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: 30 June 2021
Location: Video-conference

1. Welcome and introduction

The Chair welcomed the participants, reminded them about the basic rules as to participation in discussions via video-conference and introduced the meeting's agenda as well as its indicative timing. The Subgroup approved the agenda.

2. Communication from SANTE

2.1. Report on the application of Directive 2014/40/EU

SANTE announced that the Report on the application of Directive 2014/40/EU and the support study that gathered evidence for the Report, were published on 20 May 2021. The Report's relevant findings regarding the tobacco traceability system were presented to the Group.

2.2. Brexit-related issues

SANTE informed the Group that the UK can consult data concerning tobacco products that are intended for, manufactured, handled, traded or found in Northern Ireland, along with the meta-data required to interpret correctly the related logistic and transactional events, thanks to the special access profile that was deployed in line with Commission Decision C(2020) 7126 adopted on 16 October 2020.

2.3. Reporting on the functioning of the system

SANTE provided an overview of Dentsu's new technical specifications that were published on 15 June 2021. The overview presented the main changes related to sequence validations on certain movements of the products (for a detailed description of the technical specifications, click on the link: https://eu-secondary.dentsuaegistracking.com/eu-secondary-data-dictionary/).

2.4. 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.

2.5. Data quality statistics

SANTE presented Member State by Member State statistics on the supply chain coverage and the deliveries of tobacco products per capita, per NUTS3 regions.

Other statistics that were presented to the Group, concerned the mismatch between the intended market and actual deliveries of the products, and the multiple use of the same FID by different economic operators in certain Member States.

In this regard, SANTE stressed that the use of the same FID by different economic operators goes against the logic of Commission Implementing Regulation (EU) 2018/574 since message 1.4 of Annex II to the Implementing Regulation creates a one-to-one link between a given pair of EOID and FID (i.e. an FID can be related only to a single EOID). Even more importantly, such reporting practices are not aligned with the requirement of Article 15(5) of the Tobacco Products Directive, which stipulates that economic operators report the movements of products in their possession.

On the same topic, SANTE explained that a technical reporting operation that is done on behalf of an economic operator by an IT service provider, is not against the rules as long as the fixed link between an EOID and an FID is respected.

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.

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

2.6. European Data Protection Board's Opinion on the tobacco traceability system

SANTE presented the European Data Protection Board's Opinion on the tobacco traceability system that was adopted on 18 June 2021, and in particular, the Board's replies to the Commission's questions.

SANTE stressed that given the Board's confirmation of the existence of joint controllership between the Commission and the Member States regarding the processing of personal data in the context of the EU tobacco traceability system, the Commission and the Member States need to have in place a Joint Controllership Arrangement that allocates their responsibilities for controllership between them.

Finally, SANTE announced that it will revise the draft Joint Controllership Arrangement, taking into consideration the Board's Opinion, and send it to the members of the Group for their comments and final approval.

2.7. 1st audit year of the T&T system: Assessment of the audit reports

SANTE presented its assessment of the audit reports that were submitted for the first operational year of the tobacco traceability system.

All the Member States took the floor and indicated whether they received the reports from the auditors and whether the Subgroup is the right forum for discussing the reports' content and the corresponding processes.

2.8. 2nd audit year of the T&T system: Submission of the auditors' notifications

SANTE informed the Group that the procedure on the assessment and approval of the notifications of the proposed auditors for the second operational year of the tobacco traceability system is in progress.

In this regard, it was highlighted that auditors who were proposed by certain tobacco manufacturers and approved for the purpose of the previous audit year by the Commission, will continue their tasks in the absence of any new notifications that would need to be submitted by the concerned tobacco companies.

2.9. Anti-tampering devices' declarations: findings of the verification exercise and new research

SANTE reminded the Group that as of 21 May 2021 economic operators falling under the definition of small and medium enterprises are also obliged to install an anti-tampering device and consequently, submit the declaration form of Art. 7(2) of the Implementing Regulation. Consequently, only economic operators that follow fully manual production processes, are now exempted from the relevant obligations.

SANTE also presented the results on the review of the anti-tampering devices' declarations that have already been submitted to the Commission. More specifically, SANTE explained that for anti-tampering devices installed in non-EU facilities, certain declarations indicated wrongly the details of the non-EU manufacturer instead of the details of the EU importer(s) who is ultimately responsible for the verification of unit level UIs with an anti-tampering device. It was stressed that this approach goes against Articles 16(4) and 18(3) of the Implementing Regulation, which requires the importer to take responsibility for the registration of non-EU manufacturing facilities and machines.

Other anti-tampering devices' declarations indicated wrongly a MID instead of the relevant FID or two separate FIDs instead of one single FID. It was stressed that this approach goes against Articles 14(1), 16(1) and 18(1) of the Implementing Regulation which establish the compulsory singularity of the identifier codes for economic operators, facilities and machines (i.e. economic operators, EU facilities and machines can have only one identifier code). The cases of non-EU facilities and machines that can be registered independently by different EOs, and cash & carry

stores and Spanish local retail-level distributors providing products to vending machines in their neighbourhood and selling directly to consumers, were indicated as exceptions to this rule.

Finally, SANTE presented statistics on the total number of anti-tampering devices used for the verification of unit level UIs as declared by the anti-tampering devices providers/suppliers, the total number of machines registered (active and inactive) by the relevant tobacco companies and the number of active manufacturing machines and the EOID and FID of the same tobacco companies.

In this regard, it was emphasised that the number of the AT devices declared should be equal to the number of the (registered) active manufacturing machines. If this is the case, the anti-tampering device declaration that was submitted, is considered complete and no follow-up actions are necessary.

One Member State asked whether a statement is required for each anti-tampering device that is used. SANTE clarified that all anti-tampering devices should be declared but there is no need for separate declarations as all devices can be listed in the same declaration.

2.10. Request for documents under Article 35(4) of Implementing Regulation 2018/574

SANTE informed the Group that in accordance with Article 35(4) of the Implementing Regulation, ID issuers, providers of repository services, providers of anti-tampering devices and their subcontractors were requested by the Commission to submit the documents referred to in the same provision. It was emphasised that public authorities or undertakings governed by public law along with their subcontractors were exempted from this exercise and the obligation to submit the relevant documents as they are considered independent in accordance with Article 35(8) of the same Regulation.

SANTE clarified that entities that have an industrial or commercial character, namely operate in normal market conditions, aim to make a profit and bear the losses resulting from the exercise of their activities, were not exempted from this exercise as they cannot be considered public authorities or undertakings governed by public law.

Finally, SANTE stressed that the outcome of this exercise paved the way for further regulatory controls on the independence of certain undertakings since omissions were identified in their declarations that need to be corrected.

2.11. Data storage contracts: Overview

The Subgroup was updated on 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

One Member State presented certain enforcement actions that were taken against a tobacco wholesaler at national level. SANTE stressed the importance of the enforcement activities for the

proper functioning of the T&T system and the relevant exchange of views on these activities during the Subgroup meetings.

Another Member State raised some questions with regard to the combined use of unique identifiers and security features that need to be applied to the unit packets of tobacco products, the security features for duty free products and the costs associated with the issuance of security features. All the Member States took the floor and replied to the relevant questions.

4. Q&As / Discussions

4.1. Anti-tampering devices: functions and objectives

One Member State asked whether the manufacturers can switch off their anti-tampering devices when they are not producing tobacco products, and instead are producing non-tobacco products on the same production line. SANTE replied in the negative and stressed that the manufacturer should not switch off their anti-tampering devices when the production line is not operated. If switched off, the device cannot adequately protect the verification of the UIs in terms of correct application and readability and as a result, it does not meet the requirements of Articles 2(7) and 7(1) of the Implementing Regulation.

The same Member State also asked whether the manufacturers can use two anti-tampering devices (from the same supplier) on the same production line. SANTE clarified that there is no hindrance of having two anti-tampering devices or a back-up anti-tampering device that can be used to continue the production without disruption if the other fails to operate.

4.2. Financing the Track & Trace system

One Member State raised a question about the scope of the manufacturers' obligation to finance the tobacco traceability system. SANTE stressed that the obligation of the tobacco companies to provide all EOs with the equipment that is necessary for the recording of the tobacco products, should be separated from the obligation of the same companies to cover the costs related to the establishment, operation and maintenance of the repositories system.

The first obligation falls within the scope of Article 15(7) of the Tobacco Products Directive and was not specified in the Implementing Regulation. As a result, it is for the Member States to transpose it into their national law. On this matter, SANTE also referred to the previous discussions of the Subgroup according to which a one-time payment to economic operators would not be compliant with the obligations set out in Article 15(7) of the Directive.

4.3. Laboratory equipment sample packs

One Member State asked whether laboratory equipment packs fall within the scope of the tobacco traceability system. SANTE replied in the affirmative and clarified that test products should be tracked and traced as any other tobacco products and referred to the previous Subgroup's discussions on this topic.

The Subgroup discussed the case where test products are dispatched to a test lab and expected to be subsequently returned to the concerned manufacturer, and agreed that such a dispatch should not be followed with a deactivation message, because that would block the return of test products to the manufacturer.

4.6. Update on DG TAXUD questionnaire concerning the use of EMCS for cross-border movements for tobacco products

Following the question of one Member State, SANTE updated the Group on a survey that was prepared by DG TAXUD in order to examine if any bilateral or multilateral agreement(s) are currently applicable or foreseen in the short term future that would waive the excise movement control obligation and consequently would pose an operational problem if the reference to an excise movement (ARC or SAAD identifier) would be made compulsory. SANTE presented the results of the survey and some statistics on the EMCS codes (by Member State of origin/by destination) to the Group.

5. AOB & Closing remarks

One Member State asked about the exact role of the OLAF in the tobacco traceability system. OLAF's representative replied to this question and provided the necessary information.

On the reporting of a transit shipment via a third country e.g. from FR to NI via GB, SANTE clarified that these cases should not be treated as exports. This means that the dispatch message that the economic operator in FR should submit to the system, should indicate the NI destination as EU destination (namely message 3.3. of Annex II, Destination ID1 and then value 2-EU destination other than VM) in order to enable the economic operators in the NI facility to report these arrivals and the system to perform the necessary FIDs' validation controls.

The Chair thanked the participants for their active contribution to the meeting and looked forward to the next meeting in September 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	(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	(Ministry of Social Affairs)
Finland	(Customs department, National Supervisory Authority for Welfare and Health)
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	(Miniszterelnöki Kormányiroda, National Tax and Customs Administration)
Iceland	-
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	(General Directorate of Customs)
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)

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