed so as to allow maximum flexibility, that compatibility and interoperability should be priorities and that competition and innovation should not be hampered by the choice.

Allowed time delays

The options being analysed for the allowed time delay in event reporting were then outlined by the contractor: (near) real-time delay (D1); one day allowed delay (D2); one week allowed delay (D3).

NGO representatives were clear in their preference for (near) real-time, insisting it is necessary for effective monitoring of the supply chain. Though there was an acknowledgement from several groupings that real-time would indeed be the optimum choice for fighting illicit trade, several stakeholders – including **manufacturers, wholesalers/operators** and some **solution providers** – said that this may involve technical challenges and that a maximum delay of 24 hours would therefore be preferable. Some stakeholders said that the choice will depend on other key areas of the system (such as data storage facilities) and one suggested to differentiate between actors (i.e. shorter delays for larger manufacturers/importers, longer for smaller actors). There was a general acknowledgment that the longer the allowed delay, the greater the possibility for manipulation. A coalition organisation said that how Member States plan to use the data should be examined before a decision is made.

Methods for adding a security feature

The contractor presented the various options under review for adding a security feature: affixed (S1); printed/integrated (S2); mixed solution (S3). It was clarified that 'any method' would not imply a free system but would rather allow Member States a certain margin of choice to set specifications that meet their needs.

Several **manufacturers**, in particular smaller producers, stated their clear preference for the third option as it would allow appropriate flexibility. Larger manufacturers agreed that building on existing practices (such as tax stamps) is a good approach and stressed that it is essential to retain flexibility and innovation so as to limit the possibility of counterfeiting. One **solution provider** said that it believes tax stamps are an effective tool to fulfil this requirement, as they are capable of carrying a lot of information and as well as encrypted elements. One representative of the packaging industry said that the specifications for the security feature should be complex enough to prevent counterfeiting and that certain specifications should be harmonised among the Member States to ensure ease of control by competent authorities (e.g. requirement for security feature to be applied in the same place on each pack). One **solution provider** stressed that open specifications are preferable as narrower specifications facilitate replication. One **NGO** said that the security feature should be easily recognisable by customers and should help them to identify legal products.

(3) Conclusions

The Commission thanked participants for the comments received following each discussion point. It said it would not attempt to address specific comments or draw conclusions at this meeting as its aim was to listen and gain stakeholder input on the various options presented. The Chair assured participants that all points raised would be further considered by both the Commission and the contractor. She acknowledged that the time plan for adoption of the relevant acts is an ambitious one and said that such consultations are therefore crucial. Addressing general points raised during the meeting, she confirmed that the Commission is fully committed to respecting its obligations under the FCTC Protocol and intends to give due regard to these in the elaboration of the future acts. She added that the Commission had also taken note of the concerns of SMEs and confirmed that these are being taken into consideration. Finally, she said that the Commission was very grateful for the input received, which confirmed that there are diverging views and many different interests involved in this task. In terms of next steps, it was explained that the contractor will now look at technical specifications for the policy options discussed and that a further stakeholder workshop is planned for spring 2017. Participants will be kept informed of arrangements. It was confirmed that additional written comments would be accepted until the end of the week.

List of Participants:

Stakeholders

British American Tobacco

CECCM (Confederation of European community Cigarette Manufacturers)

Deutscher Zigarettenverband e.V. (DZV)

ESTA (European Smoking Tobacco Association)

Fetabel

HEINTZ VAN LANDEWYCK SàRL

House of Oliver Twist A/S

Imperial Tobacco

Imperial Tobacco Group

Japan Tobacco International

KARELIA TOBACCO COMPANY Inc

Kreab

Philip Morris International Management S.A.

PMI

Scandinavian Tobacco Group

Tobaksindustrien (Tobacco Manufactures Association of Denmark)

CGI - Confédération française du Commerce de Gros et International

European Tobacco Wholesalers Association (E.T.V.)

Federation of German Wholesale, Foreign Trade Services

Handelsverband Deutschland (HDE)

Latvian Traders association

LOGISTA GROUP

SANTELE BVBA

LOGISTA GROUP

Lekkerland AG & Co.AG

Association of European Cancer Leagues ECL

Association of European Cancer Leagues ECL

Comité National Contre le Tabagisme

Dutch Cancer Society

ENSP (European Network for Smoking and Tobacco Prevention)

Smoke Free Partnership
International Chamber of Commerce
Polish Chamber of Commerce
PRO SECURITATE FOUNDATION
Confederation of industry of Czech Republic (SPCR)
UNION DES FABRICANTS
BASE (Business Against Shadow Economy)
Latvian Chamber of Commerce and Industry
Bundesverband der Zigarrenindustrie
ECMA
ORION TOBACCO POLAND SP. Z O.O.
Twist nv
Asociación Canaria de Industriales Tabaqueros
German Smoking Tobacco Association
Amcor Tobacco Packaging
Arjo Solutions
AUTHENTIX
blue-infinity
Coalition Against Illicit Trade (CAIT)
De La Rue International
DOMINO PRINTING SCIENCES
Essentra plc
European Carton Makers Association (ECMA)
FATA Logistic Systems SpA
Fracturecode Corporation APS
AlpVision SA
GS1
INEXTO SA
IRPLAST SPA
ITSA
LEONHARD KURZ Stiftung & Co. KG
MEDIAPOST SPAIN, S.L. – KOVA EUROPE
NXP Semiconductors
Palacio&Asociados

SICPA

Smarm Technology Zrt

SURYS

VERIDOS MATSOUKIS SECURITY PRINTING S.A.

BUNDESDRUCKEREI

Advanced Track & Trace

Action on Smoking & Health

StichtingtegenKanker

Polish Chamber of Trade

Unizo

Honeywell

European Commission and EU Agencies

DG SANTE

CHAFEA

External Contractor

Everis