EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public Health, Cancer and Health Security
Disease Prevention and Health Promotion

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

- SUMMARY RECORD –

Date: 22 November 2022
Location: Hybrid meeting (video-conference & physical meeting)

1. Welcome and introduction

The Chair welcomed the participants, reminded them about the basic rules as to participation in discussions in hybrid mode (on-site and via video-conference) and introduced the meeting's agenda as well as its indicative timing. The draft agenda was adopted as proposed.

SANTE presented the general statistics on traceability system including total number of economic operators, facilities and machines. Then, they informed the Subgroup on the progress of the project concerning the training of the competent authorities on the use of the secondary repository.

SANTE also informed the Subgroup about the total number of Member States that have signed the Joint Controllership Arrangement regarding the personal data processing operations taking place in the context of the EU tobacco traceability system, and urged those that have not signed the text yet, to proceed with the signature. Moreover, SANTE referred to the privacy statement concerning the same set of personal data processing operations and invited all Member States to share with the Subgroup the link to the ID Issuers' website where the privacy statement is published.

2. Communication from SANTE

2.1. Revision of Commission Implementing Regulation (EU) 2018/574

SANTE provided an overview of the procedural state and next steps in the revision of Commission Implementing Regulation (EU) 2018/574 and subsequently presented the latest changes to the draft amending Implementing Regulation that were introduced after the meeting of 29 June 2022. SANTE explained the rationale for each change and discussed the draft Implementing Regulation with the Member States.

2.2. Overview of data storage contracts

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.

2.3. Presentation by Sopra Steria of the Final Report of the Expert Study

Sopra Steria presented the final report regarding the development and configuration of automatic alerts to be generated by the repositories system of the EU system of tobacco traceability. Sopra Steria summarised the overview of the completed tasks, outcomes and main challenges and suggested next steps and recommendations for the future. Member States were informed that the final report will be provided to them soon.

3. Q&As/Discussion of the Member States' questions

3.1. Extension of the traceability system's scope to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024

At the outset, SANTE recalled that from 20 May 2024, the scope of the traceability rules will cover all tobacco products. Manufactures and importers will have to notify to the Commission, by 31 December 2022, the identity of their proposed provider and a draft data storage contract.

One Member State asked whether ID issuers are obliged to issue the unique identifier codes for cigars and cigarillos before the deadline of May 2024 if they are requested by manufacturers or importers of these tobacco products. SANTE explained that the ID issuers do not have a legal obligation to issue the codes for cigars and cigarillos before the above-mentioned deadline since Articles 8(2) and 9(3) of Implementing Regulation (EU) 2018/574 need to be interpreted in the light of the higher-ranking norm in Article 15(13) of Directive 2014/40/EU, which provides that paragraphs 1 to 10 of Article 15 only apply to tobacco products other than cigarettes and roll-your-own tobacco as of 20 May 2024. However, SANTE explained that it welcomes the issuing of real UI codes to manufacturers of cigars and cigarillos before the deadline of May 2024 so that they can already prepare for the period after 20 May 2024 when cigars and cigarillos will have to bear an UI code.

In response to a question on the rules concerning the import of hand-made cigars and cigarillos, SANTE explained that if the hand-made cigars and cigarillos are imported into the EU after 20 May 2024, they will need to be marked, at the level of the unit packet, by means of unit level UIs. Regarding the reporting of the movements of these products, SANTE clarified that all the rules of the Implementing Regulation are applicable to importers. The fact that the cigars or cigarillos are fully hand-made makes no difference to the applicability of the rules. The only change is that in the request for unit level UIs the importers need to indicate the products' hand-made character.

SANTE recalled that situation is different with cigars and cigarillos that are imported into the EU before 20 May 2024 and not marked by means of unit level UIs. In this case, the products can remain in free circulation until 20 May 2026 and the importers' reporting obligations are not applicable.

Regarding imported products transported in bulk, before being packaged into unit packets, the UIs need to be applied at the latest just before importation for products already in unit packets or at the moment of product finalisation, when products are being packaged into unit packets, which may actually take place after importation, on the Union territory.

One Member State asked when and how the unique identifier (UI) and the security element should be applied on single stick cigars. SANTE referred to Article 6 of Implementing Regulation (EU) 2018/574 and explained that it is the responsibility of the manufacturer (for products manufactured in the EU) to mark these products with unit level UIs. The marking should take place in the manufacturing facility and be directly followed by the verification of those unit level UIs, as explained in Article 7 of the Implementing Regulation. Regarding the security features, economic operators may choose to apply them at a later stage in the supply chain, as long as the application takes place before the product are placed on the market.

For products manufactured outside the EU, SANTE referred to Article 6(2) of the Implementing Regulation which specifies that the unique identifiers are to be applied on the unit packet before the tobacco product is imported into the Union without specifying the exact time or place of the marking procedure. This means that the marking can either take place when the product reaches the customs warehouse or before that moment (e.g. in the manufacturing facility). Verification must be made of the unit level UIs, as explained in Article 7 of the Implementing Regulation.

For products like cigars, where the production process can be a multistage one and even take place in more than one location, the unit level UI should determine as location and time of manufacturing the product process's stage when the unit packet of the tobacco product was created. SANTE stressed that in any case, for tobacco products manufactured outside of the Union and destined to be placed on the Union market, the obligation to mark each unit packet with unit level UIs falls solely on the importer.

Regarding how the unit level UI and security feature should be applied on the unit packet, SANTE referred to the requirements of Article 15(1) and Article 16(1) of Directive 2014/40/EU, which should be respected.

3.2. One FID – One specific location for the facility

The Subgroup discussed the case of facilities' relocation in the context of the ongoing exchange of information between SANTE and specific Member States regarding the change in the location of certain facilities at two different moments.

SANTE recalled that in case an economic operator moves to a new location, the facility identifier code that is linked to the 'old' location needs to be withdrawn and a new F_ID needs to be requested for the new facility associated with the new location (regardless of whether products are moved from one facility to another).

A Member State asked about the possibility to introduce modifications of the information submitted in the initial application form via message 1.5 of Implementing Regulation (EU) 2018/574. It was discussed that the use of message 1.5 should be limited to rare occasions where an address may change with respect to the same location, e.g. with renaming of a street or a rearrangement of postal codes and their boundaries. Message 1.5 should cover such rare occasions as well as correcting clerical (encoding) errors.

Another Member State asked about the obligation of the retailers in terms of registering their facilities. SANTE replied that according to 16(3) of the Implementing Regulation, the registration is an obligation of the operator of the first retail outlet, even though they do not participate in the reporting on the movements of the products. It was further clarified that in the scenario of product movements from the first to the second retail outlet, in this particular instance, the movement does not need to be reported to the tobacco traceability system.

3.3. Reporting and downloading additional data from the system such as geographical, health and population data

SANTE explained that the data that can be reported to the tobacco traceability system are strictly defined in Implementing Regulation 2018/574. Therefore, under the current rules, there is no such possibility for reporting or downloading additional data.

3.4. Other questions

One Member State inquired about the importer's obligation to contract a primary repository and request the UIs from the ID Issuer of the respective MS where the products are placed on the market. SANTE replied that according to Articles 6(1), 9(1) and 26(1) of Implementing Regulation, the importer has the obligation to establish a primary repository by contracting the primary repository provider and to request and mark the imported tobacco products with UIs. SANTE added that the "importer" is defined in Article 2(39) of Directive 2014/40/EU as "the owner of, or a person having the right of disposal over tobacco or related products that have been brought into the territory of the Union. "Import of tobacco or related products" is also defined in Article 2(38) of the Directive as the entry into the territory of the Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement. This means that products that are placed under a customs suspensive procedure have not entered yet the territory of the Union and as a result, are not considered imported. Therefore, the importer with all

the track and trace obligations is the person who owns the products once they have been released from the customs suspensive procedure.

The same Member State asked about the practice of selling individual cigars and cigarillos from an open box. SANTE explained that in this case, the unit packet, namely the smallest individual packaging of the tobacco products that is placed on the market and sold to the consumers is the individual cigar. As a result, the individual cigar needs to comply with all the necessary requirements of Directive 2014/40/EU and the Implementing Regulation, including the obligation to be marked with a unique identifier. The practice of selling unmarked individual cigars and cigarillos without unit level UIs from an open box is not in line with Directive 2014/40/EU and the Implementing Regulation.

The same Member State also asked for clarification regarding the costs associated with the establishment of a primary repository. SANTE clarified that the Commission is not involved in the determination of the relevant costs which is a contractual issue that needs to be agreed among the private parties (primary repository providers and tobacco manufacturers/importers). SANTE referred to Article 30(1) of the Implementing Regulation, according to which the costs related to the repositories system need to be fair, reasonable and proportionate.

Another Member State inquired about the identifier codes that have already been transmitted to the economic operators in case a new ID Issuer is appointed. SANTE replied that two ID Issuers cannot co-exist at the same time. Each Member State should have only one entity responsible for generating and issuing UIs according to Article 3(1) of the Implementing Regulation. One ID Issuer should be responsible for generating and issuing UIs for products placed on the market until the end of its contract. Finally, SANTE added that the current operator of the secondary repository is finalising a technical document specifying certain technical aspects of the transfer process.

3. AOB & Closing remarks

The Subgroup discussed the reimbursement of equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled and in particular, whether Article 15(7) of Directive 2014/40/EU should be read as a one-time obligation or rather a continuous obligation. SANTE referred to the Subgroup's previous discussions on this issue according to which a one-time payment to economic operators would not be compliant with the obligations set out in Article 15(7).

The Chair thanked the participants for their active contribution to the meeting and looked forward to the next Subgroup's meeting, the date of which will be specified in due course.

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	(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	(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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