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: 24 November 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. Outcome of FCTC COP/MOP meetings

On 8-17 November 2021, the EU and its Member States participated in the 9th session of the Conference of the Parties (COP9) to the WHO's Framework Convention on Tobacco Control (FCTC) and in the 2nd session of the Meeting of the Parties (MOP2) to the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

SANTE informed the Group about the EU approach to the main topics discussed during COP9, the outcomes of the relevant discussions and shared the information on the venue of COP10 and MOP3 (Panama).

OLAF informed about the outcome of MOP2 and explained the renewed mandate of the working group on tracking and tracing as well as the MOP2 decisions and documents related to assistance to be provided to requesting Parties.

2.2. Reporting on the functioning of the system

SANTE updated the Group on the functioning of the repositories system, in particular the situation with the functioning of the primary repositories and the quality of the tobacco traceability data collected.

2.3. 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 over the year 2021 (until 31 October).

Other statistics that were presented to the Group, concerned the use of the same FID by multiple economic operators in the Member States where this wrong reporting practice takes place.

In this regard, SANTE stressed again 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).

In addition, 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.

SANTE also updated the Group on the improvements of data stored in the secondary repository. These improvements have been carried out by the secondary repository operator since September 2021.

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

The Group discussed the findings of the above statistics and updates.

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

SANTE presented the Member States' latest comments on the draft Joint Controllership Arrangement and replied to their questions concerning the role of external companies contracted to provide certain services in the tobacco traceability system, the localisation of personal data,

the time-limit for the notification of a data breach, the data subjects' requests that fall within the scope of the Joint Controllership Arrangement, and the processing operation on the administration of access rights to the tobacco traceability system.

The Subgroup agreed that the deadline for the submission of comments on the last version of the draft Joint Controllership Arrangement will be 3 December 2021. SANTE will then share with the Member States the final version of the Arrangement and provide the necessary information on the next steps concerning in particular the conclusion and signature of the Arrangement.

2.6. Preparation of an expert study on the development and configuration of automatic alerts to be generated by the EU T&T system

SANTE provided a progress update focusing in particular on the timeline of the project and relevant activities that will involve the members of the Subgroup.

2.7. Training programme in the operation of the central interfaces provided by the secondary repository of the EU T&T system

SANTE informed the Group of a new project concerning the provision of trainings to the Member States' competent authorities on the use of the existing graphical interfaces provided by the secondary repository operator. The objective of the project is to assist the Member States in making full use of the data stored in the secondary repository. SANTE provided information on the scope and timeline of the project.

The Group expressed their strong interest in participating in the training programme.

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

SANTE referred to the Commission Decision on the approval of external auditors that was adopted on 7 October 2021. The Subgroup was informed on the scope, subject matter and addressees of the Decision.

2.9. Audit of Dentsu

SANTE provided an update of the status of the project to the Group.

2.10. Submission of anti-tampering devices' declarations under Article 7(2) of Commission Implementing Regulation (EU) 2018/574

SANTE presented statistics with economic operators that have active machines but have never submitted to the Commission the anti-tampering device's declarations in accordance with Article 7(2) of Commission Implementing Regulation (EU) 2018/574. The Member States which host the facilities of the relevant economic operators, have been informed and asked to take appropriate actions.

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

SANTE provided an update of the status of this exercise, focusing in particular on companies that have not submitted the documents requested yet or companies that provided documents with certain omissions or incomplete information. The Member States which host the facilities of the relevant companies, have been informed and asked to take appropriate actions.

2.12. 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 the procedure and timeline for the application of Article 4(1)(subparagraph 2) of the Implementing Regulation that designates the ID Issuer of this Member State competent for generating and issuing unique identifiers to economic operators who place their products on the national market of this Member State. The same Member State clarified that an inter-ministerial decree modification is necessary so that the above provision can take effect, and provided information about the new fee cost of the national ID Issuer given this development.

4. Q&As / Discussions

4.1. Applying for EOID(s) as EO or importer

One Member State asked about the number of EOIDs that manufacturers and importers of tobacco products should apply for and receive. SANTE clarified that regarding economic operators (except for importers), this depends on the Member States in which the economic operators operate at least one facility. If an economic operator operates facilities in several Member States, it has to apply for EOIDs from all competent ID Issuers, namely from all ID Issuers competent for the Member States where these facilities are located.

With regard to importers, the number of the EOIDs depends on the national markets where their products are placed. This means that importers who place their products on more than one national markets need to apply for and receive identifier codes from all competent ID issuers. The importers who have already been allocated an identifier code from one of the competent ID Issuers, need to indicate it in their request for new identifier codes (see fields ‘OtherEOID_R’ and ‘OtherEOID_N’ of section 1.1. of Annex II of the Implementing Regulation). This information will allow the system to properly link all identifiers allocated to the same importer.

Another Member State asked whether an economic operator who operate facilities in two Member States, need to apply for two different EOIDs in case the competent ID Issuer of these two Member States is the same. SANTE answered in the affirmative and clarified that this approach ensures the correct application of Article 15(4) of the Implementing Regulation, namely the possibility for one of these two Member States to request, in duly justified cases that are applicable only in this Member State, the deactivation of the EOID (linked to the economic operator's facility that is located at the requesting Member State) without deactivating at the same time also the other EOID.

4.2. Unit level UIs for hand-made cigars

One Member State raised a question about the data fields a producer of hand-made cigars needs to fill in when requesting unit level UIs for their cigars, and in particular, whether the machine identifier code should also be indicated in this request. SANTE clarified that in the case of fully hand made products, the producers do not have to indicate the M_ID since the production process does not involve machinery (see field "process_type" in message 2.1. of section 2 of Annex II to the Implementing Regulation).

The same Member State asked about the location of a UI, in particular whether it has be placed on a box containing unpacked cigars or on each individual cigar. SANTE clarified that in accordance with Article 15 of Directive 2014/40/EU, all unit packets which are defined as the smallest individual packaging of a tobacco or related product that is placed on the market, have to be marked with a unique identifier. However, the Directive does not define the exact content of a unit packet of cigars, namely how many individual cigars a unit packet (of cigars) shall include. SANTE also explained that this question is related to the obligation of a tobacco product to have packaging when being placed on the market. Considering that the traceability obligations apply to the unit packet which is also a type of packaging (the smallest individual), market products can be placed on the market only if they are packaged in accordance with the labelling and packaging requirements described in Chapter II of Directive 2014/40/EU.

4.3. Possibility for EOs who have the dual role of importer and manufacturer in the same MS, to acquire two EOIDs

One economic operator asked whether a company having the dual role of manufacturer and importer (for a non-EU manufacturer) in the same Member State needs to receive an additonal EOID from the ID Issuer in order to route all events related to the imported products to the primary repository established by the non-EU manufacturer (and its other EU importers).

The Group discussed this scenario and agreed that there are two types of of importers: a) importers cooperating with only one non-EU manufacturer and being solely importers, and b)

importers cooperating with several non-EU manufacturers and/or being also an EU manufacturer themselves.

As regards the first type of importers, it is acceptable that they co-sign or join a data storage contract for a primary repository together with a non-EU manufacturer. In the regulatory terms, such an arrangement is very similar to the existence of a single data storage contract for the entire group of undertakings, e.g. national subsidiaries of the multinational group.

The same arrangement is not possible for the second type of importers who need to work with their own primary repository. This implies that these companies cannot report information to the primary repository of the non-EU manufacturer. In addition, SANTE clarified that an importer who is also an EU manufacturer and has thus already received an EOID from the competent ID Issuer, is not permitted to receive another EOID from the same ID Issuer on the basis of their double role as importer and manufacturer in the same Member State.

5. AOB & Closing remarks

The Chair thanked the participants for their active contribution to the meeting and looked forward to the next meeting in March 2022.

List of participants

Austria	(AT ID Issuer, 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	(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)
Estonia	(Ministry of Social Affairs)
Finland	(Customs department)
France	(Direction générale des douanes et droits indirects, Ministère des solidarités et de la santé-Direction générale de la santé)
Germany	(Bundesdruckerei GmbH, Federal Ministry of Food and Agriculture)
Greece	(Independent Authority for Public Revenue, General Secretariat of Information Systems for Public Administration)
Hungary	(Customs Administration)
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)
Lithuania	(State Tax Inspectorate under the Ministry of Finance, Drug, Tobacco and Alcohol Control Department)
Luxembourg	(Customs and excise administration)

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	(Folkhälsomyndigheten, Public Health Agency)

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