



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Cross-border healthcare and tobacco control

EXPERT GROUP ON TOBACCO CONTROL MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES

- SUMMARY RECORD -

Date: 16 September 2021

Location: Video-conference

Session 1 - only Member States' representatives

1. Welcome and introduction

The Chair welcomed the participants, reminded them about the basic rules as to the participation in discussions via video-conference, introduced the meeting's agenda and different sessions with a focus on the topics that would be discussed with the anti-tampering devices' providers during session 2 of the meeting. The Subgroup approved the agenda.

The Chair also announced that the updated version of the compilation document that can be found at the Commission's website on the tobacco traceability system, has been published.

2. Communication from SANTE (1st part)

2.1. FCTC MOP/COP preparations – information point

The 9th Conference of the Parties (COP9) to the Framework Convention on Tobacco Control and the 2nd Meeting of the Parties to the Protocol to Eliminate Illicit Trade on Tobacco (MOP2) – to which the EU is a Party – will take place this year from 8 to 13 and from 15 to 18 November, respectively, in a virtual setting. The agendas of COP9 and MOP2 have recently been published and most of the documents are uploaded on the FCTC website¹.

¹ <https://fctc.who.int/who-fctc/governance/conference-of-the-parties/ninth-session-of-the-conference-of-the-parties/main-documents>
<https://fctc.who.int/protocol/governance/meeting-of-the-parties/second-session-of-the-meeting-of-the-parties/main-documents>

The overall EU objective is to ensure that the outcome of COP9 and MOP2 is in line with and supports the EU policies on tobacco control and that the EU is fully coordinated and speaks with one voice on all topics. The coordination of EU common positions will take place under the Slovenian Presidency mostly during the months of September and October. DG SANTE is the lead DG responsible for COP9 and DG OLAF is the one for MOP2. The main topics for discussion in MOP2 will be the budget and workplan 2022-2023, the Investment Fund, the outcome of the two working groups (one on Tracking and Tracing, WGTT, and the other on Assistance and Cooperation, WGAC) and the Assistance Strategy.

2.2. Reporting on the functioning of the system

SANTE referred to Dentsu's new technical specifications whose deployment in production took place on 15 September 2021 (for a detailed description of the technical specifications, click on the link: <https://eu-secondary.dentsuaegistracking.com/eu-secondary-data-dictionary/>).

2.3. General statistics on traceability system

SANTE presented an overview of recent statistics on the application and movement of UIs, total numbers of economic operators, facilities and machines, packet level UIs and aggregated level UIs, router's and portal's monthly response times as well as monthly uptime of the secondary repository.

2.4. Data quality statistics

SANTE presented Member State by Member State statistics on the supply chain coverage that was focusing on the mismatch between the intended market and actual deliveries of the products for the second and third quarter of 2021. Another research that was based on the retail level data (deliveries per capita in the regions of specific Member States) was also presented to the Subgroup.

The Subgroup discussed the findings of the above statistics. SANTE pointed out that the statistics signal the existence of certain misreporting in a number of Member States, stressed the importance of enforcement actions at national level and invited the concerned Member States to step up the enforcement activities.

One Member State replied that the statistics are used by the competent authorities for the purpose of monitoring the correct application of the relevant legislation at national level.

SANTE also presented one new functionality of the interface that was developed by Dentsu, concerns historical product movement datasets and enables the dataset's precision at the level of a single day.

Finally, an overview of the total number of the traceability system's national users per Member State was presented to the Subgroup.

Session 2 - Member States' representatives and anti-tampering devices' providers

Introduction by SANTE

SANTE recalled the main rules on the anti-tampering devices that establish their functions and requirements for the availability and access to the data recorded by these devices during the verification process.

SANTE highlighted the need for the Member States who can request access to the data recorded in accordance with Article 7(5) of Commission Implementing Regulation (EU) 2018/574, to understand the functioning of the existing anti-tampering devices.

Presentations by the anti-tampering devices' providers

The representatives of the relevant companies explained the different components and technical characteristics of the anti-tampering devices, their practical role in the verification of unit level UIs and the different data storage options followed so far.

Exchange of views between the Commission, the Member States and the anti-tampering devices' providers

The representatives of the anti-tampering devices' providers replied to the Member States' questions on the role of the different parts of these devices, their compliance with the requirements of the Implementing Regulation as well as the practical steps for accessing the record of the verification process created by the anti-tampering devices.

Session 3 - only Member States' representatives

Communication from SANTE (2nd part)

2.5. Joint Controllership Arrangement regarding personal data processing in T&T system

SANTE thanked the Member States for their comments on the draft Joint Controllership Arrangement that was sent out in July 2021.

It was highlighted that the text was drafted in light of the complex, in terms of data protection, T&T system and defines solely the internal relationship of the Commission and the Member States acting as joint controllers.

Then SANTE replied to the Member States' comments on the text concerning in particular, the controllers' relationship with specific entities acting as processors, the controllers' obligations to provide information to the data subjects and to maintain a Record of processing activities, the handling of the data subjects' requests, the management of security incidents, the requirement for the processor to be a separate legal entity from the controller, the recipients of personal data and the persons authorised to process personal data in the Track and Trace system.

Finally, SANTE announced that it will prepare a revised version of the draft Joint Controllership Arrangement, taking into consideration the Member States' comments and the Subgroup's discussion, and send it to the members of the Group for their final comments.

2.6. 2nd audit year of the T&T system: assessment of the auditors' notifications

SANTE informed the Group that the Commission Decision on the external auditors notified by the tobacco companies whose primaries produced activity after the first operational year of the system, is expected to be adopted and notified to the relevant companies by the end of September 2021.

In this regard, it was highlighted that the auditors that will be approved, need to submit their annual audit reports by the end of October 2021.

2.7. Audit of Dentsu

SANTE informed that an audit of Dentsu is ongoing and that further updates would be provided in due course.

2.8. Anti-tampering devices' declarations: findings of the verification exercise

SANTE presented statistics on the manufacturers who have not yet submitted the declaration form of Article 7(2) of the Implementing Regulation although they have active manufacturing machines, namely the application of unit level UIs on products of these companies took place.

SANTE clarified that this practice constitutes an infringement of Article 7(2) of the Implementing Regulation as the relevant anti-tampering devices' declarations have not been submitted to the Commission. The involvement of the competent Member States was requested in line with Article 23 of the Tobacco Products Directive 2014/40/EU.

According to SANTE, more information would be necessary to assess whether these companies violated Article 7(1) of the same Regulation, namely did not verify the application process by means of an anti-tampering device.

2.9. Data storage contracts: Overview

The Subgroup was updated on the new draft data storage contracts that were notified to the Commission as well as the progress regarding the disclosure of the approved data storage contracts (between manufacturers/importers and providers of primary repositories) to the Member States for enforcement purposes.

3. Communication from Member States

The issue of granting manufacturers and importers access to the tobacco traceability data in duly justified cases in line with Article 15(8)(subpara 3) of the Tobacco Products Directive was discussed. One Member State asked if access can be granted in the context of a commercial conflict between two or more economic operators. The Member States which took the floor, explained that the requests for access to the relevant data come usually from police or judicial authorities regarding ongoing legal proceedings against specific economic operators, and access is granted solely to these authorities.

Another Member State raised the issue of misuse/theft of EOIDs. SANTE explained that at the moment, there is no authentication-validation of the EOID and that the authentication exists only for the credentials/client ID of the EO reporting to the system (or the service provider reporting

on behalf of the EO). Linking the client ID to each reporting event/product movement was discussed as a solution to this problem.

Finally, one Member State presented the main features of a new mobile application that was developed to control the movement of tobacco products at national level.

4. Q&As / Discussions

4.1. Article 9(4) of Implementing Regulation: Physical delivery of unit level UIs

One Member State asked whether in the case of physical delivery of unit level UIs the ID Issuer is the only entity that can deliver the UIs to the requesting manufacturers or importers. SANTE replied in the affirmative and clarified that in this case, only ID Issuers are entrusted with the tasks of delivering and encoding the UIs. However, it was also stressed that nothing prevents the scenario in which the UIs are delivered electronically, but then the economic operators print them on labels, which in turn are being affixed to products as long as the conditions of Article 15(1) of the Tobacco Products Directive are respected.

4.2. Reporting bulk packaging of tobacco products imported from a third country

One Member State asked for clarification on the obligation of importers to mark with unique identifiers packs of tobacco products resulted from a bulk package of loose tobacco that was imported in the EU. SANTE clarified that according to Article 15(1) of the Tobacco Products Directive, the obligation to mark tobacco products with unique identifiers lies at the level of the unit packet that is defined in Article 2(30) of the Directive as the smallest individual packaging of a tobacco or related product that is placed on the EU market. Regarding tobacco products manufactured outside of the EU, SANTE underlined that this obligation falls on the importer.

4.3. Defining the intended market when requesting unit level UIs

One Member State asked for clarification on the intended market that needs to be reported by manufacturers and importers requesting unit level UIs from the competent ID Issuer. SANTE explained that the Implementing Regulation (Annex II, section 2.1) defines the intended market as the intended country of retail sale. Technically, there is no possibility to update this field and the system does not block the products if they placed on a different EU market than the one that was initially declared. However, SANTE underlined that it is always necessary for manufacturers and importers to know in advance their products' intended market as this will define the language of the mandatory health warnings referred to in Article 8(1) of Tobacco Products Directive.

5. AOB & Closing remarks

The Chair thanked the participants for their active contribution to the meeting and looked forward to the next meeting in November 2021.

List of participants

Austria	Ministry of Finance - Tax and Customs Administration, Ministry of Health, Social Affairs, Care and Consumer Protection
Belgium	Customs and Excise Administration and FPS Health, Food Chain Safety and Environment
Bulgaria	The National Customs Agency
Croatia	AKD d.o.o., Customs Administration
Cyprus	Department of Customs and Excise
Czech Republic	Ministry of Agriculture, Czech Agriculture and Food Inspection Authority, State Printing Works of Securities
Denmark	Danish Safety Technology Authority, Danish Ministry of Health
Estonia	-
Finland	Customs department
France	Direction générale des douanes et droits indirects
Germany	Bundesdruckerei GmbH, Federal Ministry of Food and Agriculture
Greece	Independent Authority for Public Revenue, General Secretariat of Information Systems for Public Administration
Hungary	ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság, National Tax and Customs Administration, Government office of the Prime Minister - Minister without portfolio responsible for national property management
Iceland	Ministry of Health
Ireland	Department of Health, Office of the Revenue Commissioners
Italy	Ministry of Health, Customs and Monopolies Agency
Latvia	State Revenue Service of the Republic of Latvia, Ministry of Health
Lithuania	State Tax Inspectorate under the Ministry of Finance
Luxembourg	Administration des douanes et accises

Malta	Customs department
Netherlands	Customs Department, Ministry of Health, Welfare and Sport
Norway	Directorate of Health
Poland	Ministry of Finance, Polish Security Printing Works, Revenue Administration Regional Office in Katowice
Portugal	Tax and Customs Authority
Romania	National Agency for Fiscal Administration - Customs National Agency
Slovakia	Datacentrum under the Ministry of Finance of the Slovak Republic, Financial Directorate under the Ministry of Finance of the Slovak Republic
Slovenia	Financial Administration of Republic of Slovenia
Spain	Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas, Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas, FNMT-RCM
Sweden	Public Health Agency

European Commission

DG SANTE	Filip Borkowski Corina Vasilescu Dimitrios Apostolou Melina Ballario Nicolle Monica Dimitriu Neus Prenafeta Perez-Olivares
DG OLAF	Maria Pastor Charlotte Merlier