



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 March 2020
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 the Commission

2.1. Business continuity in view of COVID-19

2.1.1. Timeline concerning the full IT validation of reported data

SANTE referred to recent emails received from several Member States and economic operators asking for an extension of the so-called “grace period”, i.e. the last stage of the technical roll-out aimed at activating the full IT validation of traceability data by the repositories system, incl. the router, in view of the COVID outbreak.

SANTE recalled its general considerations already communicated to Member States by email. In addition, it was emphasised that the validation rules in question, which reflect the rules on reporting traceability events established with Implementing Regulation 2018/574, will only apply to the products marked with unit-level / aggregated UIs generated from 1 April 2020. SANTE also announced that Dentsu had confirmed to the Commission that it had itself fully implemented the latest technical specifications since 1 March 2020.

A majority of Member States expressed doubts as to the tobacco sector's readiness and favoured an extended timeline for the rollout of the latest specifications. A few Member States argued

against a potential prolongation of the grace period and asked SANTE to support the existing timeline.

The Chair agreed to collect further views on this topic via a follow-up email to the Subgroup.

2.2.2. Temporary absence of the competent ID issuer

SANTE reported on an earlier discussion with one Member State that had asked whether COVID outbreak would trigger the application of Article 4(5) of Implementing Regulation 2018/574. In this context, SANTE explained that it was not evident why the ID issuers would be particularly affected by the COVID-19 outbreak taking into account that all the ID issuers deliver unit packet UIs as well as all other codes by electronic means. In addition, SANTE referred to the obligation under Article 3(8) of the Implementing Regulation requiring Member States to put in place adequate measures to ensure the continuous operation of the ID issuers' services.

2.2.3. Stock exhaustion period

SANTE referred to a request for postponing the deadline of 20 May 2020 established in Article 37(1) of the Implementing Regulation in view of the COVID outbreak. SANTE underlined that the Implementing Regulation does not empower the Commission itself to prolong the stock-exhaustion period. SANTE recalled that the stock exhaustion's objective was to allow economic operators for selling the pre-launch stocks, to potentially offer the continuity of supplies in the first post-launch months, but not to adopt a strategy of operating outside the traceability system for a full additional year till its last day.

2.2.4. Installation of anti-tampering devices

A Member State asked whether COVID-19 had an impact on the obligation of the tobacco companies, which handled less than 120 million unit level UIs during 2019, to install an anti-tampering device until 20 May 2020. The Chair recognised that the current situation might pose challenges with respect to the installation of the anti-tampering devices and recalled that the manufacturers have the possibility to ask the installation from a different company than the one that produced the device (as long as both providers involved met the independence requirements set out in Implementing Regulation (EU) 2018/574).

2.2. Implementation of version 1.4 of the technical specifications

SANTE recalled the timeline for the rollout of specification 1.4. It drew attention to the staggered approach starting with the roll out of primary and secondary repositories, and then distributors and service providers, continuing with the (sequence validation) grace period for all reporting economic operators and ending with the enforcement of the full validation for all the newly manufactured products.

It was added that Dentsu's statistics concerning support activities showed a certain but manageable increase in the number of requests (support tickets) made in January and February 2020 (those requests were also related to version 1.3 of the technical specifications effective as of January 2020).

2.3. Data quality: VAT checks and EOIDs

SANTE presented some first results of VAT checks, including the figures on EOs with no VAT numbers, EOs with VAT numbers, the total number of VAT numbers respecting the correct number structure and those having a wrong structure.

SANTE also referred to the economic operators' obligation to apply for one identifier code from the competent ID issuer (Article 14 of the Implementing Regulation) and presented information per Member State on the number of economic operators who, contrary to that obligation, seem to have obtained two or more identifier codes (per economic operator).

Lastly, SANTE described some spotted problems relating to the economic operator's name field, e.g. chain store operators (franchise takers) seem to introduce the name of their chain, instead of their own name.

2.4. Bulk downloads of data-status

SANTE reported on the on-going activities in this regard. Member States were requested to signal whether they envisage asking for bulk-downloads in the near future.

2.5. Weighted average fee for UIs

SANTE presented an overview of the fees per UIs adopted by the ID issuers, including the weighted and arithmetic means.

2.6. Statistics on traceability system

SANTE presented an overview of general statistics on generation and application of UIs, total numbers of economic operators, facilities and machines, etc.

2.7. Audit guidelines

SANTE clarified that the expected audit guidelines will take the form of a non-binding legal act. However, it was underlined that the document's systematic application should be considered essential to ensure the independence and transparency of the tobacco traceability system. It was also added that the auditors will be able to use the document as a guidance on the scope of the mandatory audit and on the submission procedure for annual audit reports to the competent authorities and to the Commission.

Regarding the state of play of the adoption process, SANTE informed that the internal consultations of the text were ongoing and would be finalised soon. The guidelines were expected to be published by the end of April 2020 (the beginning of May 2020 at the latest).

SANTE clarified that it had informed the concerned economic operators that proposed auditors will have to be notified to the Commission within 45 days from the publication of the guidelines document.

2.8. Inspection mobile application

SANTE informed the Subgroup that a draft agreement, which is expected to be signed between the Commission and Dentsu, is currently being finalised. The agreement aims to establish the basis for the cooperation between the Commission and Dentsu regarding the provision of a mobile inspection application. The agreement is expected to be signed by the end of April 2020.

SANTE highlighted that although Dentsu's offer of the mobile application is extendable to Member States, nothing prevents the Commission and Member States from developing and using – in parallel – their own mobile applications connecting at no additional costs to the secondary repository.

Once concluded, the agreement will be shared with Member States.

2.9. Declarations concerning anti-tampering devices under Article 7(2) of Commission Implementing Regulation 2018/574

SANTE recalled the obligation of an independent third party that supplies and installs an anti-tampering device at the manufacturers' premises, to provide a declaration to the relevant Member States and the Commission attesting that the installed device meets the requirements of Implementing Regulation 2018/574 (Art. 7(2)).

In this regard, it was pointed out that for several economic operators (not covered with the derogations of Art. 7(6) of the Implementing Regulation and therefore obliged to have installed the anti-tampering device) the obligatory declarations were missing. SANTE added that in one case, anti-tampering device certification documents were submitted instead of the expected declaration.

SANTE reminded Member States to take appropriate measures to ensure that economic operators and their suppliers fulfil their obligations resulting from Article 7 of the Implementing Regulation.

2.10. Data Protection: presentation of final assessment on data controllership

SANTE informed the Subgroup that the issue of data controllership in the T&T system was discussed with other Commission services and the Commission Data Protection Officer who is responsible to ensure the internal application of the EU Data Protection Regulation. It was concluded that Member States and the Commission are joint controllers for the personal data processing that takes place within the T&T system since they jointly determine the means of processing activities (i.e. the establishment and functioning of the primary and secondary repositories).

SANTE also indicated that the manufacturers/importers of tobacco products could not be considered data controllers since they have no access to the personal data stored in the repositories and as a result, they cannot effectively give a follow-up to the rights invoked by data subjects.

A Joint Controllorship Arrangement (to be developed by the Commission) is expected to be a legal instrument establishing the relationship between the different parties involved in the joint controllorship. In particular, the arrangement will detail the different levels of responsibilities between the Commission and Member States and specify which controller will be responsible for fulfilling which obligations under the GDPR and Regulation 2018/1725. SANTE pointed out that parts of this arrangement will have to be made available to the data subjects so that they are informed about the roles and responsibilities of the joint controllers.

Once the arrangement is finalised, SANTE will share it with Member States for their comments. SANTE clarified that there will be no exemption from liability for Member States that will choose not to sign the Joint Controllorship Arrangement since the GDPR will continue to apply irrespective of who will sign the arrangement.

2.11. Notification of national legislation implementing Directive 2014/40/EU

SANTE reminded the Subgroup about the importance of notifying the Commission, via the National Measures of Execution (MNE) system, of national legislation introduced to implement the Tobacco Products Directive.

2.12. Publication of the UI encoding structures

SANTE informed the Subgroup that a full overview of the coding structures of unique identifiers from all the ID issuers will be published soon. The Chair underlined the importance of this exercise in the context of development of inspection applications as well as providing for future interoperability with the global system to be developed under the FCTC Protocol on Illicit Trade.

3. Communication from Member States

3.1. Mobile apps developed at national level to access repository data

A Member State presented its mobile application being developed at the national level to access the traceability data. The functions and objectives of the application as well as its potential for further extensions were explained. SANTE thanked for the presentation and assured about its continuous support to Member States developing their own tools.

4. Q&As / Discussions

4.1. Third party reporting to T&T system

A Member State asked if third parties that are themselves also economic operators in the sense of the Implementing Regulation can report to the T&T system on behalf of other economic operators. SANTE replied that in principle, there is nothing in the legislation that would prevent a third party (operator A) from providing such a service and reporting into the system on behalf of another economic operator (operator B). However, in such a case, it is important that the identifications (i.e. EOID, FIDs and MIDs) of operator B are used for reporting purposes, since operator A acts as a mere service provider. Operator B also remains legally responsible for the correctness and completeness of reports.

4.2. Deactivation of “expired” UIs

A Member State enquired how non-applied UIs are deactivated after the elapse of six months from their receipt. SANTE clarified that this rule is implemented in the validation layer of the reporting system (point 8.2.4.4 in the technical specifications). This also implies that economic operators will receive an error message from the system if they attempt to report the application of an UI after six months from the date of its receipt.

4.3. Reporting obligations for retail outlets sending tobacco products to selected facilities, where tax inspector renews tax stamps that got out dated

A Member State asked if retail outlets sending the tobacco products that were already placed on the market to other facilities (including facilities that may carry out retail activities), for the purpose of tax-stamp renewal, are obliged to report to the T&T system. After the renewal of tax stamps, the products are to be returned to the original retail outlets. SANTE clarified that retail outlets are not required to report to the system. However, it was also noted that in this scenario, products are sent to a facility where those products are not intended to be placed on the market. The operator of that facility, where the tax-stamp renewal takes place, has to report to the system in line with the rules applying to all other facilities in the distribution chain. The situation in question is similar to the case of cash & carry operators; the fact that some retail operations take place under the same roof does not exempt a given facility and its operator from the reporting obligations as regards distribution activities.

4.4 Marking of double packages

A Member State asked how doubles packages of tobacco products should be marked. SANTE clarified that doubles packages are packages of two unit packets of tobacco products and as such, they fall within the scope of `aggregated packaging` as defined in Article 2(5) of the Implementing Regulation.

SANTE further added that the distinction between `a unit packet` and `an aggregation of unit packages`, as the two types of packaging in which tobacco products are placed on the market, was established in Article 2(29) of Directive 2014/40/EU. It was recalled that Article 15(5) of Directive 2014/40/EU provides for the possibility to mark and record at aggregated packaging level provided that the tracking and tracing of all unit packets remains possible, while Article 10(1) of the Implementing Regulation further specifies that economic operators shall mark aggregated packages containing tobacco products with an aggregated level unique identifier, where they choose to comply with their recording obligations provided for under Article 15(5) of Directive 2014/40/EU.

SANTE concluded that it is up to an economic operator to mark or not to mark such double packages with aggregated UIs. However, once marked, the aggregated UIs must be used in line with the Implementing Regulation, e.g. in certain situations they may constitute the highest level of available aggregation subject to reporting.

4.5. Reporting of products intended for destruction

A Member State asked how the national competent authorities should handle ‘legally marked’ tobacco products that were confiscated. SANTE pointed out that in terms of its logistic implications; the situation is analogous to the collection of products for the purpose of lab tests at the government-operated facilities, unless the confiscated products are supposed to be given back to an economic operator. Therefore, the same line as agreed by the Subgroup of 8 May 2019 was proposed: for dispatches to governmental locations, no recording obligations apply. Instead, if it is known that the confiscated products are not to be returned (e.g. will be destroyed), economic operators should send a request for deactivation of the products concerned to the traceability system, including a comment that the deactivation concerns products that have been handed over to a national authority. SANTE clarified that in the specific case of confiscated goods, the obligation to send a request for deactivation should fall on the last legal EO known in the traceability system as handling the confiscated goods. The state authorities do not need to report to the traceability system themselves; they just need to check if the EO in question has met its obligations.

A Member State asked if UIs that have been deactivated, can be recalled (e.g. when the police finds stolen tobacco products that have been deactivated and want to return the products to the rightful owner) and if yes, which economic operator should do the recall. SANTE clarified that the reactivation of deactivated UIs is not possible. It was further explained that a product reported as stolen requires the deactivation of the corresponding UI so that when this product eventually reappears (e.g. not stolen but only temporarily lost), a new UI will be required. Only then, the product can be re-introduced into the supply chain.

A Member State asked if products destroyed at the first retail outlet need to be deactivated. SANTE replied that there are no reporting obligations for products that have already been placed on the market. If products are confiscated from or destroyed at a retail outlet and those products have been reported in the system as dispatched to a retail outlet, then there is no need for the UIs of those products to be deactivated.

Finally, a Member State asked if economic operators (i.e. wholesalers, importers or manufacturers) that receive from retail outlets products that are intended for destruction at their level need to deactivate the relevant UIs of those products. SANTE confirmed this, explaining that in this case the economic operator of a facility at which products arrive after their return from a retail outlet, first needs to report the return of those products, and then, after the products are destroyed, needs to transmit a deactivation request.

4.6. Tobacco products intended for exports to Russia: the requirement of two fiscal stamps

A Member State asked if SANTE was aware of problems that small producers of tobacco products face when they export their products to Russia in relation to a requirement for double fiscal stamps that is allegedly related to the T&T systems adopted by the EU and Russia.

It was clarified that the marking of tobacco products with national tax stamps, including potential requirements to combine UIs with a tax/fiscal stamp, is a matter of national competence and if needed, should be addressed to the relevant national competent authorities. However, the Subgroup was not aware of any requirement to include tax stamps for products that are destined for exports.

5. AOB

The collaboration between DG SANTE and DG OLAF concerning the FCTC Protocol

In response to a question on the collaboration between the two services in the context of the FCTC Protocol, OLAF and SANTE confirmed that they work closely together as a Key Facilitator of the Working Group on Tracking and Tracing established by the Protocol Parties at MOP1.

6. Closing remarks

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

List of participants

Austria	(Ministry of Finance - Tax and Customs Administration, State Monopoly Agency)
Belgium	(Customs and Excise Administration and FPS Health, Food Chain Safety and Environment)
Bulgaria	(National Customs Agency)
Croatia	(Agencija za komercijalnu djelatnost, Croatian 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)
France	(Customs)
Germany	(Bundesdruckerei GmbH)
Greece	(Independent Authority for Public Revenue and Ministry of Digital Governance - General Secretariat of Information Systems for Public Administration)
Hungary	(Government office of the Prime Minister, Ministry without portfolio responsible for national property management, the National Tax and Customs Administration)
Ireland	(Department of Health and Office of the Revenue Commissioners)
Italy	(Ministry of Health, Customs Agency, customs and monopolies agency)
Latvia	(State Revenue Service)
Lithuania	(State Tax Inspectorate under the Ministry of Finance)
Luxembourg	(Direction de la santé, Customs and Excise Administration, Incert G.I.E.)

Malta	(Customs Department)
Netherlands	(Customs and Ministry of health)
Norway	(Ministry of Health and Care Services and Directorate of Health)
Poland	(Ministry of Finance, Revenue Administration Regional Office in Katowice)
Portugal	(Tax and Customs Authority)
Romania	(Customs General Directorate)
Slovakia	(Financial Directorate under the Ministry of Finance and Datacentrum under the Ministry of Finance)
Slovenia	(Ministry of Health)
Spain	(Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas, Comisionado para el Mercado de Tabacos, FNMT-RCM.)
Sweden	(Public Health Agency)

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