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: 18 March 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 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 repositories' providers during session 2. The Subgroup approved the agenda.

The Chair referred to the EU Beating Cancer Plan that was presented by the Commission on 3 February 2021, with a focus on the Plan's objectives. In addition, the Chair analysed the contribution of the EU tobacco traceability system to these objectives.

2. Communication from SANTE

2.1. Report of Article 28 of Directive 2014/40/EU

SANTE explained that the Commission is required to submit a report on the Tobacco Products Directive's application by 20 May 2021. The Report's state of play and relevant findings regarding the tobacco traceability system were presented to the Group.

2.2. 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.

2.3. Support activities

SANTE reported on Dentsu's general statistics concerning support activities during February 2021.

2.4. Data quality statistics

SANTE presented Member by Member statistics on the percentage of the products reported as dispatched to retail outlets in the products reported as manufactured.

The Subgroup discussed the findings. SANTE pointed out that the statistics signal the existence of certain misreporting/non-compliant practices 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.

Another research that was based on the retail level data (deliveries per capita in the regions of a specific Member State) was also presented to the Subgroup. SANTE announced that the provider of the secondary repository develops new data sets for the Advanced Interface which will allow for checking stocks per facility and consequently, an easy discovery of the facilities that accumulate products.

Finally, SANTE presented an overview of the total number of the traceability system's national users per Member State as well as the Member States that have already downloaded Dentsu's mobile inspection application.

2.5. CIRCABC

SANTE announced that SCIRCABC (Secure Communication and Information Resource Centre for Administrations, Businesses and Citizens), a secure web-based service provided by the Commission to create external collaborative digital workspaces, is now established for the Subgroup. It was indicated that SANTE will manage the Tobacco Traceability workspace of CIRCABC and that all the members of the Subgroup will be granted access to the documents stored therein. The Group was informed about the process of accessing the workspace in question.

Session 2 - Member States' representatives and IT providers

Introduction by SANTE

SANTE began with a brief flashback to the past year and summed up the current situation regarding the functioning of the primary repositories in the tobacco traceability system. SANTE also recalled the key rules on the retention of and access to the data stored in the repositories.

Presentation by the provider of the secondary repository on the repositories system's functioning

The provider of the secondary repository presented statistics on the availability of the tobacco traceability system, the volumes of tobacco traceability data collected so far, the number of the tobacco traceability stakeholders, external systems and user management tools. The provider

indicated that the secondary repository and router are fully functional and the overall traceability system was stable. It also emphasised its good cooperation with all the stakeholders.

Intervention by the providers of primary repositories on the repositories system's functioning

All the representatives of the primary repositories' providers stressed the inherent complexity of the tobacco traceability system. They underlined their very good collaboration with the provider of the secondary repository which allowed for the repositories system to refine its operations, in particular in the course of the second operational year of the system.

One primary repository provider stressed the need for more streamlined guidance on how the audits of primary repositories should be performed, contrary to different audit methodologies that the external audit firms had followed during the audits covering the first operational year of the system.

Another provider indicated that the primary repositories' providers would appreciate more time in order to review and put into effect the technical specifications issued and updated by the provider of the secondary repository in accordance with Commission Implementing Regulation (EU) 2018/574. The same provider pointed out that the coordination on the adoption of changes to the technical specifications could be further improved.

One provider stressed that the Commission should ensure fair competitive market conditions for all primary repositories' providers within the applicable EU tobacco traceability framework, taking also into account the specific role of the provider appointed by the Commission to operate the secondary repository. The same provider suggested that as a potential, future safeguard a provider of the secondary repository could be subject to a standstill provision with respect to acquiring new clients for primary repositories.

Finally, another provider emphasised the need of good communication with other entities participating in the tobacco traceability system, such as the national ID Issuers.

As a follow-up to these interventions, the Group held an exchange of views with the repositories' providers on all topics discussed during this session.

Session 3 - only Member States' representatives

2.6. Brexit-related issues

SANTE informed the Group that the UK, in respect of Northern Ireland, would make use of the derogation of Article 4(1)(2nd subparagraph) of Implementing Regulation 2018/574, namely it designated competence to generate and issue unique identifiers to the UK's competent ID Issuer for the products expected to be placed on the market of Northern Ireland.

In addition, SANTE referred to the issue of goods transported from the EU to Northern Ireland via Great Britain and emphasised that dis-aggregation and re-aggregation of the concerned tobacco products outside the EU system in transit via a third country) is contrary to the applicable rules. Any alternation to the level of aggregation (that is reported at dispatch from an

EU facility) during the transit via Great Britain will block the correct reporting of the arrivals of these products at their destination in Northern Ireland. SANTE also presented the state of play as to the discussions with the UK authorities on this issue.

2.7. Consultation of the European Data Protection Board on the data controllership

SANTE announced that the Commission submitted a consultation request on the basis of Article 70(1)(b) of the Regulation (EU) 2016/679 to the European Data Protection Board to clarify the issues that halted the conclusion of a joint data controllership arrangement between the Commission and the Member States. SANTE presented the indicative timeline regarding the adoption of the Board's decision as well as the EU rules on the Board's composition, independent role and decision-making process.

2.8. Audits of the activities of the primary repository providers: audit reports

SANTE informed the Group that all the approved auditors met their obligation and submitted the annual audit reports to the Commission within the indicated deadline. SANTE also presented its preliminary observations on the audit reports that were submitted, and underlined the importance of clear findings that would include recommendations allowing the Member States and the Commission to remedy any potential irregularities.

A slide on the primary repositories' relevance for national markets was presented to the Group.

The Member States confirmed that they had not received the audit reports directly from the auditors. SANTE stressed that CIRCABC will allow the Subgroup to read the audit reports received by the Commission and have an informed discussion on their findings in the future.

2.9 Anti-tampering devices: New declaration form

SANTE informed the Group that the declaration form that the independent third parties supplying and/or installing the anti-tampering device need to submit to the Member States and the Commission in accordance with Article 7(2) of Implementing Regulation 2018/574, has been updated. It was explained that the relevant tobacco companies were invited to submit, in collaboration with their supplier/installer of anti-tampering devices, the updated declarations forms.

2.10. Anti-tampering devices: Discussion concerning the overlapping of the anti-tampering device's requirements under the EU and third-country Track and Trace systems

SANTE explained that an anti-tampering device (ATD) provider asked how an ATD could satisfy the parallel requirements resulting from two overlapping T&T systems (i.e. the systems established separately in the country/region of exportation/manufacturing and of importation/consumption). SANTE's preliminary assessment was that it was possible that the same hardware elements of an ATD, such as a camera or a scanner, are used for capturing unique identifiers. However, it was underlined that the actual data logs generated by the ATD should be separate and store only the relevant information for a given jurisdiction. The Member States agreed with SANTE's preliminary assessment.

2.11. ID Issuers: Update of information

SANTE thanked the Member States for providing promptly the updated information on their competent ID Issuers. One Member State that did not submit the requested information was invited to respond to SANTE's relevant request.

2.12. Article 4(1) derogation

SANTE reminded the Group that an overview table of the Member States that make use of the derogation stipulated in Article 4(1)(2nd subparagraph) of the Implementing Regulation was published at the Commission website dedicated to tobacco traceability. SANTE was informed that one Member State made use of the relevant derogation although this information was not reflected in the overview table. The Member State in question was invited to inform SANTE accordingly.

2.13. 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

The Member States discussed the national processes of managing tobacco traceability data (e.g. duplicate registrations, address data, invalid VAT numbers) and the national ID Issuers' services.

4. Q&As / Discussions

4.1. Deactivated facilities: Validation controls

IE reported tobacco products being moved to deactivated facilities and asked whether this was something that could be rectified in the system. SANTE acknowledged the problem, presented the available technical options, as discussed with the provider of the secondary repository, and announced that the router will implement the validation on the active/non-active status of FIDs reported in the context of messages 3.1 to 3.7 (see Annex II to Implementing Regulation 2018/574).

4.2. Returns of products from a first retail outlet to a wholesaler: existing validation controls

BE asked which entities were required to report to the system the products' returns from the first retail outlets and what type of validation controls were in place for registering the returns.

SANTE confirmed that in this case, the first reporting obligation lies with the economic operator (distributor/supplier) of the facility at which goods arrive after the return from the first retail

outlet. This EO is responsible for reporting (to the router) the return event by indicating in the 3.4 arrival message that the arriving products are a return (following complete or partial non-delivery).

Regarding the applicable validation controls (relating to EO_IDs and F_IDs), SANTE clarified that the system is not checking the EOID in the arrival message (used for the return) against the EOID in the dispatch message (to the first retail outlet), nor the FID of return in the arrival message against the FID of the dispatch message. In other words, a product can be returned to a different warehouse than the one that originally dispatched that product to the retail outlet.

4.3. Uniqueness of the human readable code

BE referred to SANTE's email asking all ID Issuers to modify, if necessary, their specifications to make sure that the human-readable code enabling electronic access to the information related to the unique identifiers stored in the repositories system, is unique in itself.

SANTE repeated the obligation stipulated in Article 23(1) of Implementing Regulation 2018/574 and stressed that the human-readable code can lead correctly to the information related to the unique identifiers stored in the repositories system only if it is unique in itself. In a different case, the correct unique identifier cannot be accessed and consequently, Article 23(1) is not respected. SANTE also explained that the lack of uniqueness of the human-readable code undermines the functioning of the system, including for product verification activities when the optical data carrier is damaged or an inspector cannot rely on a scanning device.

The Member States were invited to verify their ID Issuers' practice and any existing documentation for compliance with Article 23(1) of the Implementing Regulation.

4.4. Delivery of products by means of vending vans

BE asked how delivery of products by means of vending vans should be reported to the system. SANTE explained that in this case, the concerned economic operators need to submit: (i) message 3.3 on dispatch of tobacco products from a facility with value '4' to be indicated in the field 'Destination_ID1' delivery with VV; (ii) for each retail outlet, message(s) 3.7 on the actual delivery(ies) carried out with a vending van; and (iii) for any remaining products, message 3.4 on arrival of tobacco products at a facility with value '1' indicated in the field 'Product_Return'.

4.5. Tobacco products (other than cigarettes and roll-your-own-tobacco) being subject to the traceability system as of 20 May 2024

SANTE reminded the Subgroup that the Tobacco Products Directive implements the EU's international obligations, i.e. Article 8 of the FCTC Protocol, which requires that the traceability system covers all tobacco products. It was also noted that under Implementing Regulation 2018/574, manufacturers and importers of tobacco products other than cigarettes and roll-your-own tobacco shall notify to the Commission: a) the identity of their proposed primary repository provider; b) a draft data storage contract and c) the necessary declarations (of technical and operational expertise and of legal and financial independence) by 31 December 2022 (see point 6 in Annex I to the Implementing Regulation).

4.6. Update on the use of European data by the JRC

SANTE confirmed that the EU traceability data is used by the JRC in collaboration with OLAF.

5. AOB & Closing remarks

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

List of participants

Austria	Ministry of Finance - Tax and Customs Administration
Belgium	(Customs and Excise Administration and FPS Health, Food Chain Safety and Environment)
Bulgaria	The National Customs Agency
Croatia	(AKD - Commercial Services Agency, 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, Sikkerhedsstyrelsen)
Estonia	(Tax and Customs Board)
Finland	(Customs department, National Supervisory Authority for Welfare and Health)
France	(Customs department, DGDDI)
Germany	(Bundesdruckerei GmbH, Federal Ministry of Food and Agriculture)
Greece	(Independent Authority for Public Revenue, General Secretariat of Information Systems for Public Administration, Ministry of Digital Governance)
Hungary	(Miniszterelnöki Kormányiroda, ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság, NTCA)
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)
Norway	(Directorate of Health)
Poland	(Ministry of Finance, Polish Security Printing Works, Revenue Administration Regional Office in Katowice)
Portugal	(INCM, 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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