EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Cross-border healthcare and tobacco control

MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES

~ SUMMARY RECORD ~

Date: 10 December 2018

Place: CCAB room 5B, Brussels

1. Welcome and Introduction

SANTE welcomed all participants to the last Subgroup Meeting on Traceability and Security Features of the year. The minutes of the previous Subgroup had been approved by participants and were uploaded to the DG SANTE webpage. The Chair provided an update concerning past and future meetings. The group was reminded that in February and April of 2019 two Meetings of the Subgroup would be organised at which providers of relevant services (ID issuer, primary and secondary repository) were going to be invited to participate.

The agenda of the day was presented, underlining the fact that several questions and points for discussion had been submitted to SANTE. The Chair thanked for the transmitted questions and promised to address as many as possible under the relevant agenda points.

Austria briefed the group about a considerable national success in the fight against illicit trade. Approximately 32 tons of illegal raw tobacco were seized by customs authorities, which translated into about €7.2 million worth of cigarettes and an estimated €5.6 million in potentially lost taxes.

The group approved the agenda. No additional points were added.

2. Update from the Commission

Transposition of Articles 15 and 16 of Directive 2014/40/EU

Following a question of a Member State, SANTE clarified that there was an obligation to transpose Articles 15 and 16 of Directive 2014/40/EU into national laws. Adoption of the implementing and delegated acts on tobacco traceability and security features did not relieve a Member State from that obligation. This was in any case essential, because Articles 15 and 16 contained certain obligations that are not laid down in the implementing and delegated acts (e.g. provision of scanning equipment).

Stakeholder manual

Translations of the stakeholder manual into all EU languages were uploaded to the SANTE website. Member States were invited to share this information with all relevant stakeholders and/or provide a link to the manual on their national websites.

Update on the appointment of the provider of the secondary repository

The group was informed that the Commission was in the process of finalising the appointment of the provider of the secondary repository, the selection of which took place in the framework of a public procurement procedure among the approved providers of primary repositories. The selection was based on the best offer received. The award went to Dentsu Aegis Network Switzerland AG for a period of five years. The appointment would become final after signing a contract with Dentsu, which was expected to take place on 21 December following the expiration of the applicable standstill period. Information on the appointment would be published on the SANTE website.

SANTE will stay in close contact with the appointed provider over the comings months to monitor the implementation process, including a visit to the data storage facilities. The appointed provider would also be invited to participate in Meetings of the Subgroup in February and April.

Anti-tampering device

No objections or requests for revision were received from Member States on the proposed template of the declaration form for providers of anti-tampering devices. The template declaration form therefore was considered approved and would now be sent for translation into all EU languages, as requested during the last meeting. Once translated, the form would be shared with Member States and should be uploaded both to the website of SANTE and websites of individual Member States.

To avoid irregularities, the group agreed that it should be clarified to manufacturers and importers, as well as service providers, that the declaration form should be used in all cases.

External auditors

SANTE recalled that Directive 2014/40/EU requires that all repositories shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. No further requirements based on which such approval

should be granted were set out in the legislation. A discussion on this subject matter took place with relevant Commission services. Following this, it was currently envisaged that the most suitable approach could be for the Commission to lay down guidelines on requirements for external auditors, which must be met in order to receive approval from the Commission. There was an intention to adopt the guidelines in the second half of 2019. Member States would be updated on this matter in the course of 2019.

3. Discussion

ID issuer

Two Member States gave a presentation in relation to the ID issuer. First, a representative from the Netherlands presented their selection process to appoint a third party as the ID issuer. Then, a representative from the German Federal Printing House (Bundesdruckerei) gave a presentation with a particular focus on the development of the unique identifier.

General scope of Directive 2014/40/EU

The group discussed the scope of Directive 2014/40/EU with respect to tobacco traceability and other customs rules. SANTE recalled that Directive 2014/40/EU applied to the entire territory of the Union, which meant that its geographic scope was wider than this of the Customs Union. All tobacco products that are manufactured on Union territory would fall into the scope of Directive 2014/40/EU and therefore be subject to the rules on tobacco traceability, including cases of export products, even where those products travelled under EMCS. For tobacco products imported to the Union, those products would be subject to the rules of the directive as of the moment that they entered the territory of the Union. Products manufactured in third countries and placed under a customs suspensive procedure (‘special procedure’) upon their entry into Union territory would however only be considered imported into the Union once they were released from the suspensive procedure (‘release for free circulation’). SANTE clarified that the rules on import of products in Directive 2014/40/EU should be read in conjunction with the provisions of the Union Customs Code, especially its Articles 201 and 210.

A number of Member States inquired into the applicability of Directive 2014/40/EU to special territories of the European Union, in particular whether those with special customs and/or VAT status would be subject to tobacco traceability and security features. In light of time constraints, the Chair suggested to discuss this matter more in detail during the next Meeting of the Subgroup.

Territorial requirements for security features

Portugal introduced a table outlining different scenarios of product sales, notably sales in duty free shops, ship shops and on airplanes. The group shortly discussed these scenarios and whether products would be required to carry a security features.

On duty free shops earlier discussions were recalled and the group agreed that for sales in duty free shops located on Union territory the rules on security features applied. With respect to sales on ships and airplanes, some Member States pointed out that for these types of sales circumstances differed and that it was not always clear whether a security feature would be necessary. SANTE recalled that, according to the applicable legislation, a tobacco product was required to carry a security feature whenever it was made available to a consumer located on Union territory. Whether or not the rules on security features applied therefore depended on the geographic location of consumers at the time a tobacco product was made available to them (e.g. vessel is / is not located in EU waters, airplane is / is not located in EU airspace). One Member State noted that the tabled general scenarios were currently still under internal scrutiny in its ministries, in order to better understand the factual and legal questions that were arising.

Postal services

Austria reported that certain logistic companies, in particular postal services and other type of transport companies, had raised concerns about the implementation of the traceability system. The Austrian representative was therefore wondering whether the Commission and other Member States were aware of these concerns.

SANTE replied that over the past year it had received some general questions as to the applicability of the rules on tobacco traceability to transport companies. Discussions on this had also taken place in previous Meetings of the Subgroup and the group had agreed that these companies would be subject to reporting obligations, however, only if they were involved in transloading activities while handling tobacco products.

4. Q&A

The group discussed the questions submitted by Member States in advance of the meeting, as well as additional questions posed during this agenda point.

In response to a previous request of a Member State, SANTE proposed a more detailed reading of the term ‘machine’ as used in the legislation on tobacco traceability:

“In line with Article 2(11) of the Implementing Regulation, ‘machine’ means the equipment used for the manufacture of tobacco products which is integral to the manufacturing process. In case a given production line is composed of two or more individual pieces of equipment of which some are moveable and adaptable to other production processes, the machine for which the registration is required pursuant to

Article 18 of the Implementing Regulation should be the one responsible for the core manufacturing process, e.g. the cigarette maker for production of cigarettes."

While all participants agreed that it was preferable to agree on a common understanding of which machine in the production line qualified as 'machine' within the meaning of the legislation and therefore had to be registered in the system, two different views existed as to the type of machine that should be registered. One group of Member States supported the reading proposed by SANTE that a machine identifier code should be requested for the machine responsible for the core manufacturing process (e.g. cigarette maker), because it is the actual product that is tracked and traced. The other group of Member States proposed that machine identifier codes should be requested for the machine in the production line that is used for the packaging process, because tracking and tracing is facilitated through the unique identifier and the latter is applied to the package. The Chair thanked for the input and suggested to come back to this discussion in the next meeting.

On whether all communication from the ID issuer to the secondary repository needed to be in real-time: SANTE noted that, in principle, real-time transfer of data from the ID issuer to the repositories system was necessary in order to ensure, among others, real-time validation of data. Information on time limits applicable to the data transfer were laid down in the different provisions. For example, unique identifiers and identifier codes must be issued and sent electronically within two days. Before they are delivered to the requesting party, unique identifiers / identifier codes need to be transmitted via the router to the relevant repository.

The Commission had been asked to provide clarification about the applicability of rules on traceability and security features in the case of cross-border distance sales. For tobacco traceability, the last recording and transmission event is the dispatch of a product to the first retail outlet, that is the facility where the tobacco product is made available. In the case of cross-border distance sales, this was the dispatch to the shop which would send the product in question to the consumer. For security features, SANTE reminded of Art. 2(40) of Directive 2014/40/EU, which read that "… in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located". As such, the group agreed that the location of the consumer would determine the type of security feature that was required on the product. Some Member States noted concerns with respect to the limited reach of tracking and tracing with regard to the dispatch of products from a shop to consumers. SANTE acknowledged this concern but explained that the scope of the Directive did not allow going further than the first retail outlet. However, the Directive also allowed Member States to prohibit cross-border distance sales.

On whether, following the delivery of tobacco products to multiple vending vans, the remaining stock in the vehicle had to be reported: SANTE answered that the stock that remains after finishing the delivery tour should be recorded in the traceability system by means of an arrival message declared as 'Product_Return'.

One Member State posted a follow-up question related to deliveries that are made for the purpose of supplying both vending machines and point of sales without previous sales order. It was clarified that, in such a case, two different activities existed and therefore two different messages would have to be recorded in the system. First, dispatch to multiple vending machines and second, dispatch to multiple retail outlets via a vending van.

Another Member State asked how facilities should be registered that run different operations within the tobacco trade business (e.g. wholesaler and first retail outlet). It

was proposed to declare such a facility as 'other' and to provide further explanation in the description field.

Finally, a question was raised whether reporting obligations existed in cases of product sales where no order existed. SANTE replied that if no order was legally required and also not issued by the vendor, no recording of order information was expected.

5. Update from Member States

Appointment and operation of ID issuer

SANTE stressed once more the importance of ensuring that each Member State appoints its ID issuer and facilitates its operability as soon as possible. This was not only important for the overall functioning of the traceability system. Readiness of the ID issuer before 20 May 2019 was particularly crucial for economic operators, which had consistently stressed that full testing of the system would only be possible upon full availability of ID issuers. With respect to the latter point, SANTE noted that it believed that testing of the system by economic operators would not have to wait until every ID issuer was available, but that, to a large extent, an adequate testing phase could already be facilitated from the moment when a number of ID issuers were operational.

Tour de table with Member States

During the update round, Member States reported their national progress on the following points:

- ID issuer appointment;
- Use of the derogation in Article 4(1) of the Implementing Regulation;
- Provision of physical delivery in addition to electronic delivery, including the intention to merge UI and fiscal mark;
- Appointment of one or more National Administrator(s);
- Design of permitted security feature, including its communication to manufacturers/importers.

A number of Member States reported good progress on the appointment of their ID issuer, either being in the final phases of the selection process of having already selected the operating entity. While multiple Member States would opt for appointing a state entity as their ID issuer, other Member States had decided to select a third party subject to a public procurement procedure. No ID issuer was completely operational at this point in time, but some indicated that they would likely be able to assume full readiness in the first quarter of 2019. A few Member States also noted difficulties in obtaining the unique identification code (UIC) in accordance with ISO 15459-2. On the last point, SANTE reassured its willingness to continue supporting Member States in the appointment process. In the end, however, the appointment of ID issuers and their readiness for operation was a legal obligation to be ensured by each Member State. This also meant

that the Commission was not in a position to ask for an UIC on behalf of an ID issuer. In order to be able to assist as best as possible, SANTE asked Member States concerned to send detailed descriptions of the particular problems that they faced.

The majority of Member States indicated that they would opt for the derogation in Article 4(1) of the Implementing Regulation. Several Member States also decided to ask their ID issuers to make available physical delivery in addition to electronic delivery.

Most Member States by now had gained clarity on their competent authority/ies for tobacco traceability and security features, as well as the National Administrator, but often official allocation at Ministry level would still be necessary.

Finally, some outstanding updates were received from a few Member States regarding the design of permitted security features.

6. AOB

No additional points discussed.

7. Closing remarks

The Chair thanked participants for their input. Questions that could not be addressed due to time constraints were to be taken up in the next meeting in January. As always, participants were encouraged to refer stakeholders to the minutes, in particular the discussions and answers that were recorded therein.

The Chair closed the meeting.

Annex I

List of participants

Austria	(Federal Ministry of Labour, Social Affairs, Health and Consumer Protection; Federal Ministry of Finance)
Belgium	(FPS Finances, FPS Health, Food Chain Safety and Environment)
Croatia	(Customs Administration of the Republic of Croatia)
Cyprus	(Department of Customs and Excise, Republic of Cyprus)
Czech Republic	(Ministry of Agriculture of the Czech Republic)
Denmark	(Ministry of Health; The Danish Safety Technology Authority, The Danish Ministry of Taxation)
Estonia	(Estonian Tax and Customs Board)
Finland	(Ministry of Social and Health/ Finnish Customs)
France	(Direction Générale des Douanes)
Germany	(Federal Ministry of Food and Agriculture)
Greece	(Independent Authority for Public Revenues)
Hungary	(Ministry of Finance; National Tax and Customs Administration)
Ireland	(Department of Health; Office of the Revenue Commissioners)
Italy	(Custom monopolies agency; Ministry of Health)
Latvia	(The State Revenue Service of the Republic of Latvia)
Lithuania	(State Tax Inspectorate Under the Ministry of Finance of the Republic of Lithuania)
Luxembourg	(Customs and Excise Administration; Direction de la Santé)
Malta	(Customs Department)
Netherlands	(Permanent Representation of the Netherlands)
Poland	(Ministry of Finance)
Portugal	(Autoridade Tributária e Aduaneira; Imprensa Nacional Casa da Moeda)
Romania	(CN Imprimeria Nationala SA; National Customs Agency)
Slovakia	(Permanent Representation of Slovak Republic to the EU; Ministry of Finance, Financial Directorate)
Slovenia	(Financial administration of the Republic of Slovenia; Ministry of Health of the Republic of Slovenia)
Spain	(Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas; Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas; Fábrica Nacional de Moneda y Timbre)
Sweden	(Public Health Agency of Sweden)
United Kingdom	(H M Revenue&Customs)

Observers

Norway	(Norwegian Ministry of Health and Care Services)

Commission:

DG SANTE	Filip Borkowski
	Jan Hoffmann
	Sascha Lowenstein
	Anna Mirandola
DG OLAF	Clare Twomey