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: 23 October 2018**

**Place: CCAB, Brussels**

## 1. Welcome and Introduction

SANTE welcomed all participants to the second to last Subgroup Meeting on Traceability and Security Features of the year. The minutes of the last Subgroup were approved by participants and uploaded to the DG SANTE webpage. The Chair provided an update concerning past and future meetings. There was an intention to organise in the first half of 2019 additional meetings to which providers of relevant services (ID issuer, primary and secondary repository) were going to be invited together with the authorities.

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

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

## 2. Update from the Commission

*2.1 Report from CoP and MoP*

SANTE reported on the 8th session of the Conference of the Parties (COP8) to the Framework Convention on Tobacco Control (FCTC) and the 1st Meeting of the Parties (MOP1) to the FCTC Protocol on Illicit Trade. During COP8, the EU delegation was able to clarify an issue of potential conflicts in the regulations concerning packaging and tobacco traceability. Decision FCTC/COP8(15) calls upon all Parties to the FCTC: *"to ensure, as appropriate, the coherent implementation of the provisions of the Convention and the Protocol, taking care in particular that the rules on packaging and labelling are applied in a manner compatible with the provisions on product traceability"*. As to MOP1, it marked as an important step in fighting illicit trade at the global level. All EU proposals on substantive and budgetary matters were adopted at MOP1, with only minor modifications, including the establishment of two working groups on cooperation and assistance as well as tracking and tracing.

*2.2 Contacts with third countries*

SANTE reported on several contacts with third countries concerning tobacco traceability, including Australia, Canada and Russia. It was explained that, according to the latest exchanges, the Australian authorities were looking into the existing rules on plain packaging with an objective of adapting them ahead of the launch of the EU system of tobacco traceability on 20 May 2019. SANTE will continue to update Member States on this topic during next Subgroups.

*2.3 Primary and secondary repository*

SANTE updated Member States on the current state of the approval process for providers of primary repository. It was indicated that the Commission received 31 notifications within the first notification period following the entry into force of Implementing Regulation 2018/574.

Manufacturers/importers were advised (via our webpage) to send one notification per group of undertakings to avoid multiple notifications. It was actually the case that the operators followed the advice given by SANTE. Given the state of the notifications, SANTE was able to finalise and adopt 31 positive Commission Decisions. The assessment regarding the suitability of the third party provider was based on the written declarations, the draft contract as well as on other information available to the Commission at the time of the examination.

Member States were also informed that a list of the first eight notified and approved providers was published on the SANTE website on 10 October 2018.

The process will have to be continued considering the different deadlines for manufacturers/importers of products other than cigarettes and roll your own as well as potential new entrants.

The appointment process for the provider of the secondary repository was also discussed. Member States were informed about the intention of DG SANTE to adopt a concession of service as the procedure to appoint the provider for the secondary repository as well as the potential timeframe period to do so (i.e. 6 November – 6 January 2019). They were also informed that on 24 October 2018, an information session with all the approved providers of the primary repositories would take place.

*2.4 Other updates*

SANTE updated Member States regarding both the adoption of the linguistic corrigendum, which was uploaded to the SANTE website (see: https://ec.europa.eu/health/tobacco/tracking_tracing_system_en), and the translation of stakeholders Manuals, which was promised to be soon available.

**Discussion**

*3.1 ID issuer appointment (issuing agency code)*

SANTE recalled the discussions during the last Subgroup meeting in which it had outlined three relevant prefix (issuing agency code) allocation scenarios. Participants were reminded that the prefix of each ID issuer had to be allocated in accordance with the requirements of ISO 15459-2. Applications for an issuing agency code had to be addressed to the responsible Registration Authority, that is, Advancing Identification Matters (AIM). SANTE stressed that due regard should be given to the eligibility requirements of ISO 15459-2 that any potential ID issuer had to meet in order to be allocated a prefix. These could also be found on the AIM website.

*3.2 Unique identifier*

The group discussed the importance of coordinating an alignment of the length of unique identifiers (UIs) that were generated by different ID issuers. Participants agreed that the length of UIs was a very important criterion in the selection of the ID issuer and/or, where applicable, subcontractors. In this context, SANTE stressed that attempts to shorten the UI as much as possible should not undermine other applicable requirements (including a sufficiently negligible probability to be guessed, and independence from the tobacco industry). As well as the general consensus of earlier discussions that, as much as possible, all Member States should aim to implement a solution that was based on existing and commonly used international standards.

Participants had also submitted questions asking for clarification of the meaning of Article 8(4) of the Implementing Regulation. SANTE explained that the provision in question asked ID issuers to inform Member States and the Commission of algorithms used for the encryption and/or compression of unit level UIs. These algorithms and compression techniques formed an integral part in securing the integrity of UIs and it was therefore crucial that authorities would take all steps necessary to protect them from access by unauthorised third parties.

*3.3 Secondary repository*

Participants discussed the expected level of contribution from Member States in the development of the secondary repository, notably the user interface of the reporting tool. SANTE noted that Member States were the main client of the reporting tool. Therefore, their input was crucial, in particular with respect to the development and potential testing of the graphical user interface by the provider of the secondary repository, once appointed.

One participant asked whether special hardware were needed for authorities to access the user interfaces. SANTE answered that a computer with network access would normally be sufficient. It also recalled that the modes of accessing the graphical user management

interface had to be compatible with the building blocks of the Connecting Europe Facility (e.g. e-delivery).

The group also discussed whether certain contractual arrangements (e.g. SLA) would be desirable to ensure that access rights to the traceability data were further structured and operationalised. A follow-up on this point would take place in the next Subgroup meeting.

*3.4 Anti tampering device*

SANTE presented to Member States a draft written declaration form that should be used by providers of anti-tampering devices to declare their legal and financial independence from the tobacco industry. The draft form was based on the written declarations on technical expertise and independence, which were used by the Commission in the context of assessing proposed providers of primary repositories. Participants were asked to review the proposed form and provide feedback. If common agreement existed, the form would be made available on the websites of the Commission and of individual Member States.

On individual responsibilities of economic operators, the group noted that Article 7(1) of the Implementing Regulation required manufacturers/importers to ensure the verification process of unit level UIs. Given that the anti-tampering device formed an integral part of the verification process, it would follow that manufacturers/importers were responsible for ensuring that such a device was supplied to them and installed on site.

The group furthermore agreed that, in practice, it could make sense to allow that the required written declarations were submitted to the relevant authorities via the manufacturer/importer of the facility at which the device in question had been installed.

Finally the group discussed that it would be sensible for the competent authorities to ask for the records created with the anti-tampering devices installed on non-EU production lines relatively early on after 20 May 2019, in order to verify their proper functioning and the correct structure of the records.

*3.5 Payment of scanning devices*

The group discussed the obligation of manufacturers to provide all economic operators involved in the trade of tobacco products with the equipment necessary for the recording of products. Questions were raised in particular as to the scope of this requirement and whether it only extended to scanning equipment. SANTE pointed to the last sentence of Article 15(7) of Directive 2014/40/EU, which stated “that equipment shall be able to read and transmit the recorded data electronically to a data storage facility…”. It also recalled that the transmission of transactional information could be expected to take place separately and not in the process of scanning of UIs. In light of this, the group considered

it reasonable to assume that economic operators had to be provided with more technical equipment than merely scanning devices, in order to record and transmit all relevant data.

*3.6 Enforcement activities*

Participants concurred on the need to have a separate discussion on individual enforcement aspects related to the legislation on tobacco traceability and security features. A time slot during one of the upcoming Subgroup meetings therefore should be dedicated to this point. In light of this proposal, SANTE stressed that such discussions had to be driven by input from Member States who were responsible for the application and enforcement of the legal framework.

## 3. Q&A

The group discussed the questions submitted by Member States in advance of the meeting, as well as additional questions posed in-between.

On identifier codes, several questions were addressed in relation to the request of codes by economic operators to the competent ID issuers. SANTE recalled the rules set out in Chapter III of the Implementing Regulation.

On the pricing of UI, SANTE referred back to its previous presentation on the calculations in the Implementation Study and the Impact Assessment, which to a large extent relied on the values established in the survey carried out during the Feasibility Study. Fees may also differ dependent on the delivery method chosen, whereas it was reasonable to assume that fees for physical delivery could be slightly higher. Information from the generation and delivery of national tax stamps could be useful as a reference point in this respect.

The group then discussed to what extent UI fees may cover other services related to the UI. It was agreed that also services related to the development of the UI could be recouped through the fees per UI. The same would be true for the generation and issuing of identifier codes, i.e. the costs related to identifier codes could also be included in UI fees.

One participant furthermore asked for an overview of potential relevant criteria that should be used by Member States in the selection of an ID issuer. SANTE replied that all provisions in the Implementing Regulation that referred or related to the ID issuer should be considered (e.g. those relating to ID issuer competence, prefix code, UI structure, request and issuing rules, independence, etc.). In addition, certain other aspects would also be relevant as they had a direct impact on industry operations, notably the length of UIs, estimated fees and the use of commonly used and recognised standards.

On the applicability of the independence requirements to ID issuers, it was clarified that these would also extend to the development of the UI by the ID issuer and any involved subcontractors. It was stressed that independence of the UI development from industry was essential for the overall integrity of the traceability system.

Then a number of points were raised in relation to enforcement. It was acknowledged that Article 15 of Directive 2014/40/EU had a clear cross-border dimension, which relied on the willingness of Member States to act upon the concept of sincere cooperation, in order to ensure effective application and enforcement of the directive across the Union.

On competence of ID issuers, it was confirmed that the derogation in Article 4(1) only applied to unit level UIs.

On the requirements for security features in the context of duty free sales, SANTE recalled the discussion during the last Subgroup meeting. The reference point in the directive was the 'placing on the market' of products, which was the place and time at which a product was made available to consumers, with or without payment. Furthermore, SANTE stressed that the directive sets out the territorial applicability of Article 16 in terms of geographical scope, and that 'territory of the Union' was not to be confused with the concept of customs union. Therefore, duty free shops located in airports of Member States fell under the definition of 'first retail outlet' and tobacco products sold in these shops – regardless of their destination – had to carry a security feature. This equally applied to the sale in ship shops. Here, the group agreed that the determining factor was the geographic location of the vessel at the time when the tobacco product in question would be made available to consumers in the ship shop. With respect to the subject of tobacco product sales on airplanes and the requirement for products to carry a security features, the group decided to have a follow-up discussion during the next meeting in December

On the definition of manufacturer, SANTE recalled the discussions that took place during the last Subgroup meeting and reminded that an entity qualified as manufacturer within the meaning of the directive not only if it manufactured tobacco products, but also if it had products manufactured for it by another entity and marketed those products under its own trademark. While slightly different rules might apply to different types of manufactures dependent on where they were located in the supply chain, in practical terms, it was important that no double recording of logistic and transactional events occurred. In the case of subcontracted manufacturing (i.e. where an entity has products manufactured for it by another entity), SANTE furthermore advised that the entities concerned come to an agreement as to how they will jointly discharge all reporting obligations, including the transmission of relevant data (product movements and transactional data) to the primary repository.

On the reading of Article 22 of the Implementing Regulation regarding the quality of data carrier, the question was raised whether the referenced ISO standards demonstrated minimum standards. SANTE answered that the reference point was the high readability of permitted optical data carriers that economic operators must ensure. This basic requirement was primarily introduced in order to help all economic operators in meeting their obligation to report all movements of tobacco products without unnecessary disruptions caused by problems in reading data carriers during their successive scans. In the case of compliance with ISO 15415 (for printed 1D barcodes), or 15416 (for printed 2D barcodes), at a minimum rate of 3.5, a presumption of conformity existed. This did not mean, however, that these ISO standards had to be interpreted as a baseline requirement. Other standards might also be useful as a reference point for high readability, especially in the case of direct marked barcodes that were often used on high-speed production lines. Here the relevant reference point was rather ISO 29158.

Finally, the group discussed scanning activities in the case of physical delivery of the UI. It was noted that, depending on the scanning technology used and the way the time stamp was applied next to the UI, economic operators might be required to do two scanning

operations (UI and time stamp separately) in order to transmit the full set of required information on the product movement.

## 4. Update from Member States

SANTE recalled that there was a legal obligation for Member States to appoint ID issuers by 6 May 2019. It was stressed that this entailed not only the establishment of an entity but also its readiness to generate and issue identifier codes and UIs to economic operators. Problems with the appointment of the ID issuer would amount to non-compliance with Union law, which could carry legal consequences, including an infringement procedure against a Member State that fails to implement EU law. Absence of an ID issuer also automatically meant the exclusion of a national market and its economic operators from the traceability regime. In light of this, Member States were invited to provide clear status updates during each Subgroup meeting on the ID issuer appointment and other relevant obligations.

Updates were provided 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.

Good progress on the above issues were indicated across the majority of Member States. Several Member States indicated that a public authority (e.g. a state/national printing house) would be appointed as the ID issuer. Among those who would not opt for a public authority, a number of Member States were close to launching the selection procedure or were already in the middle of it. A number of Member States also clarified that they intended to offer physical delivery in addition to electronic delivery. Of those Member States who have a fiscal mark, several confirmed that they decided to use their tax stamps as the security feature, while others noted that they had opted for an alternative version of the security feature. Some Member States also specified that they would use a non-fiscal tax stamp for products sold in duty free shops.

## 5. AOB

No additional points discussed.

## 6. 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 December. As always,

participants were encouraged to refer stakeholders to the minutes, in particular the discussions and answers that were recorded therein. Finally, it was proposed that as of the next Subgroup meeting, national progress on the UI development could be shared with the group by means of individual Member State presentations. SANTE would follow-up on this with participants individually.

The Chair closed the meeting.

**Annex I**

**List of participants**

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|---|---|
| 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) |
| 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 |
| | Thea Emmerling |
| | Jan Hoffmann |
| | Anna Mirandola |