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: 9 June 2020
Location: Video-conference

1. Welcome and introduction

The Chair welcomed the participants and reminded them about the basic rules as to the participation in discussions via video-conference.

SANTE reminded the Subgroup of the recent developments in the field of tobacco control, i.e., menthol ban, elimination of non-traceable cigarettes and RYO products. It underlined that the first year of the traceability system required a lot of effort from the Commission and the competent authorities and expressed its firm belief that the system will be a success and that the common efforts will eventually pay off.

The Subgroup was reminded of the traceability system's recent technical problems and reassured that SANTE closely monitored those problems. SANTE also referred to the upcoming tobacco control actions, namely under the prevention pillar of Europe's Beating Cancer Plan and the Article 28 Report on the Tobacco Products Directive's application. The latter is to be submitted in a year to the EU Institutions.

The Chair introduced the meeting's agenda as well as its indicative timing. The Subgroup approved the agenda.

2. Communication from the Commission

2.1. Reporting on the functioning of the system

SANTE provided a general overview of the first operational year of tobacco traceability system. In relation to the full IT validation that became effective as of 1 April 2020, it was noted that that

the overall levels of economic activity registered in the system remained by and large stable as compared to the weeks preceding the full IT validation.

However, in particular after 20 May 2020, SANTE was informed about technical errors that affected, to a certain extent, the system's router and IT validation with respect to parts of the traceability events. Most critical errors arose from the incorrect sequencing and withholding of a certain number of messages by several primary repositories.

SANTE presented tentative measures aiming to tackle those errors. It clarified that the presented measures were still under analysis.

SANTE expressed its hope that the IT problems will be eliminated and avoided in the future and advised economic operators to follow certain steps when technical errors occur during reporting to the system (see point 4.3. on this issue).

Finally, SANTE emphasized the role of all stakeholders and their joint efforts, including the need for appropriate enforcement by Member States.

2.2. Statistics on traceability system

SANTE presented an overview of general statistics on the application and movement of UIs, total numbers of economic operators, facilities and machines, packet level UIs and aggregated level UIs.

2.3. Use management statistics

SANTE reported on Dentsu's statistics concerning support activities during May 2020.

2.4. FID data

SANTE drew recent cases where economic operators use multiple facility identifiers to the attention of the Subgroup and recalled the relevant rules of the Implementing Regulation, according to which all facilities from manufacturing to the first retail outlet can have only one FID per any given EU location (see Article 16 of the Implementing Regulation). It was recalled that the only exception, which had been discussed in the Subgroup, applies to the cash & carry stores requiring a second FID for their retail business to meet their reporting obligations.

SANTE presented a Member State by Member State overview of the cases of multiple FIDs for the same location by the same Economic Operator. SANTE offered the Subgroup that individual country reports summarising the findings concerning the multiple use of EOIDs and FIDs as well as the problems with VAT numbers will be shared with Member States.

2.5. Commission Notice on the withdrawal of the United Kingdom and EU rules on Tobacco and related products

SANTE referred to the Commission Notice on the legal situation that is expected to apply to UK and Northern Ireland after the end of the transition period established by the withdrawal

agreement signed between the UK and EU. A web-link to the relevant notice was shared with the Subgroup: https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/tobacco-products_en_0.pdf.

2.6. Inspection mobile application

SANTE presented the main provisions of the agreement that sets out the contractual terms agreed between the Commission and Dentsu on the use of the mobile application. Further, the end-user licence agreement was also presented. The Subgroup also discussed the identification of the end-users, the distribution of user access rights, the language options of the application, the available versions of operating systems as well as further technical aspects.

2.7. Joint Controllership Arrangement with regard to the processing taking place in the context of EU tobacco traceability system

SANTE reminded the Subgroup that the text was circulated for comments. It was announced that the final version of the text needs to be signed by both the Commission and Member States.

SANTE clarified that the arrangement reflects the roles and relationships of the joint controllers vis-à-vis the data subjects and is not intended to create additional rights or obligations under international or domestic law but only to allocate the respective responsibilities of the joint controllers for compliance with their obligations under the GDPR and Regulation (EU) 2018/1725.

SANTE presented the main provisions of the draft arrangement to the Subgroup. Particular emphasis was given to the specific responsibilities of each party.

One Member State reiterated its position that it was unable to share the Commission's premise that Member States are responsible as (joint) controllers over the data in the repository system and stressed that Member States have no contractual means to control the data processing carried out by the providers of primary repositories.

SANTE promised to prepare a first draft of the privacy statement and send it to Member States for comments.

2.8. Audit guidelines

SANTE recalled that the Commission Guidelines were published on 15 May, and underlined that the document aims to provide general guidance to an approved auditor on the scope of the audit and the procedure for submitting the annual audit report.

SANTE presented the main provisions of the Guidelines consisting of the main text and Annex. Depending on whether the audit system is successful or not, SANTE will be reflecting on whether there is need for additional measures to reinforce it in the future.

As for the next steps regarding the notification of external auditors, the Subgroup was informed that tobacco manufacturers and importers were invited to notify the Commission of their

proposed auditor by 29 June, i.e., within 45 calendar days from the date of publication of the Guidelines.

2.9. Declarations concerning anti-tampering devices under Article 7(2) of Commission Implementing Regulation 2018/574

SANTE recalled the rule of Article 7(2) of the Implementing Regulation and thanked the Subgroup for reminding the stakeholders about the obligation to submit a required declaration. Templates of the declaration forms can be found at the SANTE webpage.

2.10. Disclosure of data storage contracts

The Subgroup was updated on the progress in the disclosure of approved data storage contracts (between manufacturers/importers and providers of primary repositories) to Member States for enforcement purposes.

2.11. Publication of the UI encoding structures

SANTE informed the Subgroup that a full overview of the coding structures of unique identifiers from all the ID issuers is publicly available (see relevant link: https://ec.europa.eu/health/sites/health/files/tobacco/docs/tt_codingstructure_en.pdf).

3. Communication from Member States

3.1. Mobile apps developed at national level to access repository data

An ID issuer presented its mobile application being developed to access the traceability data for control purposes. The application is intended to be made available for use by the competent authorities of Member States. The functions and objectives of the application as well as its potential for further extensions were explained. SANTE thanked the ID Issuer for the presentation and assured about its continuous support to tools developed at national level to access remotely the data stored in the secondary repository.

4. Q&As / Discussions

4.1. Recording returns of products with damages

A Member State asked how to record the return of tobacco products, which have suffered damages (i.e. the UI code is no longer readable). SANTE clarified that there are two available options for the economic operators in this regard: a) to turn to their upstream business partners in order to inquire the missing information, b) to ask the respective Member State to provide them with an extract of the certain data sets in the repositories system to allow them to meet their obligations under the EU tobacco traceability legislation. In the latter case, the sharing of data extracts is subject to the assessment of individual Member States. One Member State expressed its doubts whether it was the enforcement authorities' task to function as a helpdesk.

4.2. Reporting on the movement of products to a non-EU military base located in the EU

A Member State enquired how EOID and FID codes could be assigned to a foreign military base that is situated on the EU territory.

SANTE referred to differentiation between test products sent to public authorities and those delivered to third party laboratories that was discussed during the meeting of the Subgroup of 8 May 2019. In particular, SANTE reminded that while movements of test products to non-governmental facilities are subject to the reporting obligations under the traceability system, for dispatches to governmental locations, no recording obligations apply. Economic operators should instead send a request for deactivation of the products concerned to the traceability system.

It was underlined that for the discussed scenario, a deactivation message should include a comment that it concerns products to be delivered to a military base, including its address, and such a message should be introduced in the system before products are actually dispatched.

4.3. Error messages while reporting to the T&T system

A Member State asked what an economic operator is supposed to do if it receives error messages from the T&T system.

In response to this question, SANTE listed the necessary steps the economic operators receiving errors need to follow: a) verify whether their own reporting operations are fully compliant; b) if needed, contact their supplier(s) to verify whether the earlier reporting obligations have been fully and correctly discharged; c) consider launching a support ticket with Dentsu as the router's operator if after contacting their supplier(s) the source of errors cannot be established and eliminated.

Finally, SANTE noted that the economic operators may also contact the national competent authorities, who have access to the EU system and, in duly justified cases, may consider verifying the information for economic operators.

4.4 Reporting problems for tobacco importers placing their products on several EU markets

An ID issuer referred to the case where tobacco products imported into the Union are expected to be placed on several EU markets, and reporting problems may result from the assignment of different EOIDs and FID.

SANTE stressed that the Implementing Regulation requires importers to be equipped with potentially several EOIDs, i.e. one EOID per ID issuer/intended EU market, but only one FID/MID per non-EU facility/machine. The rule of using one FID/MID should not prevent an importer from placing products on several intended EU markets.

SANTE further added that it pointed at upgrading the VAL_ENT_REL_EOID_FID validation (see Dentsu's technical specifications) by including a check against not only the "main" EOID, but also the "other" EOIDs, i.e. use the information that should be available in the "OtherEOID_N" field (see message 1.1 in Annex 2 to the Implementing Regulation). Dentsu already confirmed that they will include the above fine-tuning to the validation in the next maintenance release and communicate this update to the ID Issuers.

4.5. Commercial vessels and ferries/cruise ships

A Member State asked whether a tobacco product is considered to be placed on the EU market when it is sold on board, i.e. in a ferry/cruise that mainly goes between ports within EU.

SANTE recalled previous discussions on this topic according to which the determining factor to consider is the physical location of a product at the time when it is made available to the consumers. Where it is determined that the product will be made available to consumers outside of EU waters, a dispatch message for exports must be recorded in the traceability system and there is no need for the vessel/ship shop to acquire an FID. The 'final destination address field' in the corresponding dispatch message should include the vessel / cruise ship identification and the port from where the vessel / ship departs (or, alternatively, the homeport of the vessel / ship).

A Member State asked whether selling the tobacco product when the vessel/ferry is outside any territorial waters and on its way between two ports within the EU, is considered an export or sales within the EU as well as what is the definition of EU-waters.

In response to that question, SANTE reiterated that the main element to consider is the physical location of a product when the latter is made available to the consumers. On the definition of the EU waters, SANTE replied that the EU waters are considered the EU Member States' territorial waters, whose extension is defined by international conventions and the legislation of the Member States, in general 12 nautical miles.

A Member State asked who will be the competent national ID issuer for issuing EOID and FID in case the vessel/ferry has a homeport within the EU. SANTE recalled that economic operators should turn to the ID issuer competent for the Member State on whose territory the tobacco products are loaded onto the vessel/ferry.

A Member State asked which should be intended market for the products that are sold on these vessels/ferries. SANTE clarified that the intended market is deemed to be in the Member State where the consumer of these products is located. As for the ship broker who may not know the vessels' next stop or destination, SANTE suggested that he/she should turn to the economic

operator who is responsible for making these products available to consumers on this vessel/ferry since the latter is also responsible for determining their intended market.

A Member State asked which market is considered to be entered as "Intended market" when the delivery is considered an export and the UIs need to be issued in the Member State where the production takes place. SANTE suggested that the intended market should be coded "XZ", which is a free code at the disposal of users of ISO 3166. The same code is tentatively recommended for international waters in a geographic coding scheme developed and maintained by United Nations Economic Commission for Europe (UNECE).

4.6. Trans-loading practices: Reporting mistakes

SANTE reminded that the Subgroup of 5 September 2019 discussed a scenario in which products were shipped from a facility and directly trans-loaded from a van/truck to a vending van supplying retail outlets and agreed that economic operators should be advised to register a facility indicating the (geographic) location at which products are shifted/moved from a van/truck to a vending van. The Subgroup also agreed that an arrival message referencing the F-ID of that location is required and must be followed by a dispatch message for each vending van.

In this regard, SANTE informed the participants that it noticed at least one big economic operator ignoring the above Subgroup's advice and instead introducing a scheme with multiple trans-loading operations, which does not make sense from the point of view of the Implementing Regulation, and "pollutes" the system with incorrect information. SANTE noted that Dentsu was asked to provide more information on this to learn which Member States are affected.

4.7. Clarification on the upUI(s) data type

SANTE clarified that the upUI(s) data type reflects a human readable code that is required under Article 23(1) of the Implementing Regulation. Each ID issuer defines its variant of upUI(s). The adopted format may or may not coincide with the upUI(L) data type after trimming away the time stamp.

5. AOB & Closing remarks

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

List of participants

Austria (Ministry of Finance - Tax and Customs Administration, State Monopoly Agency, Ministry of Social Affairs, Health, Care and Consumers protection)

Belgium (Customs and Excise Administration and FPS Health, Food Chain Safety and Environment)

Bulgaria (National Customs Agency)

Croatia (AKD - Commercial Services Agency, Ltd., Customs Administration)

Cyprus (Department of Customs and Excise)

Czech Republic (Ministry of Agriculture, Czech Agriculture and Food Inspection Authority, State Printing Works of Securities, STC)

Denmark (Danish Safety Technology Authority)

Estonia (Ministry of Social Affairs)

Finland (Customs, The National Supervisory Authority for Welfare and Health)

France (Customs)

Germany (Bundesdruckerei GmbH, Bundesministerium für Ernährung und Landwirtschaft)

Greece (Independent Authority for Public Revenue, General Secretariat of Information Systems for Public Administration, Ministry of Digital Governance)

Hungary (Government office of the Prime Minister, Ministry without portfolio responsible for national property management, National Tax and Customs Administration, ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság)

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)

Lithuania	(State Tax Inspectorate under the Ministry of Finance)
Luxembourg	(Incert)
Malta	(Customs Department)
Netherlands	(Customs Department, Ministry of Health)
Norway	(Ministry of Health and Care Services Directorate of Health)
Poland	(Ministry of Finance, Revenue Administration Regional Office in Katowice, Polish Security Printing Works)
Portugal	(Tax and Customs Authority)
Romania	(Customs National Agency)
Slovakia	(Financial Directorate under the Ministry of Finance and Datacentrum under the Ministry of Finance)
Slovenia	(Financial Administration)
Spain	(Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas, Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas, FNMT-RCM, Ministry of Finance)
Sweden	(Public Health Agency)

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